# DEPARTMENT OF DEFENSE APPROPRIATIONS FOR 2011

# **HEARINGS**

BEFORE A

#### SUBCOMMITTEE OF THE

# COMMITTEE ON APPROPRIATIONS

## HOUSE OF REPRESENTATIVES

#### ONE HUNDRED ELEVENTH CONGRESS

SECOND SESSION

#### SUBCOMMITTEE ON DEFENSE

#### NORMAN D. DICKS, Washington, Chairman

PETER J. VISCLOSKY, Indiana JAMES P. MORAN, Virginia MARCY KAPTUR, Ohio ALLEN BOYD, Florida STEVEN R. ROTHMAN, New Jersey SANFORD D. BISHOP, Jr., Georgia MAURICE D. HINCHEY, New York CAROLYN C. KILPATRICK, Michigan TIM RYAN, Ohio C. W. BILL YOUNG, Florida RODNEY P. FRELINGHUYSEN, New Jersey TODD TIAHRT, Kansas JACK KINGSTON, Georgia KAY GRANGER, Texas HAROLD ROGERS, Kentucky

NOTE: Under Committee Rules, Mr. Obey, as Chairman of the Full Committee, and Mr. Lewis, as Ranking Minority Member of the Full Committee, are authorized to sit as Members of all Subcommittees.

Paul Juola, Greg Lankler, Sarah Young, Paul Terry, Kris Mallard, Adam Harris, Ann Reese, Brooke Boyer, Tim Prince, BG Wright, Chris White, Celes Hughes, and Adrienne Ramsay, Staff Assistants
Sherry L. Young, and Tracey LaTurner, Administrative Aides

#### PART 4

	Page
Defense Health Program/Wounded Warrior	1
Missile Defense Agency	125
Public Witnesses	179

Printed for the use of the Committee on Appropriations

PART 4-DEPARTMENT OF DEFENSE APPROPRIATIONS FOR 2011

# DEPARTMENT OF DEFENSE APPROPRIATIONS FOR 2011

## **HEARINGS**

BEFORE A

#### SUBCOMMITTEE OF THE

# COMMITTEE ON APPROPRIATIONS

## HOUSE OF REPRESENTATIVES

#### ONE HUNDRED ELEVENTH CONGRESS

SECOND SESSION

#### SUBCOMMITTEE ON DEFENSE

#### NORMAN D. DICKS, Washington, Chairman

PETER J. VISCLOSKY, Indiana JAMES P. MORAN, Virginia MARCY KAPTUR, Ohio ALLEN BOYD, Florida STEVEN R. ROTHMAN, New Jersey SANFORD D. BISHOP, JR., Georgia MAURICE D. HINCHEY, New York CAROLYN C. KILPATRICK, Michigan TIM RYAN, Ohio C. W. BILL YOUNG, Florida RODNEY P. FRELINGHUYSEN, New Jersey TODD TIAHRT, Kansas JACK KINGSTON, Georgia KAY GRANGER, Texas HAROLD ROGERS, Kentucky

NOTE: Under Committee Rules, Mr. Obey, as Chairman of the Full Committee, and Mr. Lewis, as Ranking Minority Member of the Full Committee, are authorized to sit as Members of all Subcommittees.

Paul Juola, Greg Lankler, Sarah Young, Paul Terry, Kris Mallard, Adam Harris, Ann Reese, Brooke Boyer, Tim Prince, BG Wright, Chris White, Celes Hughes, and Adrienne Ramsay, Staff Assistants
Sherry L. Young, and Tracey LaTurner, Administrative Aides

#### PART 4

	Page
Defense Health Program/Wounded Warrior	1
Missile Defense Agency	125
Public Witnesses	179

U.S. GOVERNMENT PRINTING OFFICE

66-611 WASHINGTON: 2011

#### COMMITTEE ON APPROPRIATIONS

DAVID R. OBEY, Wisconsin, Chairman

NORMAN D. DICKS, Washington ALAN B. MOLLOHAN, West Virginia MARCY KAPTUR, Ohio PETER J. VISCLOSKY, Indiana NITA M. LOWEY, New York JOSÉ E. SERRANO, New York ROSA L. DELAURO, Connecticut JAMES P. MORAN, Virginia JOHN W. OLVER, Massachusetts ED PASTOR, Arizona DAVID E. PRICE, North Carolina CHET EDWARDS, Texas PATRICK J. KENNEDY, Rhode Island MAURICE D. HINCHEY, New York LUCILLE ROYBAL-ALLARD, California SAM FARR, California JESSE L. JACKSON, Jr., Illinois CAROLYN C. KILPATRICK, Michigan ALLEN BOYD, Florida CHAKA FATTAH, Pennsylvania STEVEN R. ROTHMAN, New Jersey SANFORD D. BISHOP, Jr., Georgia SANFORD D. BISHOP, Jr., Geor MARION BERRY, Arkansas BARBARA LEE, California ADAM SCHIFF, California MICHAEL HONDA, California BETTY McCOLLUM, Minnesota STEVE ISRAEL, New York TIM RYAN, Ohio C.A. "DUTCH" RUPPERSBERGER, Maryland BEN CHANDLER, Kentucky
DEBBIE WASSERMAN SCHULTZ, Florida CIRO RODRIGUEZ, Texas LINCOLN DAVIS, Tennessee JOHN T. SALAZAR, Colorado PATRICK J. MURPHY, Pennsylvania

JERRY LEWIS, California C. W. BILL YOUNG, Florida HAROLD ROGERS, Kentucky FRANK R. WOLF, Virginia JACK KINGSTON, Georgia RODNEY P. FRELINGHUYSEN, New Jersey TODD TIAHRT, Kansas ZACH WAMP, Tennessee TOM LATHAM, Iowa ROBERT B. ADERHOLT, Alabama JO ANN EMERSON, Missouri KAY GRANGER, Texas MICHAEL K. SIMPSON, Idaho JOHN ABNEY CULBERSON, Texas MARK STEVEN KIRK, Illinois ANDER CRENSHAW, Florida DENNIS R. REHBERG, Montana JOHN R. CARTER, Texas RODNEY ALEXANDER, Louisiana KEN CALVERT, California JO BONNER, Alabama STEVEN C. LATOURETTE, Ohio TOM COLE, Oklahoma

BEVERLY PHETO, Clerk and Staff Director

### DEPARTMENT OF DEFENSE APPROPRIATIONS FOR 2011

THURSDAY, APRIL 22, 2010.

#### DEFENSE HEALTH PROGRAM/WOUNDED WARRIOR

#### WITNESSES

DR. CHARLES L. RICE, PRESIDENT, UNIFORMED SERVICES UNIVERSITY OF THE HEALTH SCIENCES, PERFORMING THE DUTIES OF THE ASSISTANT SECRETARY OF DEFENSE FOR HEALTH AFFAIRS, AND ACTING DIRECTOR, TRICARE MANAGEMENT ACTIVITY

LIEUTENANT GENERAL ERIC SCHOOMAKER, ARMY SURGEON GENERAL AND COMMANDER, U.S. MEDICAL COMMAND

VICE ADMIRAL ADAM M. ROBINSON, JR., MC, USN, SURGEON GENERAL OF THE NAVY

LIEUTENANT GENERAL (DR.) CHARLES B. GREEN, AIR FORCE SURGEON GENERAL

#### OPENING STATEMENT OF CHAIRMAN DICKS

Mr. DICKS. The Committee will come to order. Today, the committee will receive testimony regarding the Defense Health Program and the Wounded Warrior Program. This hearing will cover the fiscal year 2011 budget request and various medical treatment issues pertaining to Soldiers and their family members.

The Department faces a tremendous challenge with the growing cost and long-term sustainability of the military health system. The military health system has taken several important steps to prepare our military forces and our military medical forces for the future. For the first time, the Department of Defense has fully funded the Defense Health Program in the fiscal year 2011 budget submission. The request also includes \$2.5 billion for the wounded, ill, and injured. The request includes \$30.9 billion for operations and maintenance, procurement, research and development. The total military health program is \$49.6 billion for 2011. This includes the payment of \$9.3 billion to the Department of Defense Medicare-eligible Retiree Health Care Fund and \$9.3 billion in personnel, Base Closure and Realignment Commission (BRAC), and military construction costs.

The Department continues to focus on the need for mental health counseling and readjustment support for our servicemembers returning from deployments. It is important for the Department to get to the heart of the issues that soldiers and their families face during and after lengthy deployments. The Department is making strides with improvements to psychological health screening, but much more still needs to be done.

The Defense Health Program's cost continues to grow at a similar rate to that experienced in the United States health-care system at large. In addition, it is likely that benefits for members, their families, and military retirees are likely to expand over the coming years. As such, one of the themes from this hearing is what initiatives should Congress consider that would sustain health-care benefits, support the needs of troops and their family members, and improve care, yet control cost growth.

We look forward to your testimony and to a spirited and inform-

ative question-and-answer session.

Now, before we hear your testimony, I would like to call on the ranking member, my good friend, Mr. Young, who was formerly Chairman of this subcommittee.

Mr. Young.

#### Remarks of Mr. Young

Mr. Young. Mr. Chairman, thank you very much. I want to add my welcome to our distinguished witnesses today. I think no one is going to be surprised when I say that it is the opinion—my opinion and the opinion of most of this committee—that this is one of the most important hearings that we will have this year.

As the Chairman has said, the well-being and health of our troops, their families, is something that Mr. Murtha took very seriously, something that Mr. Dicks, the present chairman takes very seriously, and I and the rest of this subcommittee. And we have been stressing for years that it is essential that we take care of our Soldiers, Sailors, Marines, Airmen, Air women, and their families. They deserve the best and most affordable health care we can provide them, as do our veterans.

Just yesterday morning, in a similar hearing, we discussed the consolidation of medical facilities in the National Capital Region and what will it take to ensure a world-class health care system. If it is not already, that world-class standard should be the goal across all of medical treatment facilities, not just those in the capital region.

It is our job, your job, to make sure we take care of our injured heroes, and there is perhaps no job more important to the subcommittee than that. I know that you take this very seriously, and I appreciate your commitment to providing them the best care possible.

So welcome, again. I look forward to your testimony. Just be assured that whatever it is that you need to guarantee the proper care of our wounded warriors, our heroes, this subcommittee is interested in providing that. So let us know what it is. Thank you very much.

Thank you, Mr. Chairman.

Mr. DICKS. Thank you, Mr. Young.

Dr. Rice, would you like to start first?

Dr. RICE. Yes, sir.

Mr. DICKS. We will put all the statements in the record and you may proceed as you wish.

#### SUMMARY STATEMENT OF DR. RICE

Dr. RICE. Thank you, sir.

Thank you, Mr. Chairman and distinguished members of the committee, for the opportunity to come before you today. I am honored to be able to testify on behalf of the men and women who serve in our Military Health System, and deeply appreciative of the support that this committee has always provided military medicine. I have, as you note, submitted my written comments to the committee. I would like to make a few very brief opening remarks.

I approach my role as the Senior Medical Advisor to Secretary Gates and Secretary Stanley, at least on a temporary basis, with the advantages of multiple perspectives: as a trauma surgeon, as an educator, as a retired Navy medical officer, and as the father

of an Active Duty naval aviator.

The performance of our military medics in combat remains nothing short of remarkable. In addition to the lifesaving care on the battlefield, we are continuously improving the medical readiness of the total force. We monitor and record the health of servicemembers in the most comprehensive manner ever witnessed throughout the cycle of deployment: before, during, and after their service in the combat theaters. Despite the breakneck pace of combat, most recently our medical personnel have responded heroically to the natural disasters in Haiti and Chile. I know that you share this pride in the people who serve in our system.

Today I want to focus on those areas where greater attention is required for me, during the hopefully short time I serve in this capacity, so that you will understand where I am focusing my energies. First, our deepest obligations are reserved for the casualties returning to the United States, and to the families and other care-

givers who support them.

Substantial progress has been made since the problems with Wounded Warrior first came to light in 2007. More needs to happen on our end to ensure that the programs, services, health information, and communication are knitted together more tightly, so that we can provide clearer and more cohesive services to the families who continue to sacrifice so much.

Second, I am intently focused on the performance and the perception of the electronic health record. My intention is not to micromanage the many technological issues, but to determine whether our proposed solutions will result in a better capability for our providers, nurses, physicians, pharmacists, and all the other key members of the health care team, and deliver value for patients. The only real test for a successful electronic health record is whether it leads to higher-quality care and the improvement of the health of the population that it serves. It must not and cannot fail that test.

Third, the Department continues to implement the broad changes required by the 2005 BRAC Commission. Our approach to the right organizational construct and how we build medical facilities design must result in better services, better quality, and better access for our patients. Investments in evidence-based design concepts for our new facilities are critically important. They offer a better healing environment for patients and their families. Belvoir

will be a showcase for this new approach, a truly dazzling design that will create an unmatched healing environment.

Fourth, we are working to resolve the serious matters identified in the protests that were upheld by the General Accountability Office regarding the T3 contract awards. While the issues that we must address are serious, I am reassured and want to reassure you that the internal issues affecting these awards have not affected the day-to-day service for our beneficiaries.

Nonetheless, our efforts to control TRICARE cost growth are closely linked to the effective implementation of new contracts, and it is in the best interest of the government and of the organizations involved in these contract decisions to move toward a definitive

conclusion.

Finally, I want to briefly comment on the larger issue of national health care reform that has been the focus of so much recent attention. Although the military health care system is a unique system of care, we do not function apart from the civilian health care system used by the American people. In fact, almost 70 percent of the care our beneficiaries receive is delivered by our civilian colleagues.

TRICARE benefits are administered separately from the new health-care reform law. We know that the DOD medical benefit is, appropriately, one of the most comprehensive benefits of any employer. One visit to the Walter Reed or the National Naval Medical Center or Wilford Hall or Brooke, demonstrates why this should be

so, more than any words I can offer here.

Yet there are other potential benefits that will accrue to the military services when more Americans are covered by insurance. This includes a more medically fit recruiting pool, greater investments in comparative effectiveness research that will help all practitioners of care with developing scientifically validated approaches to medicine, and a more secure transition for those members of our Armed Forces who decide to separate prior to full retirement.

I will be working with my health care colleagues at Health and Human Services and elsewhere to ensure that we are appropriately involved in the implementation of health care reform initiatives that both reassure our beneficiaries and promote the goals of re-

form.

One area in which legislation has been proposed to match TRICARE to the new health insurance requirements is the extension of health insurance coverage to children of eligible beneficiaries to the age of 26. Our staff is performing preliminary actuarial work to determine the anticipated additional cost to the Department for this coverage expansion and to develop an equitable premium for this expanded coverage as directed by legislation.

Mr. Chairman, I want to thank you again for your leadership and for your steadfast support of the military health system, and

I look forward to answering your questions.

Mr. DICKS. Thank you, Dr. Rice. [The statement of Dr. Rice follows:]

#### STATEMENT BY

#### CHARLES L. RICE, M.D.

PRESIDENT, UNIFORMED SERVICES UNIVERSITY OF THE HEALTH SCIENCES, PERFORMING THE DUTIES OF THE ASSISTANT SECRETARY OF DEFENSE, HEALTH AFFAIRS AND ACTING DIRECTOR, TRICARE MANAGEMENT ACTIVITY

#### REGARDING

THE MILITARY HEALTH SYSTEM: BUDGET OVERVIEW

**BEFORE THE** 

HOUSE COMMITTEE ON APPROPRIATIONS SUBCOMMITTEE ON DEFENSE

April 22, 2010

FOR OFFICIAL USE ONLY UNTIL RELEASED BY THE HOUSE COMMITTEE ON APPROPRIATIONS

Mr. Chairman, Members of the Committee, thank you for the opportunity to discuss the Military Health System (MHS)'s priorities and budget for Fiscal Year (FY) 2011.

We have enduring obligations to the men and women of our Armed Forces, and to their families who serve with them, and to the millions of retired military personnel who have served us in the past.

This obligation begins the moment a recruit walks through our doors. In our budget for the coming year, we acknowledge that lifetime commitment we have to those who serve today or have served in the past, and to their families.

For those service members who honorably conclude their service before reaching military retirement, we have an obligation to ensure their medical experience is fully captured and easily shared with the Department of Veterans Affairs (VA) or with their own private physician. For those who retire from military service, our obligation to them and their families often extends for a lifetime.

And, for those who have borne the greatest burden, through injury or disease suffered in our nation's conflicts, we have an even higher obligation to the wounded and their families. As Secretary Gates stated with the introduction of the Defense budget, "Recognizing the strain that post-9/11 wars have put on so many troops and their families, the department will spend more than \$2 billion for wounded warrior initiatives, with a special focus on the signature ailments of current conflict, such as post-traumatic stress disorder (PTSD) and traumatic brain injury. We will sustain health benefits and enlarge the pool of medical professionals. We will broaden electronic information-sharing between the Department of Defense (DoD) and VA for wounded warriors making the transition out of military service."

The budget we are putting forward reflects our commitment to the broad range of responsibilities of the MHS – the medical readiness requirements needed for success on today's battlefield; the medical research and development necessary for success on tomorrow's; the patient-centered approach to care that is being woven through the fabric of the MHS; the transformative focus we are placing on the health of our population; the public health role we play in our military community and in the broader American community; the reliance we have on our private sector health care partners who provide indispensable service to our service members and families; and our responsibility to deliver all of these services with extraordinary quality and service.

As our military forces in Afghanistan are engaged in combat operations to expand the security, governance, and development environment for the people of Afghanistan; as we continue with the careful hand-off of responsibilities to the elected leaders of Iraq; and, as Marines provide security and the joint medical team provides care for the

people of Haiti, we are mindful of the trust and investment that the American people have made in military medicine. We will continue to honor that trust.

#### MHS Mission and Strategic Plan

The MHS overarching mission remains as in years past: to provide optimal health services in support of our nation's military mission – anytime, anywhere.

Over the last twelve months, the Office of the Assistant Secretary of Defense for Health Affairs has worked with our Service Surgeons General and the entire Joint MHS leadership team to update and refine the MHS Strategic Plan.

In the process, we sought the expertise and advice from leaders both within our system and external to the MHS, to include renowned experts at the Mayo Clinic, Kaiser Permanente, Geisinger Health System, the Cleveland Clinic, Intermountain Health, and the Institute for Healthcare Improvement.

This effort resulted in unanimous support for adopting 'The Quadruple Aim' as the foundation for our strategic plan in the coming years.

The Quadruple Aim borrows liberally (and with permission) from the Institute for Healthcare Improvement's (IHI) "Triple Aim," and is further tailored to the unique mission of the MHS. The four core components of the Quadruple Aim are:

- Readiness Ensuring that the total military force is medically ready to deploy and
  that the medical force is ready to deliver health care anytime, anywhere in
  support of the full range of military operations, including combat support,
  defense support to civil authorities, and humanitarian assistance/disaster relief
  missions as we witnessed most recently in Haiti.
- Population Health Improving the health of our population by encouraging healthy behaviors and reducing the likelihood of illness through focused prevention and the development of increased resilience.
- Experience of Care Providing a care experience that is patient and family centered, compassionate, convenient, equitable, safe, evidence-based, and always of the highest quality.
- Cost Creating value by focusing on measuring and enhancing quality healthcare; eliminating inefficiencies; reducing unwarranted variation; and emphasizing investments in health that reduce the burden and associated cost of preventable disease in the long term.

The outcome of this strategic planning effort is more than the plan itself. The values and strategies we have articulated in our plan are reflected in our proposed budget.

Whereas we take great pride in the past accomplishments of the joint MHS team, the overview we provide in the following pages for our fiscal year 2011 strategic priorities is forward-looking, not merely a reflection of past accomplishments. By aligning this testimony with our strategic plan, we link our budget proposal and priorities to our strategic focus inherent in the four core components of the Quadruple Aim.

#### Readiness

A fit, healthy, and protected force is the starting point in ensuring a medically ready force. We have a core set of individual medical readiness (IMR) measures that inform both our line commanders and our medical teams about the individual preparedness of a service member to deploy.

We will continue to use our monitoring systems so that we reduce the rate of deployment limiting conditions. We will also focus on disparities between the Active and Reserve Components in terms of IMR, and improve the medical readiness of the Total Force.

A critical companion strategic matter for the Department is the psychological health of our people. Between 20-30% of our service members who have deployed to Operation Iraqi Freedom or Operation Enduring Freedom (OIF/OFF) have reported some form of psychological distress. As has been widely noted, suicide rates in the Armed Forces have also been rising. DoD and the individual Services are studying every suicide or suicide attempt closely, and we have collectively introduced a number of new programs and initiatives to reduce the occurrence of suicide. We are engaging commanders, the medical research community and fellow service members in a multi-tiered effort to understand and implement effective strategies to deter suicide; to reduce the stigma of seeking professional help and counseling; and to ensure there are adequate personnel resources to meet a clear and growing demand for mental health services.

We remain focused on accelerating our research into and the adoption of evidencebased care treatments for personnel with PTSD and traumatic brain injury. Secretary Gates continues to be personally interested in seeing us move information from the research realm to the field in a much more rapid manner.

We are proposing another \$669 million to support our requirements in meeting these critical needs in support of psychological health. Significant funds are also directed to other critical battlefield medical research and development needs.

In addition, our investments in Defense Centers of Excellence and the Defense and Veterans Brain Injury Center are funded and poised for delivering world-class care and service to our military and veteran populations.

Finally, in FY 2010 and FY 2011, we will be undertaking actions to expand our measures of "readiness." Specifically, we will be assessing how to better measure "family readiness." There is no question that the health and resiliency of the entire family is tied to the readiness of the individual Soldier, Sailor, Airman, and Marine. Our efforts will be directed toward measures that help us proactively identify and address health risks within a family prior to deployment.

#### **Population Health**

There are few organizations in the world that compare to the DoD in having the right incentives to truly invest in population health efforts. A significant number of military personnel and their families will have their health care managed by DoD or other federal and private sector partners for their lifetimes. Accordingly, we will continue to develop and employ the best tools and programs to transform our culture to one focused not just on expertly treating disease and injury, but to one focused on sustaining the health and well-being of our population.

There are a number of tools and programs at our disposal to improve overall population health. The Department will continue to invest deeply in our preventive service programs. We will improve our provider support tools so that opportunities for education or preventive treatment can be engaged at all patient-provider opportunities.

We will closely track our performance in delivering preventive services using the Health Employer Data Information System (HEDIS) measures. HEDIS allows us the opportunity to compare ourselves among each Service or MTF, but equally importantly, to compare ourselves against our private sector counterparts. In 2009, we witnessed impressive gains in preventive service delivery as compared to both national norms and national benchmarks, particularly in the Army and Navy, after introducing pay for performance incentive programs.

We recognize, however, that not all measures are moving in the right direction. For example, we are seeing continued high levels of tobacco usage among our youngest service members. We are also seeing rising rates of obesity in our non-active duty population (along with the related morbidities, particularly diabetes).

As an aspect of our strategic imperatives, we are seeking to more directly and more personally engage patients to take a more active role in managing their health. We will seek to influence behaviors through increased positive actions (better nutrition and increased physical activity) and reduced negative habits (tobacco use and excessive alcohol intake).

Our efforts to improve the overall health status of our population do not operate in a vacuum. Improvements are made one patient at a time; one patient visit at a time. In this regard, our efforts in this strategic arena are directly tied to our efforts at the

individual level with their experience with the care received -- and the topic of the next section.

#### **Experience of Care**

One of our foremost and sustained priorities is to improve the experience of care for those who are most intimately interacting with our MHS every day – the wounded, ill, and injured from our current conflicts who are moving through the joint patient evacuation system, from point of injury in the theater of operations, to the point of definitive care in the United States, where many are recovering at our flagship military medical centers in the National Capital Area and other medical centers around the country.

We remain grateful for the support of the Congress, and especially this Committee, to ensure we have the resources to provide the very best health care for our forces and their families, and in particular for the wounded, ill, and injured.

We propose a budget of more than \$670 million to support the spectrum of services for the wounded, ill, and injured – services which include enhanced case management, improvements to our Disability Evaluation System, and greater data sharing with the VA and other private sector medical organizations.

Central to our efforts is the obligation to expedite the administrative elements of our disability cases, and work to get our Wounded Warriors to the best possible location to facilitate their recovery. We are expediting our Medical Evaluation Board (MEB) process toward a goal of completing all MEBs within 30 days.

We have also successfully piloted efforts with the VA to have both Departments' medical examination requirements completed in a single exam—which increases the timeliness of processing and increases satisfaction with the entire experience for the service member.

Enhancing the care experience is not limited, however, to our wounded warriors. It is imperative that we offer solutions and improvements for our entire beneficiary population we serve.

The overriding issue in our system has historically been and continues to be "access to care." Simply put, access is about getting the right care for the right patient at the right time.

Our efforts to improve access in the coming year will be focused on expanding our "Medical Home" initiatives. The Patient Centered Medical Home provides patients with a known provider or small team of providers, who will get to know that patient and her or his medical problems. The continuity of care offered by this model, when coupled

with enhanced access to the provider through telephone messaging or secure electronic communication and timely appointing, will enhance the quality and safety of care and improve the patient experience. This model has been endorsed by professional medical societies (the American Academy of Pediatrics and the American Academy of Family Physicians, American College of Physicians, and American Osteopathic Association), several large third party payers, employers, and health plans. Its adoption in the MHS reflects the continuation of a journey toward improving patient access and satisfaction.

We will be providing our enrolled population with clear communications about how to access the appropriate level of medical care to meet their needs at any time, 24 hours a day - seven days a week. We will offer our patients with multiple modes of accessing care, to include expansion of telephone access, and secure, web-based patient-provider messaging service.

#### Per Capita Cost Control

We are proposing a fully funded budget for FY 2011. The MHS serves 9.5 million beneficiaries, to include active duty members and their families, members of the Reserve Component and their families, and retired military personnel and their families. It is important to note that this number that has grown with the increased active duty end strength as well as the expansion of health benefits to members of the Reserve Component. Thus, while real cost growth will continue to rise, we, nonetheless, will be focused on controlling per capita costs within our system.

Our primary and most strategically important bulwark against unmanaged cost growth for the coming year is quality. Our efforts to develop, proliferate and adhere to evidence-based guidelines will have the most dramatic effect on our costs. In this instance, we will again compare ourselves against each other and against private sector data using the Dartmouth Atlas as our guide. Our goal is to reduce inappropriate variation in the utilization of services.

The urgency of addressing costs in FY 2011 is clear from our budget request. A major increase in the budget request includes \$1.2 billion for private sector care costs due to an increase in users of TRICARE and an increase in utilization of the TRICARE benefit.

We recognize that this focus on quality and utilization does not diminish the need for wise and informed management actions to also control costs. In FY 2011, we will also:

- continue implementation of Federal Ceiling Pricing of retail pharmaceuticals;
- continue implementation of the Outpatient Prospective Payment System, which
  reduces the reimbursement paid for outpatient care at inpatient private sector
  care facilities;
- standardize medical supply chain management across the full range of military health care operations;

- increase efforts to identify and detect fraud, waste, abuse, and overpayments to civilian medical providers; and
- pursue the first fully integrated Joint DoD/VA healthcare collaboration consisting
  of the North Chicago Veterans Affairs Medical Center and the Navy Health Clinic,
  Great Lakes, Illinois.

Through improved access to care from the medical home initiative and adherence to evidence-based care guidelines, we are hoping to reduce the need for referrals to private sector sources wherever possible, and to decrease utilization of emergency room services (when used as a source for non-emergent primary care).

We recognize that the MHS is not immune from the cost growth challenges faced by our private sector peers. And, the ever-increasing value of the TRICARE benefit against private sector plans and premiums will likely place additional pressure on the MHS budget. Yet, along with the civilian and military leadership of the Department, we are mindful of the trade-offs being made every day to sustain this system of care.

#### Learning and Growth

Fiscal Year 2011 promises to be both exciting and challenging, as many of the Department's most significant health efforts will be advanced in bold and meaningful ways. The 2005 Base Realignment and Closure actions, which impact medical facilities in multiple joint medical markets, the joint Medical Education and Training Campus, and co-location of medical headquarters, will come to fruition in September 2011. Additionally, work on the Electronic Health Record (EHR) will continue on the trajectory toward improved system effectiveness and interoperability. And the Department will continue to address and resolve governance issues related to emerging requirements to organize, execute, and oversee Joint peacetime health care activities.

In this dynamic environment, supporting the Quadruple Aim is an objective that must continue to grow and support the people who serve the MHS. Our major initiatives for this year center on (1) furthering the MHS; contribution to medical science, (2) delivering information to enable better healthcare decisions, and (3) ensuring a fully capable workforce most prepared to support our strategic initiatives.

Our medical research program continues to grow, with the leadership of Secretary Gates and the ongoing support of Congress. Significant funding has been dedicated to TBI and psychological health; battlefield medicine; threats from the full range of chemical, biological, radiobiological and nuclear threats. Our EHR continues to serve a vital function in support of our clinicians and patients. The incredibly rich clinical data repository is capturing care delivered throughout our system, to include outpatient services in the combat theaters. And, in each successive year, we are able to transfer more health information more easily with our counterparts in the VA.

Yet, our EHR has not been without its technical challenges. For FY 2011, we are proposing a total of \$875 million for modernization efforts and to enable data interoperability with the Virtual Lifetime Electronic Record (VLER), being jointly led by DoD and the VA. VLER is an ambitious and needed undertaking to integrate medical, personnel benefits, and financial information in a single virtual record for veterans.

Finally, vital to our ability to deliver a high quality, accessible and cost-effective health system is a workforce that is trained and ready to operate in a fast-paced environment. We are investing in recruitment and retention programs to sustain our system. We have proposed legislation that will allow us to offer post-graduate scholarships for MHS civilians. We are partnering with universities, marketing our job opportunities to their graduates. Outreach activities include attending job fairs, speaking at professional conferences, and marketing through our MHS website. Partnering with the VA has allowed us to share recruiting opportunities, improving our mutual ability to recruit scarce medical professionals. In all, our MHS human capital programs will continue to allow us to extol the benefits of public service while supporting our strategic initiatives.

We are proud to serve with the talented, dedicated and resourceful team of public servants and military volunteers who comprise the MHS. And, we are committed to enhancing their professional experience in service to the country.

#### UNIFIED MEDICAL BUDGET REQUEST FOR FY 2011

The Defense Health Program (DHP), the appropriation that supports the MHS, is under mounting financial pressure. The DHP has more than doubled since 2001 – from \$19 billion to \$50.7 billion in FY 2011.

The majority of DoD health spending supports health care benefits for military retirees and their dependents, not the active force. We project that up to 65 percent of DoD healthcare spending will be going toward retirees in FY 2011 – up from 45 percent in FY 2001. As civilian employers' health costs are shifted to their military retiree employees, TRICARE is seen as a better, less costly option and they are likely to drop their employer's insurance. These costs are expected to grow from 6 percent of the Department's total budget in FY 2001 to more than 10 percent in FY 2015.

Despite these fiscal challenges, the FY 2011 budget request provides realistic funding for projected health care requirements.

The Unified Medical Budget, the Department's total request for healthcare in FY 2011, is \$50.7 billion. This includes the DHP appropriation, including Wounded, Ill and Injured Care and Rehabilitation; Military Personnel, Military Construction, and normal cost contributions for the Medicare-Eligible Retiree Healthcare.

#### **Defense Health Program**

The largest portion of the request, or \$30.9 billion, will be used to fund the DHP, which is comprised of Operation & Maintenance (O&M), Procurement and Research, Development, Test & Evaluation (RDT&E). A little over \$29.9 billion is for O&M, which funds most day-to-day operational costs of healthcare activities;

#### Military Personnel and Construction

For Military Personnel, the Unified Medical Budget includes \$7.9 billion to support the more than 84,000 military personnel who provide healthcare services in military theaters of operations and fixed health care facilities around the world. These services include medical and dental care, global aeromedical evacuation, shipboard, and undersea medicine, and global humanitarian assistance and response.

Funding for medical Military Construction (MILCON) includes \$1.0 billion to improve our medical infrastructure. We are committed to building new hospitals using the principles of Evidence-Based Design (EBD). We are excited to be able to open a national showcase in EBD, the new Fort Belvoir Hospital, in 2011.

MILCON funding will also be directed toward infrastructure enhancements at the National Interagency Biodefense Campus at Fort Detrick, Maryland – a vital resource for the nation.

#### **DoD Medicare-Eligible Retiree Health Care Fund**

The estimated normal cost of the Medicare-Eligible Retiree Health Care Fund in FY 2011 is \$10.9 billion. This funding includes payments for care in MTFs, to private health care providers, and to reimburse the Services for military labor used in the provision of healthcare services.

#### CONCLUSION

Mr. Chairman, the Military Health System continues to provide world-class medical care for a population that demands and deserves the best care anywhere. I am proud to represent the men and women who comprise the MHS. I am proud to submit to you and your committee members a budget that is fully funded and that we can successfully execute in the coming year.

I am pleased that I am able to provide you a budget with a direct and specific link to our strategic planning efforts of the last year.

Thank you again, Mr. Chairman, for the opportunity to be with you today. I look forward to your questions.

[END]

#### Mr. DICKS. General Schoomaker.

#### SUMMARY STATEMENT OF GENERAL SCHOOMAKER

General Schoomaker. Chairman Dicks, Representative Young, distinguished members of the Defense Subcommittee, thank you for inviting us to discuss the Defense Health Programs and our respective service medical programs. I am now in my third congressional hearing cycle as the Army Surgeon General and the Commanding General of the Army Medical Command. I can tell you that these hearings are valuable opportunities for me to talk about the accomplishments of Army medicine and to hear your collective perspectives regarding military health promotion and health care.

I, and I know my colleagues as well, are saddened to be in this hearing today without one of military medicine's strongest supporters. Chairman Jack Murtha was a friend of the Military Health System, of Army medicine, and a soldier on point for the Nation. I extend my personal sympathies to his family and to those with whom he worked closely, to those in his district he represented so

faithfully, and to those he inspired. He is deeply missed.

Chairman Dicks, I certainly look forward to working with you in your new role and to continue the great support and guidance this

committee has provided for the Military Health System.

I am pleased to tell you that the President's budget submission for fiscal year 2011 fully funds the Army Medical Department's needs. Your support of the President's proposed budget will be

greatly appreciated.

One area of special interest to this subcommittee is our comprehensive effort to improve warrior care, from the point of injury through evacuation and inpatient treatment to rehabilitation and return to duty. This is really a tri-service effort and done very cooperatively with my colleagues to the left. There is nothing more gratifying than to care for these wounded or injured heroes.

We in Army medicine continue to focus our effort on wounded, ill, and injured warriors, and I want to thank Congress for your unwavering support. You all have been very, very instrumental in the improvements that Army medicine has made in this regard and across the Joint force. The support of this committee has allowed us to hire additional providers to staff our Warrior Transition Units, to conduct relevant medical research, and to build the healing campuses, the first of which will be opened at Fort Riley, Kansas in late May.

I am convinced that Army has made some lasting improvements. The most improvement may be a change in the mindset from a focus on disability to an emphasis on ability and achievement. Each of these warriors has an opportunity and the resources to create their own future as soldiers or as productive private citizens. In fulfilling our moral obligation to our soldiers, we have established a comprehensive program of world-class medical care, of re-habilitation, professional development, and personal goal setting. Today, we have 29 Warrior Transition Units and nine commu-

nity-based Warrior Transition Units out in individual States, staffed by more than 3,900 personnel who manage the care and support for approximately 9,000 soldiers and their families who are

currently in the program.

The cornerstone of any warrior's successful transition is what we call the Army's Comprehensive Transition Plan. It is the warrior's holistic plan for his or her future. As detailed in my written testimony, the Comprehensive Transition Plan is tailored to a warrior's individual situation. It takes account of six demands: career, phys-

ical, social, emotional, spiritual, and family support needs.

A second area of special interest for this committee is psychological health. Army Medicine, under the direction of our new Deputy Surgeon General, Major General Patty Horoho, most recently the Commanding General of the Western Regional Medical Command—and, sir, I know that you know her very well—at Fort Lewis, is finalizing a comprehensive behavioral health system of care plan. This comprehensive system of care is intended to standardize and to synchronize the vast array of behavioral health activities that occur across the Medical Command and throughout the Army's force generation cycle—this iterative cycle of deployment, of support for families and the soldier, while they are in deployment, and reintegrating them when they return from deployment. I look forward to sharing more information with you over the next months as we roll out this exciting initiative.

In keeping with our focus on preventing injury and illness, Army Medicine and Army leadership is currently engaged in an all-out effort to change the military mindset regarding traumatic brain injury, especially the milder form, or concussion. Our goal is nothing less than a cultural change in fighter management after potential concussive events on the battlefield. To achieve this goal, we are educating the force so as to have trained and prepared soldiers, leaders, and medical personnel to provide early recognition, treatment, and tracking of concussive injuries, ultimately designed to protect the warrior's health—no different than what would occur on a sports field in America today.

I brought with me today a packet. It is called "The Brain Injury Awareness Tool Kit." I ask that we be permitted to share this with you and your staffs. It contains patient information materials as well as an informative DVD—a kind of concussive brain injury 101, that is used to educate soldiers before they deploy overseas. This further highlights strong efforts by Army's leadership and the DOD leadership to reduce the stigma associated with seeking help for this injury and for any behavioral health problem that may occur

jointly or separately from the brain injury.

The end state of these efforts is that every servicemember sustaining a possible concussion will receive early detection, state-of-the-art treatment, and a return-to-duty evaluation in the long-term digital health record that Dr. Rice referred to earlier, to track their management. I truly believe our evidence-based directive approach to concussion management will change the military culture regarding head injuries and impact the well-being of the force.

In closing, I am very optimistic about the future of Army Medicine. I feel very privileged to serve the men and women of Army Medicine as soldiers, Americans, and as global citizens. Thanks for holding this hearing and for your steadfast support of the Military

Health System and Army Medicine.

[The statement of General Schoomaker follows:]

#### **UNCLASSIFIED**

#### **FINAL VERSION**

#### STATEMENT BY

LIEUTENANT GENERAL ERIC B. SCHOOMAKER, MD, PhD THE SURGEON GENERAL OF THE UNITED STATES ARMY AND COMMANDER, US ARMY MEDICAL COMMAND

COMMITTEE ON APPROPRIATIONS SUBCOMMITTEE ON DEFENSE

UNITED STATES HOUSE OF REPRESENTATIVES

SECOND SESSION, 111<sup>TH</sup> CONGRESS

FY11 DEFENSE HEALTH PROGRAM AND WARRIOR CARE

APRIL 22, 2010

NOT FOR PUBLICATION UNTIL RELEASED BY THE COMMITTEE ON APPROPRIATIONS Chairman Dicks, Representative Young, and distinguished members of the Defense Subcommittee, thank you for inviting us to discuss the Defense Health Program and our respective Service wounded Warrior programs. Now in my third Congressional hearing cycle as the Army Surgeon General and Commanding General, US Army Medical Command (MEDCOM), I can tell you that these hearings are valuable opportunities for me to talk about the accomplishments and challenges of Army Medicine and to hear your collective perspectives regarding military healthcare. You and your staff members ask some difficult questions, but these questions help keep us focused on those we serve—the Soldiers, Sailors, Marines, Airmen, Coast Guardsmen, Family members, and Retirees as well as the American public. I hope you also find these hearings beneficial as you review the President's budget submission, which this year fully funds the Army Medical Department's needs, and determine priorities and funding levels for the next fiscal year.

The US Army Medical Department is a complex, globally-deployed, and world class team. My command element alone, the MEDCOM, is an \$11 billion international health improvement, health protection, emergency response and health services organization staffed by 70,000 dedicated Soldiers, civilians, and contractors. I am in awe at what these selfless servants have done over the past years—their accomplishments have been quietly, effectively, powerfully successful. While we have experienced our share of crises and even tragedies, despite eight years of continuous armed conflict for which Army Medicine bears a heavy load, every day our Soldiers and their Families are kept from injuries, illnesses, and combat wounds through our health promotion and prevention efforts; are treated in cutting-edge fashion when prevention fails; and are supported by an extraordinarily talented medical force to include those who serve at the side of the Warrior on the battlefield. We mourn the loss of 26 teammates in the Fort Hood shootings—six dead and 20 wounded—but are inspired by the resolve shown by their units to continue their missions and the exemplary

performance of the 467<sup>th</sup> and 1908<sup>th</sup> Medical Detachments serving in Afghanistan today.

One particular area of special interest to this subcommittee is our comprehensive effort to improve Warrior care from point of injury through evacuation and inpatient treatment to rehabilitation and return to duty. I am convinced the Army has made some lasting improvements, and I was recently heartened to read the comments of a transitioning Warrior that reinforced these perceptions. She commented:

As I look back in the past I am able to see with a reflective eye...the people that have helped me fight this battle, mostly my chain of command, who have always stood beside me instead of in front of me. They have gone out of their way to do what was best for me and I cannot say I would be here still if I hadn't had such wonderful support.... This is my story at the WTB and all in all, I just had to make aware to everyone that has helped that I am very grateful and I truly appreciate all of the work you have done for me.

There is nothing more gratifying than to care for these wounded, ill, and injured heroes. We in Army Medicine continue to focus our efforts on our Warriors in Transition and I want to thank Congress for your unwavering support. The support of this committee has allowed us to hire additional providers, staff our Warrior transition units (WTUs), conduct relevant medical research, and build healing campuses. We have come a long way, and I firmly believe that we have a superb program for our wounded, ill, and injured, but we know it is not perfect. As I highlight some of the changes over the last year, I welcome your guidance as we continue to make significant improvements in the way we care for our Warriors and their Families.

In fulfilling our moral obligation to our Soldiers, we have established a comprehensive program of world class medical care, rehabilitation, professional development, and personal goal setting. We have a responsibility to preserve the fighting spirit, sustain our force, and retain experienced Soldiers. We also have a responsibility to assist and be responsive to Soldiers' Families. Today, we have 29 WTUs and 9 Community Based WTUs staffed by more than 3,900

personnel who manage the care and support for 9,147 Soldiers and their Families.

The recently released recommendations of General (Ret) Frederick
Franks' review of the Medical Evaluation Board (MEB) and Physical Evaluation
Board (PEB) processes provide for a transition from a system of compensation
and disability to an abilities-based system that promotes resilience, selfassurance, re-education, and employment. General (Ret) Franks made fortythree tactical or supporting recommendations in the areas of command
emphasis, education and training, policy, and process. Army leadership is
reviewing the recommendations in the context of the on-going efforts of the
Wounded, Ill, and Injured Senior Oversight Committee, chaired by the Deputy
Secretaries of the Departments of Defense and Veterans Affairs, have already
implemented 8, and are considering implementation of additional
recommendations through an Execution Order signed by the Army Chief of Staff.

We have instituted multiple feedback mechanisms to ensure we are meeting the needs of our wounded, injured and ill Warriors and their Families. The cornerstone of any Warrior's successful transition is the Army's Comprehensive Transition Plan (CTP), which is a Warrior's holistic plan for hus/her future created within the first 30 days of assignment to a WTU. The CTP is tailored to a Warrior's individual situation and takes into account six domains: career, physical, social, emotional, spiritual, and family. To aid in creating the CTP, each Warrior is first formally trained in goal setting. An occupational therapist then assists the Warrior in selecting a career track based on his/her capabilities and desires. Next, a licensed clinical social worker convenes a multidisciplinary team to assist the Warrior in setting 30, 60, and 90-day goals in each of the other five domains. Each quarter thereafter, the multi-disciplinary team reconvenes to review and adjust the Warrior's goals. As Warriors progress through rehabilitation and pre-transition phases of their lifecycle, their CTP progress is assessed weekly by their Squad Leader and Nurse Case Manager through a self-assessment and validation process throughout the remainder of their assignment in the WTU.

The last phase of this process is the Army's follow up in the post-transition phase. This phase will be used to assess the overall effectiveness of the Warrior Transition Command's execution of the Warrior Care and Transition Program. Using survey instruments, we will collect data from our WTU alumni (most of whom are veterans) to assess the effectiveness of the overall care and transition program which will enable us to identify areas for improvement or changes as necessary.

We have invested heavily in ensuring that our seriously injured Warriors (those with a disability rating of 30 percent or higher or a combined rating of 50 percent or greater for conditions that are the result of combat or are combat-related) have an Army Wounded Warrior (AW2) Advocate assigned to them. The AW2 program assists and advocates for the Warrior from time of injury and continues throughout the Warrior's lifecycle of care. AW2 Advocates contact their assigned Soldier/veteran and Families to provide personalized support and ensure full use of benefits to recover physically, prepare financially and to build their skills for a rewarding career in the military or as a civilian. The advocates assist with day-to-day issues in recovery as well as longer-term transition decisions. AW2 Advocates are assigned to most military installations and Department of Veterans Affairs (VA) medical facilities throughout the nation. The Army Reserve and Army National Guard have similar AW2 Advocate positions to follow up with Reserve Component Soldiers and veterans.

Additionally, the Army and the Department of Veterans Affairs (VA) have integrated several procedures to ensure Soldiers and their Families have a successful transition when they will not be returning to the force. Since FY2008, both departments trade senior advisors to serve as liaisons ensuring coordination and open communication between departments. At 15 military treatment facilities (MTFs), the VA has assigned a total of 26 VA liaisons to coordinate the transition of Warriors to VA medical facilities and VA polytrauma centers. VA liaisons register and enroll service members into the VA healthcare system, coordinate care with VA program managers, coordinate with the Veteran Benefits Administration staff to provide wounded, ill, and injured Warriors with benefit

information, integrate with Army staff at MTFs, and educate veterans, service members, and families about VA healthcare.

The VA has assigned benefits advisors to support VA benefits information and claims processing at all WTUs. VA personnel support the nine Community-Based WTUs in the same manner. The VA ensures Vocational Rehabilitation and Employment (VR&E) counselors are available for Warriors at WTUs. VR&E counselors provide employment, career and educational counseling to Soldiers separating from Active Duty. They are learning about the Army's CTP and how the plan supports our wounded, ill, and injured. These VR&E counselors and VA liaisons will use the CTP to better assist Soldiers and their Families.

In speaking of our Families, we are looking forward to carrying out the provisions in the 2010 defense authorization bill to provide the much deserved additional compensation to caregivers of Warriors who suffer catastrophic illness or injury in the line of duty. While we await resolution on eligibility criteria and final implementation guidance from the DoD Wounded Warrior Care and Transition Program Office, we are leaning forward by developing the Army's implementation guidance for executing the provisions. We have met with our stakeholders to ensure we are prepared for swift execution of this much-deserved benefit for the affected Families.

In the remainder of my testimony today, I will discuss how we are providing optimal stewardship of the investment the American public and this Committee have made in Army Medicine.

We lead and manage Army Medicine through the Kaplan & Norton Balanced Scorecard performance improvement framework that I introduced to you in last year's testimony. The Scorecard balances missions and resources across a broad array, while ensuring that near-term measures of success are aligned with longer-term, more strategic results. This balancing is depicted on the Scorecard's Strategy Map, which shows how we marshal our resources, train and develop our people, and focus our internal processes and efforts so as to balance competing goals. Ultimately our means, ways, and ends contribute

toward accomplishing our mission and achieving our strategic vision. The five strategic themes that guide our daily efforts are:

- · Maximize Value in Health Services
- · Provide Global Operational Forces
- · Build the Team
- Balance Innovation with Standardization
- Optimize Communication and Knowledge Management

Although distinct themes, they inevitably overlap and weave themselves through everything we do in Army Medicine.

The first strategic theme--Maximize Value in Health Services— is built on the belief that providing high quality, evidence-based services is not only the right for our Soldiers and Families; it results in the most efficient use of resources within the healthcare system, thus delivering value to not only our Patients, but indeed, the Nation. In fact, what we really want to do is move from a healthcare system to a system for health.

We have resisted simply inventing a new process, inserting a new diagnostic test or therapeutic option *in vacuo* or adding more layers of bureaucracy but are truly adding value to the products we deliver, the care we provide, and the training of our people. This requires focusing on the clinical outcome for the patient and the community and maintaining or even reducing the overall resource expenditure needed to achieve this objective. It has occurred through adoption of evidence-based practices and reducing unwarranted practice variation--even "unwarranted administrative practice variation" for the transactional processes in our work. As one example of this, Army Medicine is expanding upon our Performance Based Budget model to link resources to clinical and quality outputs. The Healthcare Effectiveness and Data Information Set (HEDIS<sup>R</sup>) is a tool used by more than 90% of America's health plans (> 400 plans) to measure performance on important dimensions of care, namely, the prevention of disease and evidence-based treatments for some of the most common and onerous chronic illnesses. The measures are very specifically

defined, thus permitting comparison across health plans. Since 2007, we have been providing financial incentives to our hospitals, clinics and clinicians for superior compliance in key HEDIS measures. Currently, we track nine measures and compare our performance to national benchmarks. Our performance has improved on each measure, in one case by 63%. We have demonstrated that these incentives work to change organizational behavior to achieve desired outcomes in our health system. Put quite simply, our beneficiaries, patients and communities are receiving not only better access to care but better care—objectively measured.

As the DoD budget and health-/healthcare-related costs come under increasing scrutiny, this element of our strategy will be even more critical for us. As the United States struggles to address improvements in health and healthcare outcomes while stabilizing or reducing costs of our national system of care, we in Army Medicine and the Military Health System will surely keep the goal of maximizing value in our cross-hairs...or we will find our budgets tightening without a way to measure the effects on our patients' and our communities' health and well-being.

All of these remarkable achievements would be without meaning or importance to our Soldiers, their Families and our patients if we do not provide access and continuity of care, especially within the direct care system of our medical centers, community hospitals, health centers, and clinics. I am looking carefully at my commanders' leadership and success in ensuring that their medical and dental treatment facilities provide timely access and optimize continuity of care. We have undertaken major initiatives to improve both access and continuity—this is one of the Army Chief of Staff's and my top priorities. After conducting thorough business case analyses, Army Medicine is expanding product lines in some markets and expanding clinical space in others. At 14 locations, we are establishing Community Based Primary Care Clinics by leasing and operating clinics located in off-post communities that are close to where active duty Families live, work, and go to school. These clinics will provide a patient-centered medical home for Families and will provide a range of benefits:

- Improve the readiness of our Army and our Army Family
- · Improve access to and continuity of care
- · Reduce emergency room visits
- Improve patient satisfaction
- Implement Best Practices and standardization of services
- Increase physical space available in military treatment facilities (MTFs)
- Improve physical and psychological health promotion and prevention

Along with the rest of the Military Health System, Army Medicine is embracing the Patient-Centered Medical Home concept, which is a recommended practice of the National Committee for Quality Assurance and is endorsed by a number of medical associations, several large third-party payers, and many employers and health plans. The Patient-Centered Medical Home improves patient satisfaction through its emphasis on appropriate access, continuity and quality, and effective communication. The goal is simple: consult with one consistent primary care provider-nurse team for all your medical needs. The seven core features of the Medical Home are:

- Personal Primary Care Provider (primary care manager/team)
- Primary Care Provider Directed Medical Practice (the primary care manager is team leader)
- Whole Person Orientation (patient centered, not disease or provider centered)
- Care is Coordinated and/or Integrated (across all levels of care)
- Quality and Safety (evidenced-based, safe medical care)
- Enhanced Access (meets access standards from the patient perspective)
- Payment Reform (incentivizes the development and maintenance of the medical home)

I look for 2010 to be the year Army Medicine achieves what we set out to improve two years ago in access and continuity, key elements of our covenant with the Army Family, led by our Chief of Staff and Secretary of the Army.

Unlike civilian healthcare systems that can focus all of their energy and resources on providing access and continuity of care, the Military Health System has the equally important mission to **Provide Global Operational Forces**.

The partnership between and among the medical and line leadership of Operations Iraqi Freedom and Enduring Freedom, Central Command, Army Forces Command, US Army Reserve Command, National Guard Bureau, Army Medical Department Center & School, Medical Research and Materiel Command, Army G3/5/7, and others has resulted in a dynamic reconfiguration of the medical formations and tactics, techniques, and procedures required to support the deployed Army, joint and coalition force. Army Medicine has never missed movement and we continue to achieve the highest survivability rate in the history of warfare. Army Medicine leaders have never lost sight of the need to first and foremost make a difference on the battlefield.

This will not change--it will even intensify in 2010 as the complexity of the missions in Afghanistan increases. And this is occurring even while the need to sustain an Army and joint force which is responsibly withdrawing from Iraq puts more pressure on those medics continuing to provide force health protection and care in Operation Iraqi Freedom. This pressure on our All-Volunteer Army is unprecedented. Healthcare providers, in particular, are subject to unique strains and stressors while serving in garrison as well as in deployed settings. The MEDCOM has initiated a defined program to address provider fatigue with current efforts focused on sustaining the healthy force and identifying and supporting higher risk groups. MEDCOM has a healthy healthcare workforce as demonstrated by statistically significant lower provider fatigue and burnout than: The Professional Quality of Life Scale (ProQol) norming sample of 1187 respondents; and Sprang, Clark and White-Woosley's study of 222 civilian behavioral health (BH) providers. But as our Chief of Staff of the Army has told

us: this is not an area where we just want to be a little better than the other guy—we want the healthiest and most resilient healthcare provider workforce possible.

The Provider Resiliency Training (PRT) Program was originally designed in 2006, based on Mental Health Advisory Team findings. The US Army Medical Department Center and School (AMEDDC&S) developed a military-specific model identifying "provider fatigue" as the military equivalent of compassion fatigue. In June of 2008, MEDCOM implemented a mandated PRT program to educate and train all MTF personnel to include support staff on the prevention and treatment of signs and symptoms of provider fatigue. The stated goal of PRT is to mitigate the negative effects of exposure to combat, to deployment, to secondary trauma from caring for the casualties of war as well as the unremitting demand for healthcare services and from burnout. All will ultimately improve organizational effectiveness. The AMEDDC&S currently offers three courses in support of the MEDCOM PRT: the Train the Trainer Course; the Professional Resiliency Resident Course; and the PRT Mobile Training.

None of our goals and themes would be achievable without the right mix of talented professionals within Army Medicine and working with Army Medicine; what our Balanced Scorecard refers to as **Build The Team**: a larger, more inclusive joint medical team; an adaptive & responsive interagency team (VA, DHS, DHHS/NIH/NIAID, CDC, USDA, etc.); an effective coalition team; and a military-civilian/academic-operational team. The teams we build must be aligned with the Army, Defense, and National Military Strategy and long-term goals, not based solely on personalities and the arcane interests of a few. My Deputy Surgeon General, subordinate leaders, and others have been increasingly more deliberate and disciplined in how we form and sustain these critical partnerships.

Effective joint, interagency and coalition team-building has been a serious challenge for some time now. I see the emphasis on our ability to craft these teams grow in 2010. The arrival of September 15, 2011--the deadline for the 2005 BRAC--will be one of the key milestones and tests of this skill. My regional commanding generals in San Antonio and Washington, DC have taken lead roles

in this endeavor. Let there be no question among those who underestimate our collective commitment to working as a team and our shared vision to serve the Nation and protect and care for the Warriors and his or her Family—we are One Team!

In addition to building external teams, we need to have the right mix and quality of personnel internal to Army Medicine. In Fiscal Year 2010 (FY10) and continuing into FY11 the Army requested funding for programs to improve our ability to attract and retain the professional workforce necessary to care for our Army. Our use of civilian hiring incentives (Recruiting, Retention, & Relocation) increased in FY10 by \$90M and should increase by an additional \$30M in FY11. In FY11, civilian hiring incentives will equate to 4.8% of total civilian pay. We have instituted and funded civilian recruiting programs at the MEDCOM, regional, and some local levels to seek qualified healthcare professionals. For our military workforce, we are continuing our successful special salary rates, civilian nurse loan repayment programs, and civilian education training programs. Additionally, our Health Professional Scholarship Program and loan repayments will increase in FY10 by \$26M and continue into FY11. This program supports 1,890 scholarships and 600 participants in loan repayments—it is as healthy a program as it has ever been. Let me point out that our ability to educate and train from within the force—through physician, nursing, administrative, medic and other programs in professional education—is a vital capability which we cannot permit to be degraded or lost altogether. In addition to providing essential enculturation for a military healthcare provider, administrator and leader, these programs have proven to be critical for our retention of these professionals who are willing to remain in uniform, to deploy in harm's way and to assume many onerous duties and assignments in exchange for education in some of the Nation's best programs. Army and Military Graduate Medical, Dental, Nursing and other professional education has undoubtedly played a major role in our remaining a viable force this far into these difficult conflicts.

The theme of evidence-based practice runs through everything we do in Army Medicine and is highlighted throughout our Balanced Scorecard. Evidence-based practices mean integrating individual clinical expertise with the best available external clinical evidence from systematic research. Typical examples of evidence-based practices include implementation of clinical practice guidelines and dissemination of best practices. I encourage my commanders and subordinate leaders to be innovative, but across Army Medicine we **Balance Innovation with Standardization** so that all of our patients are receiving the best care and treatment available. Standardization efforts include:

- The MEDCOM AHLTA Provider Satisfaction (MAPS) initiative
- Care of combat casualties through the Joint Theater Trauma System
  (JTTS), enabled by the use of a Joint Theater Trauma Registry (JTTR)—
  both of which I will discuss further below—which examines every
  casualty's care and outcome of that care, including en route care during
  medical evacuation (MEDEVAC) with an eye toward standardizing care
  around the best practices
- The Virtual Behavioral Health Pilot (aka Comprehensive Behavioral Health Integration) being conducted at Schofield Barracks and Ft. Richardson
- Our initiative to reduce Ventilator Associated Pneumonia events in our ICUs by adopting not only industry best practices, but sending out an expert team of MEDCOM professionals to evaluate our own best practices and barriers to success
- Our standardized events-driven identification and management of mild TBI/concussion on the battlefield coupled with early diagnosis and treatment of Post-Traumatic Stress Reactions/Acute Stress Reactions as close in time and space to the events which lead to these reactions

Programs which are in the process of maturing into best practices for more widespread dissemination are:

• The Confidential Alcohol Treatment & Education Pilot (CATEP)

- The standardized and now automated Comprehensive Transition Plan for Warriors In Transition in our WTUs and CBWTUs
- A standardized program to "build trust in Army Medicine" through hospitality and patient/client/customer service in our medical, dental, and veterinary treatment facilities and throughout the MEDCOM
- Standardized support of our Active, National Guard, and Reserve forces
  engaged in the reiterative, cyclic process of the Army Force Generation
  Model (ARFORGEN) including but not restricted to preparation for combat
  medics and medical units, Soldier Readiness Processing of deploying
  units, ensuring full medical readiness of the force, restoration of dental
  and behavioral health upon redeployment, support of the total Army
  Family while Soldiers are deployed, and provision of healthcare for
  mobilized and demobilizing Reserve Component Soldiers and their
  Families.

These and many other standardized efforts reflect a change in how we do the business of Army Medicine. We can no longer pride ourselves on engaging in a multiplicity of local "science projects" being conducted in a seemingly random manner by well-meaning and creative people but without a focus on added value, standard measures of improved outcomes, and sustainability of the product or process. Even the remarkably agile response to the behavioral health needs-assessment and ongoing requirements at Fort Hood following the tragic shooting were conducted in a very deliberate and effective fashion which emphasized unity of command and control, alignment of all efforts and marshalling of resources to meet a well-crafted and even exportable community behavioral health plan.

The emphasis which Army Medicine leaders have placed on disciplining these innovative measures so as to harvest best practices, subject them to validation at other sites, and rapidly proliferate them across the MEDCOM and Army in a standard fashion has been remarkable. It is the essence of **Optimizing Communication and Knowledge Management**.

Many of our goals, internal processes and enablers, and resource investments are focused on the knowledge hierarchy: collecting <a href="data">data</a>; coalescing it into <a href="information">information</a> over time and space; giving it context to transform it into <a href="knowledge">knowledge</a>; and applying that knowledge with careful outcome measures to achieve <a href="wisdom">wisdom</a>. This phenomenon of guiding clinical management by the emergence of new knowledge is perhaps best represented by Dr. Denis Cortese, former President and Chief Executive Officer of the Mayo Clinic. He laid out this schematic earlier this year after participating in a set of workshops which centered on healthcare reform. We participated to explore how the Federal system of care might contribute to these changes in health improvement and healthcare delivery.

What Dr. Cortese depicted is a three-domain ideal representation of healthcare delivery and its drivers. We share this vision of how an ideal system should operate. His notion is that this system of care should focus on optimizing individual health and healthcare needs, leveraging the knowledge domain to drive optimal clinical practices. This transition from the knowledge domain to the care delivery domain now takes 17 years. The clinical practice domain then informs and drives the payer domain to remunerate for effective clinical outcomes. What occurs too often today is what I call "widget-building" or "turnstile" medical care which chases remuneration for these encounters—too often independent of whether it is the best treatment aimed at the optimal outcome. To transform from a healthcare system to a system for health, we need to change the social contract. No longer should we be paid for building widgets (number of clinic visits or procedures), rather, we should be paid for preventing illness and promoting healthy lifestyles. And when bad things happen to good people—which severe illness and injury and war continuously challenge us with-we should care for these illnesses, injuries and wounds by the most advanced evidence-based practices available, reducing unwarranted variation in practice whenever possible.

Our Military Health System is subtly different in that we have two practice domains—garrison and battlefield. Increasingly, we leverage the clinical domain

to provide feedback into the knowledge domain—with the help of the electronic health record—AHLTA—and specialized databases. We do this in real time and all under the umbrella of the regulatory domain which sets and enforces standards.

The reengineering of combat trauma care borne of rapid turnaround of new-found, data-driven knowledge to new materiel and doctrinal solutions is one of the premier examples of this concept. The simplest example is our continuous re-evaluation of materials and devices available to Soldiers, combat life savers, combat medics and the trauma team at the point of injury and in initial trauma management and the intellectual framework for their application to rapidly improve outcomes from combat-injured Warriors.

After making the first major change in 40 years to the field medical kit—the Improved First Aid Kit (IFAK)—we have modified the contents of the kit at least three times since May 2005 based upon ongoing reviews of the effectiveness of the materials and head-to-head comparisons to competing devices or protocols. In like fashion, we have modified protocols for trauma management through active in-theater and total systemic analyses of the clinical outcomes deriving from the use of materials and protocols.

The specialized system in this endeavor is a joint and inter-agency trauma system which creates the equivalent of a trauma network available for a major metropolitan area or geographic region in the US but spread across three continents, 8000 miles end-to-end—the Joint Theater Trauma System (JTTS). Staffed and led by members of the Army, Navy, Marine Corps and Air Force, it is truly a joint process. It is centered on the US Army Institute of Surgical Research in San Antonio, Texas. The specialized database in this effort and an essential element of the JTTS is the Joint Theater Trauma Registry (JTTR)—a near-comprehensive standardized database which has been developed for each casualty as soon as possible in the treatment evacuation chain—usually at level II or III healthcare in theater. One of the most important critical applications of the JTTS and JTTR at present is the ongoing analysis of MEDEVAC times and the casualties being managed during evacuation. This is our effort to minimize

the evacuation time for casualty in a highly dispersed force which is subjected in Afghanistan to the "tyranny of terrain and weather."

The decisions about where and how many trauma teams should be placed around the theater of operation as well as where to place MEDEVAC crews and aircraft is a delicate balancing act—one which balances the risk of putting care providers and MEDEVAC crews and helicopters at risk to the enemy and the elements with the risk of loss of life and limb to Warriors whose evacuation may be excessively prolonged. The only way to fully understand these competing risks is to know the outcomes of care and evacuation by injury type across a wide range of MEDEVAC missions. This analysis will help us understand if we still require a "Golden Hour" for every casualty between initial management at the point of injury and arrival at a trauma treatment site (like an Army Forward Surgical Team, the Marine Forward Resuscitative Surgical System or a Combat Support Hospital) or whether we now have a "Platinum 15 Minutes" at the point of injury which extends the Golden Hour.

This methodology and these casualty data are being applied to the next higher level of inquiry: how do we prevent injury and death of our combatants from wounds and accidents at the point of potential injury? Can we design improved helmets, goggles, body armor, vehicles and aircraft to prevent serious injuries? These questions are answered not only through the analysis of wound data, both survivable and non-survivable, through the JTTS and data from the virtual autopsy program of the Office of the Armed Forces Medical Examiner, but also by integrating these data with information from the joint operational, intelligence, and materiel communities to enable the development of improved tactics, techniques, and procedures and materiel improvements to protective equipment worn by the Warriors or built into the vehicles or aircraft in which they were riding. This work is performed by the Joint Trauma Analysis and Prevention of Injury in Combat program, a component of the DoD Blast Injury Research Program directed by the National Defense Authorization Act for 2006. To date it has been an effective means of improving the protection of Warriors and

preventing serious injury and death even as the enemy devises more lethal and adaptive weapons and battlefield tactics, techniques, and procedures.

We in Army Medicine are applying these knowledge management tools and approaches to the improvement of health and the delivery of healthcare back home as well. We are coupling these knowledge management processes with a funding strategy which incentivizes our commanders and clinicians to balance productivity—providing episodes of care—with optimal outcome: the right kind of prevention and care.

Among our greatest team achievements in 2009 was our effort to better understand how we communicate effectively with our internal and external stakeholders, patients, clients and customers. We adopted a formal plan to align our messages--ultimately all tied to Army goals and those on our Balanced Scorecard. Our creation of a Strategic Communications Directorate to ensure alignment of our key messages, to better understand and use social media, to expedite cross-talk and learning among such diverse groups as the Office of Congressional Liaison, Public Affairs, Protocol, Medical History, the Borden Institute, the AMEDD Regiment and others speaks directly to these efforts.

While we are still in the "advanced crawl/early walk" phase of knowledge management, we know from examples such as the Joint Theater Trauma System and the Performance Based Budget Model that we can move best practices and newly found evidence-based approaches into common or widespread use if we aggressively coordinate and manage our efforts and promote transparency of data and information and the knowledge which derives from it. We have begun a formal process under the Strategy & Innovation Directorate to move the best ideas in both clinical and transactional processes into standard practices across the MEDCOM in a timely way. This will be achieved through a process to identify, validate, and transfer best practices. We endeavor to be more agile and adaptive in response to a rapidly changing terrain of US and Federal healthcare and operational requirements for a Nation at war.

In closing, I am very optimistic about the next two years. We have weathered some serious challenges to trust in Army Medicine. Logic would not predict that we would be doing as well as we are in attracting, retaining and career developing such a talented team of uniformed and civilian medical professionals. However, we continue to do so year after year--a tribute to all our Officer Corps, the leadership of our Non-Commissioned Officers, and our military and civilian workforce. The results of our latest Medical Corps Graduate Medical Education Selection Board and the Human Capital Distribution Plan show continued strength and even improvements over past years. The continued leadership and dedicated service of officers, non-commissioned officers, and civilian employees are essential for Army Medicine to remain strong, for the Army to remain healthy and strong, and for the Nation to endure. I feel very privileged to serve with the men and women of Army Medicine during this historic period as Army Medics, as Soldiers, as Americans and as global citizens.

Thank you for holding this hearing and your unwavering support of the Military Health System, Army Medicine, and our wounded injured and ill Soldiers. Thanks to your tremendous support and that of the Army Senior Leaders, the Warrior Care and Transition Program is well resourced to enable and inspire Soldiers toward positive and productive futures. I look forward to working with you and your staff and addressing any of your concerns or questions.

# Mr. DICKS. Admiral Robinson.

# SUMMARY STATEMENT OF ADMIRAL ROBINSON

Admiral ROBINSON. Good morning, Chairman Dicks, distinguished members of the subcommittee. I want to thank you for your unwavering support of Navy Medicine, particularly as we continue to care for those who go in harm's way, their families, and all beneficiaries.

I am honored to be with you today to provide an update on Navy Medicine. Navy Medicine: World-Class Care Anytime, Anywhere. This poignant phrase is arguably the most telling description of Navy Medicine's accomplishments in 2009, and continues to drive our operational tempo and priorities for the coming year and beyond.

Throughout the last year, we saw challenges and opportunities. And moving forward, I anticipate the pace of operations and demands will continue to increase. We have been stretched in our ability to meet our increasing operational and humanitarian assistance requirements as well as maintain our commitment to provide care to a growing number of beneficiaries. However, I am proud to say that we are responding to this demand with flexibility and agility more so than ever before.

The foundation of Navy Medicine is force health protection. Nowhere is this more evident than in Iraq and Afghanistan. During my October 2009 trip to theater, I again saw the outstanding work of our medical personnel. The Navy Medicine team is working side by side with Army and Air Force, medical personnel and coalition forces to deliver outstanding health care to our troops and civilians alike. As our Wounded Warriors return from combat and begin the healing process, they deserve a seamless and comprehensive approach to their recovery. We want them to mend in body, mind, and spirit.

Our patient- and family-centered concept of care brings together medical treatment providers, social workers, case managers, behavioral health providers, and chaplains. We are working closely with our line counterparts in the Marine Corps Wounded Warrior Regiments and the Navy's Safe Harbor program to support the process for Sailors, Marines, and for their families.

An important focus area for all of us continues to be traumatic brain injury. We are expanding TBI training to health care providers throughout the Fleet and Marine Corps. We are also implementing a new in-theater traumatic surveillance system and conducting important research. Our strategy is both collaborative and integrative, by actively partnering with the other services, the Defense Center of Excellence for Psychological Health and Traumatic Brain Injury, the Department of Veterans Affairs, and leading academic medical and research centers to make the best care available to our warriors.

We must act with a sense of urgency to continue to help build resiliency among our Sailors and Marines as well as the caregivers who support them. We are aggressively working to reduce the stigma surrounding psychological health and operational stress concerns. Programs such as the Navy's Operational Stress Control, Marine Corps Combat Operational Stress Control, FOCUS (Families Overcoming Under Stress) Caregiver Occupational Stress Control, and our suicide prevention programs are in place and matur-

ing to provide support to personnel and their families.

Mental health specialists are being placed in operational environments and forward-deployed to provide services where and when they are needed. The Marine Corps is sending more mental health teams to the front lines, and Operational Stress Control and Readiness teams, known as OSCAR, will soon be expanded to include the battalion level. A mobile care team of Navy Medicine mental health professionals is currently deployed to Afghanistan, conducting mental health surveillance, consulting with command leadership, and coordinating mental health care for Sailors throughout the Area of Responsibility (AOR).

An integral part of Navy's Maritime Strategy is humanitarian assistance and disaster relief. In support of Operation United Response-Haiti, we deployed USNS Comfort from her homeport in Baltimore within 77 hours of the order and ahead of schedule. She was on station in Port au Prince 5 days later. From the beginning, the operational tempo onboard Comfort was high, and our personnel were challenged both professionally and personally. For many, this was a career-defining experience. And I was proud to welcome the crew home last month and congratulate them for their

outstanding performance.

I am encouraged with our recruiting efforts within Navy Medicine and we are starting to see the results of new incentive programs. But while overall manning levels for both officer and enlisted personnel are relatively high, ensuring we have the proper specialty mix continues to be a challenge both in the Active and the Reserve components. Several wartime critical specialties as well as advanced practice nursing and physician assistants are in demand. We are facing shortfalls for general dentists, oral maxillofacial surgeons, and many of our mental health specialists, including clinical psychologists, and social workers. We continue to work hard to meet this demand, but fulfilling the requirement among these specialties is expected to present a continuing challenge.

Research and development is critical to Navy Medicine's success and our ability to remain agile to meet the evolving needs of our warfighters. It is where we find solutions to our most challenging problems and, at the same time, provide some of medicine's most

significant innovations and discoveries.

Research efforts targeted at wound management, including enhanced wound repair and reconstruction, as well as extremity and internal hemorrhage control and phantom limb pain in amputees present definitive benefits. These efforts support our emerging expeditionary medical operation and aid in support of our Wounded Warriors.

Clearly, one of the most important priorities for the leadership of all the services is the successful transition to the Walter Reed National Military Medical Center onboard the campus of the National Naval Medical Center Bethesda. We are working diligently with the lead DOD organization—Joint Task Force, National Capital Region Medical—to make sure that this significant and ambitious project is executed properly and without any disruption of

services to our Sailors, Marines, and their families, and all other beneficiaries for whom we are privileged to serve.

In summary, I believe we are at an important crossroads for military medicine. Commitment to our Wounded Warriors and their families must never waver, and our programs of support and hope must be built and sustained for the long haul. And the long haul is the rest of the century, when the young Wounded Warriors of today mature into our aging heroes in the years to come. They will need our care and support, as will their families, for a lifetime.

On behalf of the men and women of Navy Medicine, I want to thank the committee for your tremendous support, for your confidence, and for your leadership. It has been my pleasure to testify

before you today, and I look forward to your questions.

Mr. DICKS. Thank you, Admiral Robinson. [The statement of Admiral Robinson follows:]

# Not for Publication until released by the House Appropriations Committee

# Statement of

Vice Admiral Adam M. Robinson, Jr., MC, USN

Surgeon General of the Navy

Before the

**Subcommittee on Defense** 

of the

**House Appropriations Committee** 

Subject:

The State of Navy Medicine

22 April 2010

Not for Publication until released by the House Appropriations Committee

# United States Navy Biography

# Vice Admiral Adam M. Robinson, Jr. Medical Corps Surgeon General Chief, Bureau of Medicine and Surgery

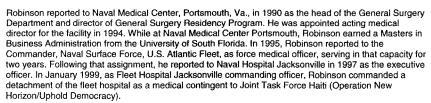
Vice Admiral Adam M. Robinson Jr. assumed duties as the 36th Surgeon General of the Navy and Chief of the Navy's Bureau of Medicine and Surgery on August 27, 2007.

Robinson, a native of Louisville, Ky, entered the naval service in 1977 and holds a Doctor of Medicine from the Indiana University School of Medicine, Indianapolis, through the Armed Forces Health Professions Scholarship Program. Following completion of his surgical internship at Southern Illinois University School of Medicine, Springfield, he was commissioned.

Robinson's first assignment was as general medical officer, Branch Medical Clinic, Fort Allen, Puerto Rico, before reporting to the National Naval Medical Center, Bethesda, Md., in 1978 to complete a residency in general surgery. His subsequent duty assignments included: staff surgeon, U.S. Naval Hospital, Yokosuka, Japan, and ship's surgeon, USS Midway (CV-41).

After completing a fellowship in colon and rectal surgery at Carle
Foundation Hospital, University of Illinois School of Medicine (198485), Robinson reported to the National Naval Medical Center,
Bethesda, as head of the Colon and Rectal Surgery Division. While there, he was called to temporary duty

in 1987 as ship's surgeon in USS John F. Kennedy (CV-67) and in 1988 as ship's surgeon in USS Coral Sea (CV-43).



In August 1999, Robinson reported to the Bureau of Medicine and Surgery (BUMED) as director of readiness and was selected as the principle director, Clinical and Program Policy in the Office of the Assistant Secretary of Defense for Health Affairs in September 2000, where he also served as the acting deputy assistant Secretary of Defense for Health Affairs, Clinical and Program Policy. Robinson was assigned as commanding officer, U.S. Naval Hospital Yokosuka from September 2001 to January 2004,



after which he received assignment back to BUMED as deputy chief of BUMED for Medical Support Operations with additional duty as acting chief of the Medical Corps. In July 2004, Robinson reported as commander, National Naval Medical Center, Bethesda, Maryland. He assumed the duties as commander, Navy Medicine National Capital Area Region in October 2005.

The author of numerous presentations and publications, Vice Adm. Robinson holds fellowships in the American College of Surgeons and the American Society of Colon and Rectal Surgery. He is a member of the Le Societe Internationale de Chirurgie, the Society of Black Academic Surgeons, and the National Business School Scholastic Society, Beta Gamma Sigma. He holds certification as a Certified Physician Executive from the American College of Physician Executives.

Robinson's personal decorations include the Distinguished Service Medal, Legion of Merit (two awards), Defense Meritorious Service Medal (two awards), Meritorious Service Medal (three awards), Navy Commendation Medal, Joint Service Achievement Medal, Navy Achievement Medal and various service and campaign awards.

# Introduction

Chairman Dicks, Congressman Young, distinguished Members of the Subcommittee, I am honored to be with you today to provide an update on the state of Navy Medicine, including some of our accomplishments, challenges and strategic priorities. I want to thank the Committee Members for your unwavering support of Navy Medicine, particularly as we continue to care for those who go in harm's way, their families and all beneficiaries.

Navy Medicine – World Class Care ... Anytime, Anywhere. This poignant phrase is arguably the most telling description of Navy Medicine's accomplishments in 2009 and continues to drive our operational tempo and priorities for the coming year and beyond. Throughout the last year we saw challenges and opportunities; and moving forward, I anticipate the pace of operations and demands placed upon us will continue to increase. Make no mistake: We have been stretched in our ability to meet our increasing operational and humanitarian assistance requirements, as well as maintain our commitment to provide Patient and Family-Centered care to a growing number of beneficiaries. However, I am proud to say to that we are responding to this demand with more flexibility and agility than ever before. We are a vibrant, world-wide health care system fully engaged and integrated in carrying out the core capabilities of the Maritime Strategy around the globe. Regardless of the challenges ahead, I am confident that we are well-positioned for the future.

Since becoming the Navy Surgeon General in 2007, I have invested heavily in our strategic planning process. How we accomplish our mission is rooted in sound planning, sharp execution and constructive self-assessment at all levels of our organization. I

challenged our leadership to create momentum and establish a solid foundation of measurable progress. It's paying dividends. We are seeing improved and sustained performance in our strategic objectives. Just as importantly, our planning process supports alignment with the Department of Navy's Strategic Plan and Operations Guidance.

Navy Medicine's commitment to Patient and Family-Centered Care is also reflected in our resourcing processes. An integral component of our Strategic Plan is providing performance incentives that promote quality and directly link back to workload and resources. We are evolving from a fiscal planning and execution process rooted in historical data, to a system which links requirements, resources and performance goals. This transformation to Performance Based Budgeting properly aligns authority, accountability and financial responsibility with the delivery of quality, cost-effective health care

The President's budget for FY11 adequately funds Navy Medicine to meet its medical mission for the Navy and Marine Corps. The budget also provides for the maintenance of our facilities. We appreciate the Committee's strong support of our resource requirements.

# **Force Health Protection**

The foundation of Navy Medicine is Force Health Protection. It's what we do and why we exist. In executing our Force Health Protection mission, the men and women of Navy Medicine are engaged in all aspects of expeditionary medical operations in support of our warfighters. The continuum of care we provide includes all dimensions of physical and psychological well-being. This is our center of gravity and we have and

will continue to ensure our Sailors and Marines are medically and mentally prepared to meet their world-wide missions.

Nowhere is our commitment to Force Health Protection more evident than in our active engagement in military operations in Iraq and Afghanistan. As these overseas contingency operations evolve, and in many respects become increasingly more dangerous, we are seeing burgeoning demand for expeditionary combat casualty care in support of joint operations. I recently returned from a trip to Afghanistan and I again saw the outstanding work of our medical personnel. The Navy Medicine team is working side-by-side with Army and Air Force medical personnel and coalition forces to deliver outstanding health care to our troops and civilians alike.

We must continue to be innovative and responsive at the deckplates and on the battlefield. Since the start of Operation ENDURING FREEDOM and Operation IRAQI FREEDOM, the Marine Corps has fielded new combat casualty care capabilities which include: updated individual first aid kits with combat gauze, advanced tourniquets, use of Tactical Combat Casualty Care principles, troop training in Combat Lifesaver, and the use of Factor VII - a blood clotting agent used in trauma settings. In addition, Navy Fleet Hospital transformation has redesigned expeditionary medical facilities that are lighter, modular, more mobile, and interoperable with other Services' facilities.

Our progress is also evident in the innovative work undertaken by a Shock

Trauma Platoon (STP) two years ago in Afghanistan. This team, comprised of two
physicians, two nurses, a physician assistant and 14 corpsmen, essentially created a
mobile emergency room - a seven-ton truck with a Conex container and welded steel
plates - that went into combat to administer more expedient and effective care in austere

settings. This prototype led to the creation of the Mobile Trauma Bay (MTB), a capability that both Marine Corps and Navy Medicine leadership immediately recognized as vital to the warfighter and an unquestionable life-saver on the battlefield. MTB use has already been incorporated into our Afghanistan shock trauma platoon operations, and they are already positively impacting forward resuscitative and stabilization care. We understand that the Marine Corps has fully embraced the MTB concept and is planning to add additional units in future POM submissions.

# **Humanitarian Assistance and Disaster Response**

An integral part of the Navy's Maritime Strategy is humanitarian assistance and disaster response. In the wake of the devastating earthquake in Haiti earlier this year, our Nation moved forward with one of the largest relief efforts in our history to save lives, deliver critically needed supplies and provide much-needed hope. The response was rapid, as Navy deployed ships and expeditionary forces, comprised of more than 10,000 personnel, to provide immediate relief and support for the Haitian people. In support of Operation UNIFIED RESPONSE, Navy Medicine answered the call. We deployed USNS COMFORT (T-AH 20) from her homeport in Baltimore within 77 hours and ahead of schedule – going from an industrial shipboard site to a ready afloat Naval hospital, fully staffed and equipped. She was on station in Port-au-Prince five days later and treating patients right away. From the beginning, the operational tempo onboard USNS COMFORT has been high with a significant trauma and surgical caseload. Medical teams from the ship are also ashore to help in casualty evaluation, triage crush wounds, burn injuries and other health issues. Providing care around the clock, our

personnel were challenged both professionally and personally. For many, this was a career-defining experience and certainly reflects the Navy's commitment as a "Global Force for Good." I spoke to the crew as they were preparing to get underway, and personally related just how important this mission is and why it is a vital part of the Navy's Maritime Strategy.

Navy Medicine provided additional support that included the deployment of a Forward Deployed Preventive Medicine Unit (FDPMU) and augmented Casualty Receiving and Treatment Ship (CRTS) medical staff capabilities onboard USS BATAAN (LHD 5). We also recognized the potential psychological health impact on our medical personnel involved in this humanitarian assistance mission and ensured we had trained Caregiver Occupational Stress Control (CgOSC) staff onboard.

The ship departed Haiti on 10 March 2010. Prior to getting underway, the crew gathered for a memorial ceremony in honor of the people of Haiti. The men and women of USNS COMFORT, and all involved in this mission, saved lives, alleviated suffering, and brought hope in the midst of devastation. Their performance and spirit of caring was exemplary.

Navy Medicine is inherently flexible and capable of meeting the call to support multiple missions. I am proud of the manner in which the men and women of Navy Medicine leaned forward in response to the call for help. In support of coordination efforts led by the Department of State and the U.S. Agency for International Development, and in collaboration with nongovernmental organizations, both domestic and international, our response demonstrated how the expeditionary character of our

Naval and Marine forces are uniquely suited to provide assistance during interagency and multinational efforts.

# **Concept of Care**

Navy Medicine's Concept of Care is Patient and Family-Centered Care. It is at the epicenter of everything we do. This concept is elegant in its simplicity yet extraordinarily powerful. It identifies each patient as a participant in his or her own health care and recognizes the vital importance of the family, military culture and the military chain of command in supporting our patients. My goal is for this Concept of Care – this commitment to our patients and their families – to resonate throughout our system and guide all our actions. It is enabled by our primary mission to deliver force health protection and a fully ready force; mutually supported by the force multipliers of world class research and development, and medical education. It also leverages our emphasis on the health and wellness of our patients through an active focus on population health.

# **Caring for Our Heroes**

When our Warriors go into harm's way, we in Navy Medicine go with them. At sea or on the ground, Sailors and Marines know that the men and women of Navy Medicine are by their side ready to care for them. There is a bond of trust that has been earned over years of service together, and make no mistake, today that bond is stronger than ever. Our mission is to care for our wounded, ill and injured, as well as their families. That's our job and it is our honor to have this opportunity.

As our Wounded Warriors return from combat and begin the healing process, they deserve a seamless and comprehensive approach to their recovery. We want them to mend in body, mind and spirit. Our focus is multidisciplinary-based care, bringing together medical treatment providers, social workers, case managers, behavioral health providers and chaplains. We are working closely with our line counterparts with programs like the Marine Corps' Wounded Warrior Regiments and the Navy's Safe Harbor to support the full-spectrum recovery process for Sailors, Marines and their families.

Based on the types of injuries that we see returning from war, Navy Medicine continues to adapt our capabilities to best treat these conditions. When we saw a need on the West Coast to provide expanded care for returning Wounded Warriors with amputations, we established the Comprehensive Combat and Complex Casualty Care (C5) Program at Naval Medical Center, San Diego, in 2007. C5 manages severely injured or ill patients from medical evacuation through inpatient care, outpatient rehabilitation, and their eventual return to active duty or transition from the military. We are now working to expand utilization of Project C.A.R.E – Comprehensive Aesthetic Recovery Effort. This initiative follows the C5 model by ensuring a multidisciplinary approach to care, yet focuses on providing state-of-the-art plastic and reconstructive surgery for our Wounded Warriors at both Naval Medical Center San Diego and Naval Medical Center Portsmouth, with potential future opportunities at other treatment facilities.

We have also significantly refocused our efforts in the important area of clinical case management at our military treatment facilities and major clinics serving Wounded

Warriors to ensure appropriate case management services are available to all who need them. The Clinical Case Management Program assists patients and families with clinical and non-clinical needs, facilitating communication between patient, family and multi-disciplinary care team. Our clinical case managers collaborate with Navy and Marine Corps Recovery Care Coordinators, Federal Recovery Coordinators, Non-Medical Care Managers and other stakeholders to address Sailor and Marine issues in developing Recovery Care Plans. As of January 2010, 192 Clinical Case Managers are assigned to Military Treatment Facilities and ambulatory care clinics caring for over 2,900 Sailors, Marines and Coast Guardsmen.

# **Psychological Health and Post-Traumatic Stress**

We must act with a sense of urgency to help build resiliency among our Sailors and Marines, as well as the caregivers who support them. We recognize that operational tempo, including the number and length of deployments, has the potential to impact the psychological health of service members and their family members. We are aggressively working to reduce the stigma surrounding psychological health and operational stress concerns which can be a significant barrier to seeking mental health services for both military personnel and civilians. Programs such as Navy Operational Stress Control, Marine Corps Combat Operational Stress Control, FOCUS (Families Overcoming Under Stress), Caregiver Occupational Stress Control (CgOSC), and our suicide prevention programs (A-C-T Ask-Care-Treat) are in place and maturing to provide support to personnel and their families.

The Navy Operational Stress Control program and Marine Corps Combat

Operational Stress Control program are the cornerstones of the Department of the

Navy's approach to early detection of stress injuries in Sailors and Marines and are

comprised of:

- Line led programs which focus on leadership's role in monitoring the health of their people.
- Tools leaders may employ when Sailors and Marines are experiencing mild to moderate symptoms.
- Multidisciplinary expertise (medical, chaplains and other support services) for more affected members.

Decreasing the stigma associated with seeking psychological health care requires a culture change throughout the Navy and Marine Corps. Confronting an ingrained culture will take time and active leadership support. Stigma reducing interventions span three major fronts: (1) education and training for individual Sailors and Marines that normalizes mental health care; (2) leadership training to improve command climate support for seeking mental health care; and (3) encouragement of care outreach to individual Sailors, Marines, and their commands. This past year saw wide-spread dissemination of Operational Stress Control (OSC) doctrine as well as a Navy-wide education and training program that includes mandatory Navy Knowledge Online courses, instructor led and web-based training.

Navy Medicine ensures a continuum of psychological health care is available to service members throughout the deployment cycle – pre-deployment, during deployment, and post-deployment. We are working to improve screening and surveillance using

instruments such as the Behavior Health Needs Assessment Survey (BHNAS) and Post-Deployment Health Assessment (PDHA) and Post-Deployment Health Reassessment (PDHRA).

Our mental health specialists are being placed in operational environments and forward deployed to provide services where and when they are needed. The Marine Corps is sending more mental health teams to the front lines with the goal of better treating an emotionally strained force. Operational Stress Control and Readiness (OSCAR) teams will soon be expanded to include the battalion level, putting mental health support services much closer to combat troops. A Mobile Care Team (MCT) of Navy Medicine mental health professionals is currently deployed to Afghanistan to conduct mental health surveillance, command leadership consultation, and coordinate mental health care for Sailors throughout the AOR. In addition to collecting important near real-time surveillance data, the MCT is furthering our efforts to decrease stigma and build resilience.

We are also making mental health services available to family members who may be affected by the psychological consequences of combat and deployment through our efforts with Project FOCUS, our military treatment facilities and our TRICARE network partners. Project FOCUS continues to be successful and we are encouraged that both the Army and Air Force are considering implementing this program. We also recognize the importance of the counseling and support services provided through the Fleet and Family Support Centers and Marine Corps Community Services.

Beginning in 2007, Navy Medicine established Deployment Health Centers

(DHCs) as non-stigmatizing portals of care for service members staffed with primary care

and psychological health providers. We now have 17 DHCs operational. Our health care delivery model supports early recognition and treatment of deployment-related psychological health issues within the primary care setting. Psychological health services account for approximately 30 percent of all DHC encounters. We have also increased mental health training in primary care, and have actively partnered with Line leaders and the Chaplain Corps to develop combat and operational stress control training resources. Awareness and training are keys to our surveillance efforts. Over 4,000 Navy Medicine providers, mental health professionals, chaplains and support personnel have been trained to detect, screen and refer personnel who may be struggling with mental health issues.

We must continue to recognize the occupational stress on our caregivers. They are subject to the psychological demands of exposure to trauma, loss, fatigue and inner conflict. This is why our Caregiver Occupational Stress Control programs are so important to building and sustaining the resiliency of our providers. We cannot overlook the impact on these professionals and I have directed Navy Medicine leadership to be particularly attuned to this issue within their commands.

# **Traumatic Brain Injury**

While there are many significant injury patterns in theater, an important focus area for all of us remains Traumatic Brain Injury (TBI). Blast is the signature injury of OEF and OIF – and from blast injury comes TBI. The majority of TBI injuries are categorized as mild, or in other words, a concussion. Yet, there is much we do not yet know about these injuries and their long-term impacts on the lives of our service members.

The relative lack of knowledge about mild TBI amongst service members and health care personnel represents an important gap that Navy Medicine is seriously addressing. We are providing TBI training to health care providers from multiple disciplines throughout the fleet and the Marine Corps. This training is designed to educate personnel about TBI, introduce the Military Acute Concussion Exam (MACE) as a screening tool for mild TBI, inform providers about the Automated Neurocognitive Assessment Metric (ANAM) test, and identify a follow-up for assessment including use of a repeatable test battery for identification of cognitive status. We have recently established and are now expanding our TBI program office to manage the implementation of the ANAM as a pre-deployment test for service members in accordance with DoD policy. This office will further develop models of assessment and care as well as support research and evaluation programs.

All the Services expect to begin implementation of a new in-theater TBI surveillance system which will be based upon incident event tracking. Promulgated guidelines will mandate medical evaluation for all service members exposed within a set radius of an explosive blast, with the goal to identify any service member with subtle cognitive deficits who may not be able to return to duty immediately.

Navy Medicine has begun implementing the ANAM assessment at the DHCs and within deploying units as part of an Assistant Secretary of Defense (Health Affairs) mandate. We have also partnered with Line leadership, or operational commanders, to identify populations at risk for brain injury (e.g., front line units, SEAL units, and Navy Explosive Ordinance Disposal units). In addition, an in-theater clinical trial for the

treatment of vestibular symptoms of blast-exposure/TBI was completed at the USMC mTBI Center in Al Taqqadum, Iraq.

Both our Naval Health Research Center and Navy-Marine Corps Public Health Center are engaged with tracking TBI data through ongoing epidemiology programs.

Goals this year include the establishment of a restoration center in-theatre to allow injured Sailors and Marines a chance to recover near their units and return to the fight.

Additionally, the National Naval Medical Center's Traumatic Stress and Brain Injury Program provides care to all blast-exposed or head-injured casualties returning from theatre to include patients with an actual brain injury and traumatic stress. Navy Medicine currently has TBI clinics at San Diego, Portsmouth, Camp Pendleton and Camp Lejeune with plans for further expansion reflecting our commitment to the treatment of this increasingly prevalent injury.

We are employing a strategy that is both collaborative and integrative by actively partnering with the other Services, Defense Center of Excellence for Psychological Health and Traumatic Brain Injury, the Department of Veterans Affairs, and leading academic medical and research centers to make the best care available to our Warriors afflicted with TBI.

# Excellence in Research and Development (R&D)

Research and development is critical to Navy Medicine's success and our ability to remain agile to meet the evolving needs of our warfighters. It is where we find solutions to our most challenging problems and, at the same time, provide some of

medicine's most significant innovations and discoveries. Our R&D programs are truly force-multipliers and enable us to provide world-class health care to our beneficiaries.

The approach at our research centers and laboratories around the world is straightforward: Conduct health and medical research, development, testing, evaluation and surveillance to enhance deployment readiness. Each year, we see more accomplishments which have a direct impact on improving force health protection. The contributions are many and varied, ranging from our confirmatory work in the early stages of the H1N1 pandemic, to the exciting progress in the development of a malaria vaccine. Research efforts targeted at wound management, including enhanced wound repair and reconstruction as well as extremity and internal hemorrhage control, and phantom limb pain in amputees, present definitive benefits. These efforts also support our emerging expeditionary medical operations and aid in support to our Wounded Warriors.

# The Navy Medicine Team

Navy Medicine is comprised of compassionate and talented professionals who continue to make significant contributions and personal sacrifices to our global community. Our team includes our officers, enlisted personnel, government civilian employees, contract workers and volunteers working together in a vibrant health care community. All have a vital role in the success of our enterprise. Our priority is to maintain the right workforce to deliver the required medical capabilities across the enterprise, while using the appropriate mix of accession, retention, education and training incentives.

Overall, I am encouraged with our recruiting efforts within Navy Medicine and we are starting to see the results of new incentive programs. But while overall manning levels for both officer and enlisted personnel are relatively high, ensuring we have the proper specialty mix continues to be a challenge. Several wartime critical specialties including psychiatry, family medicine, general surgery, emergency medicine, critical care and perioperative nursing, as well as advanced practice nursing and physician assistants, are undermanned. We are also facing shortfalls for general dentists, oral maxillofacial surgeons, and many of our mental health specialists including clinical psychologists and social workers. We have increasing requirements for mental health professionals as well as for Reserve Component Medical Corps, Dental Corps, Medical Service Corps and Nurse Corps officers. We continue to work hard to meet this demand, but fulfilling the requirements among these specialties is expected to present a continuing challenge.

I want to also reemphasize the priority we place on diversity. We are setting the standard for building a diverse, robust, innovative health care workforce, but we can do more in this important area. Navy Medicine is stronger and more effective as a result of our diversity at all levels. Our people are our most important resource, and their dignity and worth are maintained through an atmosphere of service, professionalism, trust and respect.

# Partnerships and Collaboration

Navy Medicine continues to focus on improving interoperability with the Army,
Air Force, Department of Veterans Affairs (VA), as well other federal and civilian
partners to bring operational efficiencies, optimal technology and training together in

support of our patients and their families, our missions, and the national interests. Never has this collaborative approach been more important, particularly as we improve our approaches to ensuring seamless transitions for our veterans.

We remain committed to resource sharing agreements with the VA and our joint efforts in support of improving the Disability Evaluation System (DES) through the ongoing pilot program at several MTFs. The goal of this pilot is to improve the disability evaluation process for service members and help simplify their transitions. Together with the VA and the other Services, we are examining opportunities to expand this pilot to additional military treatment facilities. Additionally, in partnership with the VA, we will be opening the James A. Lovell Federal Health Care Center in Great Lakes, Illinois – a uniquely integrated Navy/VA medical facility.

We also look forward to leveraging our inter-service education and training capabilities with the opening of the Medical Education and Training Campus (METC) in San Antonio in 2010. This new tri-service command will oversee the largest consolidation of service training in DoD history. I am committed to an inter-service education and training system that optimizes the assets and capabilities of all DoD health care practitioners yet maintains the unique skills and capabilities that our hospital corpsmen bring to the Navy and Marine Corps – in hospitals, clinics at sea and on the battlefield.

Clearly one of the most important priorities for the leadership of all the Services is the successful transition to the Walter Reed National Military Medical Center onboard the campus of the National Naval Medical Center, Bethesda. We are working diligently with the lead DoD organization, Joint Task Force – National Capital Region Medical, to

ensure that this significant and ambitious project is executed properly and without any disruption of services to our Sailors, Marines, their families, and all our beneficiaries for whom we are privileged to serve.

# The Way Forward

I believe we are at an important crossroads for military medicine. How we respond to the challenges facing us today will likely set the stage for decades to come. Commitment to our Wounded Warriors and their families must never waver and our programs of support and hope must be built and sustained for the long-haul – and the long-haul is the rest of this century when the young Wounded Warriors of today mature into our aging heroes in the years to come. They will need our care and support as will their families for a lifetime. Likewise, our missions of cooperative engagement, through humanitarian assistance and disaster response, bring opportunities for us, our military and the Nation. It is indeed a critical time in which to demonstrate that the United States Navy is truly a "Global Force for Good."

Navy Medicine is a vibrant, world-wide health care system comprised of compassionate and talented professionals who are willing to make contributions and personal sacrifices. This team - our team - including officer, enlisted, civilians, contractors, and volunteers work together as a dynamic health care family. We are all essential to success.

Navy Medicine will continue to meet the challenges ahead and perform our missions with outstanding skill and commitment. On behalf of the men and women of Navy Medicine, I want to thank the Committee for your tremendous support, confidence

and leadership. It has been my pleasure to testify before you today and I look forward to your questions.

Mr. Dicks. We want to welcome General Green. This is his first time testifying before our subcommittee. We welcome you.

# SUMMARY STATEMENT OF GENERAL GREEN

General Green. Thank you, sir. Chairman Dicks, Representative Young, and distinguished members of the committee, thank you for the opportunity to join you today and address our common goal of providing the best care to our warriors and families. The Air Force Medical Service does whatever it takes to get our Wounded Warriors home safely.

Over 1,600 Air Force medics are currently deployed to 40 locations in 20 countries, delivering state-of-the-art preventive medicine, rapid lifesaving care, and critical care air evacuation. We have now moved over 70,000 patients safely from Iraq and Afghanistan. Air Force medics are responding globally in humanitarian missions as well as on the battlefield, and in the last 6 months we contributed significant support to the treatment and evacuation of

Indonesian, Haitian, and Chilean earthquake victims.

You may have heard or seen national news reports about an amazing operation that took place last month at Craig Joint-Theater Hospital in Bagram. Air Force Major Doctor John Bini is a seasoned theater hospital trauma surgeon stationed at Wilford Hall Medical Center who is deployed to Bagram. When the radiologist discovered a live explosive round in an Afghan patient's head, there was no hesitation as Major Bini and his anesthesiologist, Major Doctor Jeffrey Rengel put on body armor and went to work. They evacuated the OR, leaving only the two of them and a bomb technician with a patient, and within 10 minutes removed the live round. Miraculously, the patient has been discharged and is recovering, able to walk, talk, and feed himself.

At home, our health-care teams share patient-centered care to produce healthy and resilient airmen and provide families and retirees with full-spectrum health care. Our suicide and resiliency programs are targeting those at highest risk for interventions. We have embedded mental health in our family health clinics to increase access and reduce stigma. Family liaison officers and recovery care coordinators assist our Wounded Warriors and families with seamless transition and are the backbone of the Air Force

Wounded Warrior and Survivor Care programs.

This is what Air Force and Army medics, along with Navy corpsmen, are all about. We are trained and ready as a team to meet the mission wherever, whenever, and however needed, with cutting-edge techniques and equipment or the most basic of resources, if this is our only option. We have the lowest died-of-wounds rate in history because of well-trained, highly skilled, and extraordinary people. Our brave and dedicated men and women put service before self and demonstrate excellence in all they do.

Thank you for your immeasurable contributions to the success of our mission. We deeply appreciate all that you do to ensure we recruit and retain these very special medics who are devoted to providing trusted care anywhere. We could not achieve our goals of better readiness, better health, and best value for our heroes and

their families without your support.

I thank you and stand ready to take any questions from the committee.

Mr. DICKS. Thank you for your statement.

[The statement of General Green follows:]



# **United States Air Force**

Presentation

Before the House Appropriations Subcommittee on Defense

# Air Force Medical Programs

Witness Statement of Lieutenant General (Dr.) Charles B. Green, Air Force Surgeon General

April 22, 2010

Not for publication until released by the House Appropriations Subcommittee on Defense

April 22, 2010



# **BIOGRAPHY**



# UNITED STATES AIR FORCE

# LIEUTENANT GENERAL (DR.) CHARLES B. GREEN

Lt. Gen. (Dr.) Charles B. Green is the Surgeon General of the Air Force, Headquarters U.S. Air Force, Washington, D.C. General Green serves as functional manager of the U.S. Air Force Medical Service. In this capacity, he advises the Secretary of the Air Force and Air Force Chief of Staff, as well as the Assistant Secretary of Defense for Health Affairs on matters pertaining to the medical aspects of the air expeditionary force and the health of Air Force people. General Green has authority to commit resources worldwide for the Air Force Medical Service, to make decisions affecting the delivery of medical services, and to develop plans, programs and procedures to support worldwide medical service missions. He exercises direction, guidance and technical management of more than 42,800 people assigned to 75 medical facilities worldwide.

General Green was commissioned through the Health Professions Scholarship Program and entered active duty in 1978 after completing his Doctorate of Medicine degree at the Medical College of Wisconsin in Milwaukee. He completed



residency training in family practice at Eglin Regional Hospital, Eglin AFB, Fla., in 1981, and in aerospace medicine at Brooks AFB, Texas, in 1989. He is board certified in aerospace medicine. An expert in disaster relief operations, he planned and led humanitarian relief efforts in the Philippines after the Baguio earthquake in 1990, and in support of Operation Fiery Vigil following the 1991 eruption of Mount Pinatubo.

General Green has served as commander of three hospitals and Wilford Hall Medical Center. As command surgeon for three major commands, he planned joint medical response for operations Desert Thunder and Desert Fox, and oversaw aeromedical evacuation for operations Enduring Freedom and Iraqi Freedom. He has served as Assistant Surgeon General for Health Care Operations and, prior to his current assignment, Deputy Surgeon General.

### **EDUCATION**

- 1974 Bachelor of Science degree in chemistry, University of Wisconsin-Parkside, Kenosha
- 1978 Doctorate in Medicine and Surgery, Medical College of Wisconsin, Milwaukee
- 1981 Residency in family practice, Eglin Regional Hospital, Eglin AFB, Fla.
- 1987 Air Command and Staff College, by seminar
- 1988 Master's degree in public health, Harvard University, Cambridge, Mass.
- 1989 Residency in aerospace medicine, Brooks AFB, Texas

### April 22, 2010

2000 Air War College, by correspondence

### **ASSIGNMENTS**

- 1. June 1978 July 1981, family practice resident, later, chief resident, Eglin AFB, Fla.
- 2. July 1981 August 1984, flight surgeon, U.S. Air Force Hospital, Mather AFB, Calif.
- 3. August 1984 September 1985, officer in charge, Family Practice Clinic, Wheeler AFB, Hawaii
- 4. September 1985 August 1987, Chief of Clinic Services, Hickam AFB, Hawaii
- 5. September 1987 June 1988, student, graduate aerospace medical resident, Harvard University, Cambridge, Mass.
- 6. June 1988 July 1989, resident in aerospace medicine, U.S. Air Force School of Aerospace Medicine, Brooks AFB, Texas
- 7. July 1989 August 1991, Chief of Aerospace Medicine, and Commander, 657th Tactical Hospital, Clark AB, Philippines
- AB, 1 milliphiles 8. September 1991 August 1993, Commander, 65th Medical Group, Lajes Field, Portugal 9. August 1993 August 1995, Commander, 366th Medical Group, Mountain Home AFB, Idaho
- 10. August 1995 January 1997, Commander, 96th Medical Group, Eglin AFB, Fla.
- 11. January 1997 July 1999, Command Surgeon, U.S. Central Command, MacDill AFB, Fla.
- 12, July 1999 June 2001, Command Surgeon, North American Aerospace Defense Command, U.S. Space Command and Air Force Space Command, Peterson AFB, Colo.
- 13. June 2001 July 2003, Command Surgeon, U.S. Transportation Command and Headquarters Air Mobility Command, Scott AFB, III.
- 14. July 2003 July 2005, Commander, 59th Medical Wing, Wilford Hall Medical Center, Lackland AFB, Texas
- 15. July 2005 August 2006, Assistant Surgeon General for Health Care Operations, Office of the Surgeon General, Bolling AFB, D.C.
- 16. August 2006 August 2009, Deputy Surgeon General, Headquarters U.S. Air Force, Bolling AFB, D.C. 17. August 2009 - present, Surgeon General of the Air Force, Headquarters U.S. Air Force, Washington,

### SUMMARY OF JOINT ASSIGNMENTS

- 1. January 1997 July 1999, Command Surgeon, U.S. Central Command, MacDill AFB, Fla., as a colonel 2. July 1999 - June 2001, Command Surgeon, North American Aerospace Defense Command and U.S. Space Command, Peterson AFB, Colo., as a colonel
- 3. June 2001 July 2003, Command Surgeon, U.S. Transportation Command, Scott AFB, Ill., as a brigadier general
- 4. July 2003 July 2005, Director, DOD Region 6 (TRICARE South) Lackland AFB, Texas, as a major general

### FLIGHT INFORMATION

Rating: Chief flight surgeon

Flight hours: 1.200

Aircraft flown: B-52, C-5, C-9, C-21, C-130, C-141, H-53, KC-135, T-43, F-15, F-16, P-3, T-37, T-38, UH-1 and UH-60

# MAJOR AWARDS AND DECORATIONS

Defense Superior Service Medal with oak leaf cluster Legion of Merit Defense Meritorious Service Medal Airman's Medal

Meritorious Service Medal with four oak leaf clusters

Joint Service Commendation Medal

Air Force Commendation Medal with two oak leaf clusters

Air Force Achievement Medal

National Defense Service Medal with bronze star

Armed Forces Expeditionary Medal

# Witness Statement HAC-Defense Medical and Wounded Warrior Hearing

April 22, 2010

Humanitarian Service Medal with bronze star Philippine Bronze Cross

PROFESSIONAL MEMBERSHIPS AND ASSOCIATIONS
American Medical Association
American College of Physician Executives
Fellow, Aerospace Medical Association
Fellow, American Academy of Family Physicians
Uniformed Services Academy of Family Physicians
Aerospace Medical Association
Society of U.S. Air Force Flight Surgeons (former President)
Air Force Association
Association of Military Surgeons of the United States

# **EFFECTIVE DATES OF PROMOTION**

Captain June 18, 1978 Major May 26, 1984 Lieutenant Colonel May 25, 1990 Colonel May 31, 1994 Brigadier General Aug. 1, 2001 Major General Sept. 1, 2004 Lieutenant General Aug. 3, 2009

(Current as of August 2009)

April 22, 2010

Chairman Dicks, Representative Young, and distinguished members of the Committee, it is an honor and a privilege to appear before you representing the Air Force Medical Service and our 60,000 Total Force medics. I'm looking forward to working with you during my tenure as Air Force Surgeon General. I pledge to do all in my power to support the men and women of the Armed Forces and this great country. Thank you for your immeasurable contributions to the success of our mission.

"Trusted Care Anywhere" is the Air Force Medical Service's vision for 2010 and beyond. In the domain of Air, Space and Cyberspace, our medics contribute to the Air Force, Joint, and coalition team with world class medical capabilities. Our 60,000 high performing Total Force medics around the globe are trained and ready for mission success. Over 1,600 Air Force medics are now deployed to 40 locations in 20 countries, building partnership capability and delivering state of the art preventive medicine, rapid life-saving care, and critical air evacuation. In all cases, these efforts are conducted with joint and coalition partners. At home, our health care teams assure patient-centered care to produce healthy and resilient Airmen, and provide our families and retirees with full spectrum health care.

Today's focus is on world-class health care delivery systems across the full spectrum of our operations. From theater hospitals in Balad and Bagram, to the efforts of humanitarian assistance response teams, to the care of our families at home, we put patients first. We are transforming deployable capabilities, building patient-centered care platforms, and investing in our people, the foundation of our success. We are expanding collaboration with joint and coalition partners to collectively strengthen rapid response capabilities. Globally, Air Force medics are diligently working to balance the complex demands of multiple missions in current and expanding areas of operations.

We are committed to advancing capabilities through education and training, research, and infrastructure recapitalization. Recent efforts in these areas have paid huge dividends, establishing new standards in virtually every major category of full spectrum care including humanitarian assistance. The strategic investments assure a trained, current, and deployable medical force today and tomorrow. They reinforce a culture of learning to quickly adapt medical systems and implement agile organizations to produce healthier outcomes in diverse mission areas.

While we've earned our Nation's trust with our unique capabilities and the expertise of our people, we constantly seek to do better! I would like to highlight our areas of strategic focus and share some captivating examples of Air Force medics in action.

# Transforming Expeditionary Medicine and Aeromedical Evacuation Capabilities

Our success on the battlefield underscores our ability to provide "Trusted Care,

Anywhere." The joint and coalition medical teams bring wounded warriors from the battlefield
to an operating room within an unprecedented 20 to 40 minutes! This rapid transfer rate enables
medics to achieve a less than 10 percent died-of-wounds rate, the best survival rate ever seen in
war.

In late July, a British soldier sustained multiple gunshot wounds in Afghanistan. After being stabilized by medical teams on the ground, who replaced his blood supply more than 10 times, doctors determined the patient had to be moved to higher levels of care in Germany. It took two airplanes to get the medical team and equipment in place, another aircraft to fly the patient to Germany, three aircrews and many more personnel coordinating on the ground to get this patient to the next level of care. Every member of the joint casualty care and aeromedical

evacuation teams selflessly gave their all to ensure this soldier received the compassionate care he deserved. After landing safely at Ramstein Air Base in Germany, the soldier was flown to further medical care at a university hospital by helicopter. This case highlights the dedication and compassion our personnel deliver in the complex but seamless care continuum. This tremendous effort contributes to our unprecedented survival rate.

As evidenced in this story, our aeromedical evacuation system (AE) and critical care air transport teams (CCATT) are world-class. We mobilize specially trained flight crews and medical teams on a moment's notice to transport the most critical patients across oceans. Since November 2001, we have transported more than 70,000 patients from Afghanistan and Iraq.

We are proud of our accomplishments to date, but strive for further innovation. As a result of battlefield lessons learned, we have recently implemented a device to improve spinal immobilization for AE patients that maximizes patient comfort and reduces skin pressure. We are working toward an improved detection mechanism for compartment syndrome in trauma patients. The early detection and prevention of excess compartment pressure could eliminate irreversible tissue damage for patients. In February 2010, a joint Air Force and Army team will begin testing equipment packages designed to improve ventilation, oxygen, fluid resuscitation, physiological monitoring, hemodynamic monitoring and intervention in critical care air transport.

# Information Management/Information Technology

Our Theater Medical Information Program Air Force (TMIP AF) is a software suite that automates and integrates clinical care documentation, medical supplies, equipment, and patient movement. It provides the unique capabilities for in-transit visibility and consolidated medical

information to improve command and control and allow better preventive surveillance at all Air Force deployed locations. This is a historic first for the TMIP AF program.

Critical information is gathered on every patient, then entered into the Air Force Medical Service (AFMS) deployed system. Within 24 hours, records are moved and safely stored at secure consolidated databases in the United States. During the first part of 2010, TMIP AF will be utilized in Aeromedical Evacuation and Air Force Special Operations areas.

### **Expeditionary Medicine and Humanitarian Assistance**

We have also creatively developed our Humanitarian Assistance Rapid Response Team (HARRT), a U.S. Pacific Command (USPACOM) initiative, to integrate expeditionary medical systems and support functions. The HARRT provides the USPACOM Commander with a rapid response package that can deploy in less than 24 hours, requires only two C-17s for transport and can be fully operational within hours of arrival at the disaster site. This unique capability augments host nation efforts during the initial stages of rescue/recovery, thus saving lives, reducing suffering, and preventing the spread of disease. So far, HARRT successfully deployed on two occasions in the Pacific. Efforts are underway to incorporate this humanitarian assistance and disaster relief response capability into all AFMS Expeditionary Medical System (EMEDS) assets.

Air Force medics contribute significant support to the treatment and evacuation of Haiti earthquake victims. The Air Force Special Operations Command (AFSOC) sent 47 medics to support AFSOC troops on the ground within 12 hours following the disaster to perform site assessments, establish preventive public health measures, and deliver life-saving trauma care to include surgical and critical care support. This team was also instrumental in working with

United States Southern Command and United States Transportation Command to establish a patient movement bridge evacuating individuals from Haiti via air transport.

As part of the U.S. Air Force's total force effort, we sent our EMEDS platform into Haiti and rapidly established a 10-bed hospital to link the hospital ship to ground operations. The new EMEDS includes capabilities for pediatrics, OB/GYN and mental health. Personnel from five Air Force medical treatment facilities (MTFs) are supporting Operation Unified Response, as well as volunteers from the Air Reserve Forces.

# Build Patient-Centered Care and Focus on Prevention to Optimize Health

We are committed to achieving the same high level of trust with our patients at home through our medical home concept. Medical home includes initiatives to personalize care, and to improve health and resilience. We are also working hard to optimize our operations, reduce costs and improve patient access. We partner with our federal and civilian colleagues to continuously improve care to all our beneficiaries.

# **Family Health Initiative**

To achieve better health outcomes for our patients, we implemented the Family Health Initiative (FHI). FHI mirrors the American Academy of Family Physicians' "Patient Centered Medical Home" concept and is built on the team-approach for effective care delivery. The partnership between our patients and their health care teams is critical to create better health and better care via improved continuity, and reduce per capita cost.

Our providers are given full clinical oversight of their care teams and are expected to practice to the full scope of their training. We believe the results will be high quality care and improved professional satisfaction. Two of our pilot sites, Edwards AFB, CA, and Ellsworth AFB, SD, have dramatically improved their national standings in continuity, quality, access to

care, and patient satisfaction. Eleven other bases are implementing Medical Home, with an additional 20 bases scheduled to come on-line in 2010.

We are particularly encouraged by the results of our patient continuity data in Medical Home. Previous metrics showed our patients only saw their assigned provider approximately 50 percent of the time. At Edwards and Ellsworth AFBs, provider continuity is now in the 80-90 percent range.

We still have work to do, such as developing improved decision support tools, case management support, and improved training. Implementing change of this size and scope requires broad commitment. The Air Force Medical Service has the commitment and is confident that by focusing on patient-centered care through Medical Home, we will deliver exceptional care in the years ahead.

The Military Health System's Quadruple Aim of medical readiness, population health, experience of care and per capita cost serves us well. Patient safety remains central to everything we do. By focusing on lessons learned and sharing information, we continually strive to enhance the safety and quality of our care. We share our clinical lessons learned with the Department of Defense (DoD) Patient Safety Center and sister Services. We integrate clinical scenarios and lessons learned into our simulation training. We securely share de-identified patient safety information across the Services through DoD's web-based Patient Safety Learning Center to continuously improve safety.

#### April 22, 2010

# Improving Resilience and Safeguarding the Mental Health of Our Airmen

Trusted care for our beneficiaries includes improving resilience and safeguarding their mental health and well-being. We are engaged in several initiatives to optimize mental health access and support.

Air Force post-deployment health assessment (PDHA) and post-deployment health reassessment (PDHRA) data indicates a relatively low level of self-reported stress. However, about 20-30 percent of service members returning from OIF/OEF deployments report some form of psychological distress. The number of personnel referred for further evaluation or treatment has increased from 25 percent to 50 percent over the past four years, possibly reflecting success in reducing stigma of seeking mental health support. We have identified our high-risk groups and can now provide targeted intervention and training.

We recently unveiled "Defenders Edge," which is tailored to security forces Airmen who are deploying to the most hostile environments. This training is intended to improve Airmen mental resiliency to combat-related stressors. Unlike conventional techniques, which adopt a one-on-one approach focusing on emotional vulnerability, "DEFED" brings the mental health professional into the group environment, assimilating them into the security forces culture as skills are taught.

Airmen who are at higher risk for post traumatic stress are closely screened and monitored for psychological concerns post-deployment. If treatment is required, these individuals receive referrals to the appropriate providers. In addition to standard treatment protocols for post traumatic stress disorder (PTSD), Air Force mental health professionals are capitalizing on state-of-the-art treatment options using Virtual Reality. The use of a computergenerated virtual Iraq in combination with goggles, headphones, and a scent machine allow

service members to receive enhanced prolonged exposure therapy in a safe setting. In January 2009, 32 Air Force Medical Service therapists received Tri-Service training in collaboration with the Defense Center of Excellence at Madigan Army Medical Center. The system was deployed to eight Air Force sites in February 2009 and is assisting service members in the treatment of PTSD.

Future applications of technology employing avatars and virtual worlds may have multiple applications. Service member and family resiliency will be enhanced by providing pre- and post-deployment education; new parent support programs may offer virtual parent training; and family advocacy and addiction treatment programs may provide anger management, social skills training, and emotional and behavioral regulation.

### Rebuilding Our Capabilities by Recapturing Care and Reducing Costs

Our patients appropriately expect AFMS facilities and equipment will be state-of-the art and our medical teams clinically current. They trust we will give them the best care possible. We are upgrading our medical facilities and rebuilding our capabilities to give patients more choice and increase provider satisfaction with a more complex case load. In our larger facilities, we launched the Surgical Optimization Initiative, which includes process improvement evaluations to improve operating room efficiency, enhance surgical teamwork, and eliminate waste and redundancy. This initiative resulted in a 30 percent increase in operative cases at Elmendorf AFB, Alaska, and 118 percent increase in neurosurgery at Travis AFB, California.

We are engaged in an extensive modernization of Wright-Patterson Air Force Base

Medical Center in Ohio with particular focus on surgical care and mental health services. We
are continuing investment in a state-of-the-art new medical campus for the San Antonio Military

Medical Center at Lackland AFB, TX. Our ambulatory care center at Andrews AFB, MD, will

provide a key capability for the delivery of world-class health care in the National Capital Region's multi-service market.

By increasing volume, complexity and diversity of care provided in Air Force hospitals, we make more care available to our patients; and we provide our clinicians with a robust clinical practice to ensure they are prepared for deployed operations, humanitarian assistance, and disaster response.

### Partnering With Our Private Sector and Federal Partners

Now more than ever, collaboration and cooperation with our private sector and federal partners is key to maximizing resources, leveraging capabilities and sustaining clinical currency. Initiatives to build strong academic partnerships with St. Louis University, Wright State University (Ohio); University of Maryland; University of Mississippi; University of Nebraska-Lincoln; University of California-Davis and University of Texas-San Antonio, among others, bolster research and training platforms and ultimately, ensures a pipeline of current, deployable medics to sustain Air Force medicine.

Our long history of collaborating with the Department of Veterans Affairs (VA) also enhances clinical currency for our providers, saves valuable resources, and provides a more seamless transition for our Airmen as they move from active duty to veteran status. The Air Force currently has five joint ventures with the VA, including the most recent at Keesler AFB, MS. Additional efforts are underway for Buckley AFB, CO, to share space with the Denver VA Medical Center, which is now under construction.

The new joint Department of Defense-Veterans Affairs disability evaluation system pilot started at Malcolm Grow Medical Center at Andrews AFB, MD in November 2007. It was expanded to include Elmendorf AFB, AK; Travis AFB, CA and Vance AFB, OK; and MacDill

AFB, FL, in May 2009. Lessons learned are streamlining and expediting disability recovery and processing, and creating improved treatment, evaluation and delivery of compensation and benefits. The introduction of a single comprehensive medical examination and single-sourced disability rating was instrumental to improving the process and increasing the transparency.

Services now allow members to see proposed VA disability ratings before separation.

We continue to work toward advances in the interoperability of the electronic health record. Recent updates allow near real-time data sharing between DoD and Veterans Affairs providers. Malcolm Grow Medical Center, Wright-Patterson Medical Center, and David Grant Medical Center are now using this technology, with 12 additional Air Force military treatment facilities slated to come online. New system updates will enhance capabilities to share images, assessment reports, and data. All updates are geared toward producing a virtual lifetime electronic record and a nationwide health information network.

### Warrior and Survivor Care

Our unwavering commitment to our wounded, ill, and injured Airmen and their families remains strong and we have hired 17 Recovery Care Coordinators (RCCs) at locations throughout the United States, with plans to add another 11 RCCs this year. RCCs have proven to be an invaluable asset to our wounded, ill, and injured Airmen and their families. Their development of comprehensive recovery plans to guide our Airmen through recovery, rehabilitation, and reintegration have been effective in helping our Airmen and their families adapt to the life-altering challenges they face as a result of service to our Nation. Our goal is to ensure RCCs are available to serve seriously wounded, ill, and injured Airmen throughout the country whether active duty, Air National Guard, or Air Force Reserve Airmen.

The Air Force has also changed personnel policies to reflect a more abilities-based approach with regards to assignments, retention, promotions, and retraining of our wounded Airmen. Our first priority is to offer combat wounded Airmen the opportunity to remain on active duty, should they desire. TSgt Del Toro, one of our most severely wounded Airmen, reenlisted in February of this year and is now serving as a Tactical Control Recruiter and orientation instructor at Lackland Air Fore Base. We have found that the combat experience of our heroic wounded Airmen is an asset we need to treasure and use to educate our Airmen.

The Air Wounded Warrior Program (AFW2) provides support and assistance to over 650 combat-injured Airmen, with a commitment of lifetime support. AFW2 consultants assist in a wide-variety of issues including transition assistance, benefits advisory service, employment counseling, and job placement services in the Air Force. The AFW2 program is growing by approximately 18 Airmen per month, and we plan to staff the program accordingly to ensure our Airmen continue to receive the best possible service and support.

Serious wounds, illness, and injuries to our Airmen are life-altering events for entire families. The Air Force philosophy is to provide the best possible care and service to the family structure that is affected by these life-altering events. We have a lifetime commitment to our Airmen and their families. Our medical and personnel communities work closely together to ensure we are meeting that commitment.

# Year of the Air Force Family

This is the "Year of the Air Force Family," and we are working hand in hand with Air Force personnel and force management to ensure our Exceptional Family Member Program (EFMP) beneficiaries receive the assistance they need.

April 22, 2010

In September 2009, the Air Force sponsored an Autism Summit where educational, medical, and community support personnel discussed challenges and best practices. In December 2009, the Air Force Medical Service provided all Air Force treatment facilities with an autism tool kit. The kit provided educational information to providers on diagnosis and treatment. Also, Wright-Patterson AFB, OH is partnering with Children's Hospital of Ohio in a research project to develop a comprehensive registry for autism spectrum disorders, behavioral therapies, and gene mapping.

The Air Force actively collaborates with sister Services and the Defense Center of Excellence for Psychological Health and Traumatic Brain injury (DCoE) to offer a variety of programs and services to meet the needs of children of wounded warriors. One recent initiative was the "Family Connections" website with Sesame Street-themed resources to help children cope with deployments and injured parents. In addition, DoD-funded websites, such as afterdeployment.org, providing specific information and guidance for parents/caregivers to understand and help kids deal with issues related to deployment and its aftermath.

Parents and caregivers also consult with their child's primary care manager, who can help identify issues and refer the child for care when necessary. Other resources available to families include counseling through Military OneSource, Airman and Family Readiness Centers, Chaplains, and Military Family Life Consultants--all of whom may refer the family to seek more formal mental health treatment through consultation with their primary care manager or by contacting a TRICARE mental health provider directly.

## Investing in Our People: Education, Training, and Research

## **Increased Focus on Recruiting and Retention Initiatives**

To gain and hold the trust of our patients, we must have highly trained, current, and qualified providers. To attract those high quality providers in the future, we have numerous efforts underway to improve recruiting and retention.

We've changed our marketing efforts to better target recruits, such as providing Corpsspecific DVDs to recruiters. The Health Profession Scholarship Program remains vital to
attracting doctors and dentists, accounting for 75 percent of these two Corps' accessions. The
Air Force International Health Specialist program is another successful program, providing Air
Force Medical Service personnel with opportunities to leverage their foreign language and
cultural knowledge to effectively execute and lead global health engagements, each designed to
build international partnerships and sustainable capacity.

The Nursing Enlisted Commissioning Program (NECP) is a terrific opportunity for Airmen. Several Airmen have been accepted to the NECP, completed degrees, and have been commissioned as Second Lieutenant within a year. To quote a recent graduate, 2<sup>nd</sup> Lt. April C. Barr, "The NECP was an excellent way for me to finish my degree and gave me an opportunity to fulfill a goal I set as a young Airman...to be commissioned as an Air Force nurse."

For our enlisted personnel, targeted Selective Reenlistment Bonuses, combined with continued emphasis on quality of life, generous benefits, and job satisfaction have positively impacted enlisted recruiting and retention efforts.

## Increasing Synergy to Strengthen GME and Officer/Enlisted Training

We foster excellence in clinical, operational, joint and coalition partner roles for all Air Force Medical Service personnel. We are increasing opportunities for advanced education in general dentistry and establishing more formalized, tiered approaches to Medical Corps faculty development. Senior officer and enlisted efforts in the National Capital Region and the San Antonio Military Medical Center are fostering Tri-Service collaboration, enlightening the Services to each others' capabilities and qualifications, and establishing opportunities to develop and hone readiness skills.

The Medical Education and Training Campus (METC) at Fort Sam Houston, Texas, will have a monumental impact on the Department of Defense and all military services. We anticipate a smooth transition with our moves completed by summer 2011. METC will train future enlisted medics to take care of our service members and their families and will establish San Antonio as a medical training center of excellence.

Our Centers for the Sustainment of Trauma and Readiness Skills at St. Louis University, University of Maryland-Baltimore Shock Trauma and University of Cincinnati College of Medicine remain important and evolving training platforms for our doctors, nurses and medical technicians preparing to deploy. We recently expanded our St. Louis University training program to include pediatric trauma. Tragically, this training became necessary, as our deployed medics treat hundreds of children due to war-related violence.

Partnerships with the University Hospital Cincinnati and Scottsdale, AZ, trauma hospitals allow the Air Force's nurse transition programs to provide newly graduated registered nurses 11 weeks of rotations in emergency care, cardiovascular intensive care, burn unit, endoscopy, sameday surgery, and respiratory therapy. These advanced clinical and deployment readiness skills

prepare them for success in Air Force hospitals and deployed medical facilities, vital to the care of our patients and joint warfighters.

# Setting Clear Research Requirements and Integrating Technology

Trusted care is not static. To sustain this trust, we must remain agile and adaptive, seeking innovative solutions to shape our future. Our ongoing research in procedures, technology, and equipment will ensure our patients and warfighters always benefit from the latest medical technologies and clinical advancements.

Air Force Medical Service vascular surgeons, Lieutenant Colonels Todd Rasmussen and William "Darrin" Clouse, have completed 17 research papers since 2005 and edited the vascular surgery handbook. On January 10, 2009 a U.S. Marine sustained bilateral posterior knee dislocations with subsequent loss of blood flow to his lower legs following an improvised explosive device attack in the Helmand Province. Casualty evacuation delivered the Marine to our British partners at Camp Bastion, a level II surgical unit within an hour. At Bastion, British surgeons applied knowledge gained from combat casualty care research and restored blood flow to both legs using temporary vascular shunts. Medical evacuation then delivered the casualty to the 455<sup>th</sup> Expeditionary Medical Group at Bagram. Upon arrival, our surgeons at Bagram performed definitive vascular reconstruction and protected the fragile soft tissue with negative pressure wound therapy. The Marine is currently recovering at the National Military Medical Center in Bethesda and is expected to have functional limbs.

In another example, a 21-year-old Airman underwent a rare pancreatic autotransplantation surgery at Walter Reed Army Medical Center (WRAMC) to salvage his body's ability to produce insulin. The airman was shot in the back three times by an insurgent at

a remote outpost in Afghanistan. The patient underwent two procedures in Afghanistan to stop the bleeding, was flown to Germany, then to WRAMC. Army surgeons consulted with University of Miami's Miller School of Medicine researchers on transplantation experiments. The surgeons decided to attempt a rare autotransplantation surgery to save the remaining pancreas cells. WRAMC Surgeons removed his remaining pancreas cells and flew them over 1,000 miles to the University of Miami Miller School of Medicine. The University of Miami team worked through the night to isolate and preserve the islet cells. The cells were flown back to WRAMC the next day and successfully implanted in the patient. The surgery was a miraculous success, as the cells are producing insulin.

These two cases best illustrate the outcome of our collaborations, culture of research, international teamwork, innovation, and excellence.

## Shaping the Future Today Through Partnerships and Training

Under a new partnership with the University of Illinois at Chicago, we are researching directed energy force protection, which focuses on detection, diagnosis and treatment of directed energy devices. We are exploring the discovery of biomarkers related to laser eye injuries, development of films for laser eye protection and the development of a "tricorder" prototype capable of laser detection and biomarker assessment. Additional efforts focus on the use and safety of laser scalpels and the development of a hand-held battery operated laser tool to treat wounds on the battlefield.

We continue our seven-year partnership with the University of Pittsburgh Medical Center to develop Type II diabetes prevention and treatment programs for rural and Air Force communities. Successful program efforts in the San Antonio area include the establishment of a

April 22, 2010

Diabetes Center of Excellence, "Diabetes Day" outreach specialty care, and efforts to establish a National Diabetes Model for diabetic care.

Another partnership, with the University of Maryland Medical Center and the Center for the Sustainment of Trauma and Readiness Skills (C-STARS) in Baltimore is developing advanced training for Air Force trauma teams. The project goal is to develop a multi-patient trauma simulation capability using high fidelity trauma simulators to challenge trauma teams in rapid assessment, task management, and critical skills necessary for the survival of our wounded warriors. A debriefing model is being developed to assist with after action reviews for trauma team members.

Radiofrequency technology is contributing to medical process improvements at Keesler AFB, MS. Currently, Keesler AFB is analyzing the use of automatic identification and data capture (AIDC) in AFMS business processes. The AIDC evaluation focuses on four main areas: patient tracking, medication administration, specimen tracking, and asset management. Further system evaluation and data collection is ongoing in 2010 with an expansion of AIDC use in tracking automated data processing equipment.

### Conclusion

As a unique health system, we are committed to success across the spectrum of military operations through rapid deployability and patient-centered care. We are partnering for better outcomes and increasing clinical capacity. We are strengthening our education and training platforms through partnerships and scanning the environment for new research and development opportunities to keep Air Force medicine on the cutting edge.

April 22, 2010

We will enhance our facilities and the quality of health care to ensure health and wellness of all entrusted to our care. We do all this with a focus on patient safety and sound fiscal stewardship. We could not achieve our goals of better readiness, better health, better care and reduced cost without your support, and so again, I thank you.

In closing, I share a quote from our Air Force Chief of Staff, Gen. Norton A. Schwartz, who said, "I see evidence every day the Medical Service is "All In," faithfully executing its mission in the heat of the fight, in direct support of the warfighter, and of families back home as well." I know you would agree that "All In" is the right place to be.

### IMPACT OF VOLCANIC ASH ON WOUNDED WARRIOR TRANSPORT

Mr. DICKS. It is very impressive to be at Ramstein and Landstuhl and see these planes fly in with these wounded warriors.

Mr. Young.

Mr. Young. Mr. Chairman, I wanted to say we had a really good hearing yesterday. Dr. Rice pretty much led the discussions, and was very, very helpful. There were a couple of questions that we presented, and I am not sure we got the answers exactly accu-

rately, so I want to go back to one or two of them.

One, the Chairman mentioned about Landstuhl and Ramstein and the transporting of wounded heroes. We have both been there a number of times and experienced seeing this happen. But my question yesterday was—there was some kind of notice was published that said that we would be bypassing Landstuhl now and coming directly to Andrews. The response was that they think that was just temporary because of the volcanic ash. I would like to get confirmation on that; whether that is the case or whether—if in fact it is the practice now to bypass Landstuhl when you can.

General GREEN. No, sir. That was done solely because of the restrictions on aircraft in Europe because of the volcanic ash. And so we basically rerouted the airplanes through Balad and rotated them up through Rota and then back into here. It is very temporary. We have had four or five airplanes do it. There has been no effect on the casualty evacuation. As of today, Ramstein and Landstuhl are back up again and the casualties will go through there again.

# WALTER REED/BETHESDA CONSOLIDATION

Mr. Young. Well, I am amazed at how well that system works. These kids are getting good care immediately on the scene, at the battlefield, and on the way home. I have met a lot of those aircraft as they brought wounded heroes. I am just impressed with the care that they get. As a matter of fact, I get in trouble on occasion, because every time there is a little news story about something that went wrong with military medicine, my comments are brought back to haunt me. But I have seen miracles, what I consider miracles, at Walter Reed and at Bethesda.

And, General Green, I am not that familiar with your medical facilities, just because of the proximity here. But I think that our Wounded Warriors get outstanding medical care and I think your

medical professionals are outstanding.

Having said that, also, again, yesterday we talked briefly about the merger of the medical facilities in the capital area. I get different responses when I talk to different people, those who are at the hospitals. How is that going? You all have a little different position than the witnesses that were here yesterday because each of you represent your service. But now we have this merger. What happens to the identity of your service, what happens to the chain of command? Who is really in charge of this consolidated medical facility? Let's start with that.

General Schoomaker. Sir, I will take the first. We are the Army, and we are losing one of our major and most vulnerable institu-

tions. As you know, Walter Reed and the Walter Reed campus, which is 100 years old this year—or last year—I think, sir, it is going remarkably well. I think we already know, the three of us sitting here, that on a day-to-day basis at Walter Reed and Bethesda and Malcolm Grow, and at Fort Belvoir, for that matter, but to a lesser degree, the staffs are already integrated. Training programs are already integrated.

I personally have undergone surgeries over the last several years at Walter Reed and at Bethesda. Frankly, the staffs are fully integrated. You have Navy surgeons working on soldiers, marines, and airmen in an Army hospital, and you have Army surgeons and dermatologists and OBs that are delivering services to the same mix

at a Navy facility.

And so I think what we are now doing is all the necessary steps at a granular level to make sure the civilian workforce from Walter Reed—which is the one most affected by this—is moved successfully; that they know where they are going and what jobs they are going to have.

But as Admiral Robinson and his subordinate commander there, Admiral Nathan, points out, even 90 percent of the people currently working at Navy are going to go to different slots within different sites within a brand-new facility. So everybody is being af-

fected, and I think it is being done in a very proactive way.

I might say, sir, in reference to the earlier comment about the trip through Rota, correct me if I am wrong, but it is still an onerous trip. It adds considerably to the length of the evacuation. I would also comment that every time you see a patient at Walter Reed or Bethesda, you are seeing the results of Air Force Medicine, because they wouldn't be there and they wouldn't be alive and doing as well as they are, were it not for the intensive care that they receive in the air from the Air Force.

Admiral ROBINSON. I would like to underscore what General Schoomaker said. I think he hit many of the major issues that are there. I would emphasize that in terms of care, the CCAT, Air Force, Army, and Navy, and the care of Wounded Warriors and trauma care, et cetera, there is no equal in the world. We have come together to give that care. And it shows in the interoperability and the ethos of all three services in making sure we get

what we need for our Wounded Warriors.

I think the same continues in the National Capital Area. I think that I am going to take my Chief of Naval Operation's position here today to say the care that we give here must follow the rule of first principles. First principles say: Let us do what we have to do. So let us do the BRAC and let us at the same time take care of Wounded Warriors. And then, since our services are already integrated and we are joint from a medical-care perspective, then we can take on some of the challenges of the governance and the other things that we need to look at in terms of the long haul for medical care.

But in terms of making sure that we are focused on patient care and on Wounded Warriors and care issues, which are the issues that we cannot leave behind, I think we are doing that. If we continue to do that, I think we are going to be very successful in the BRAC issue. And just like the Army said that it is losing a venerable institution, the Navy is losing a venerable institution, too, in the National Naval Medical Center and the Bethesda Naval Hospital. Both of those institutions go away. There is a new institution called the Walter Reed National Military Medical Center. It may sit on a Navy base on Wisconsin Avenue, but it is no longer a Navy hospital in the tradition of Bethesda, nor will it be an Army hospital in the tradition of Walter Reed. And it will also include Air Force physicians, medics, nurses, and ancillary medical personnel from Malcolm Grow. It will be a joint hospital that will care for our Wounded Warriors into the future.

### JOINT MEDICAL FACILITIES

General Green. Malcolm Grow, which is the smaller of the medical centers here in town, was actually due to close about 2 years ago. Because of the BRAC and trying to ensure that we had extra capability as we saw all of the construction, we have kept the doors open in terms of the inpatient facility through the end of 2011. It will become an ambulatory surgical facility, and we are keeping roughly the same amount of manpower here, with nearly 172 of our staff that will be working up in the Walter Reed National Military Medical Center. We have also combined residencies with the Army down at Belvoir and have family practice residents in the residency at Belvoir.

My response in terms of how it is going is, I think it is going well. We know how to execute a JTF. Air Force is simply one component of that JTF. We believe that they have the authorities that they need and that we are working closely with them. If you go to Bethesda campus today, you will find that roughly 55 of the nurses, the ICU nurses, are there. Those same nurses are the ones we trained to do Critical Care Air Transport Teams (CCATs) and also provide a lot of the work on aircraft when it is their turn to deploy.

So I think it is a very good joint effort in terms of how we are bringing this together. There are still issues in terms of financing and guidance as we move into more joint operations back here at home. But we know how to do this. Our clinical care is very joint. And so I would say it is going well, sir.

# FORT HOOD

Mr. Young. Well, I appreciate what you have said. If you recall, two of you were here last year for the hearing, and I expressed some concern about morale, because a lot of the medical professionals, the doctors, were wondering where do I go next; what is my next job; where is my next location? But having been in Walter Reed and Bethesda considerably, and recently, I see at Walter Reed a lot of Navy doctors and nurses. At Bethesda I see a lot of Army doctors and nurses. And I think the morale issue is basically dramatically improved because people didn't—last year they didn't really know what was happening. This year I think they have a pretty good idea of what is happening. I give you all credit for making sure that your services were identified, but that you have been able to make this merger.

I know I have taken an awful lot of time. Mr. Chairman, one more question I wanted to ask. We are concerned—many of us—many are concerned about the situation with Major Hasan and the shooting at Fort Hood. There has been some criticism that maybe his problem should have been detected before he ever got to Fort Hood. Are there any changes in watching something like this to make sure that if there is a suspicion, that we deal with it before it becomes a threat to life and limb?

Dr. RICE. Congressman Young, I will speak with my hat on as the President of the Uniformed Services University. As you know, Major Hasan received his M.D. Degree at the Uniformed Services University and then came back to do a fellowship. I want to be careful in what I say because we have not yet sent our report on our analysis up to Secretary Gates. As you know, there is an ongoing criminal investigation.

This touched the faculty, staff, students, and alumni of the Uniformed Services University very deeply. And we have undertaken a very thorough review. I have received a summary of that analysis just this morning, and I think we will be able to provide some recommendations to Secretary Gates very shortly.

I will defer to General Schoomaker, who can discuss the Army side of that review.

General Schoomaker. Yes, sir. Again, mindful that this is an open investigation, the Army's subsequent completion of the investigation that was begun by the Wes Clark Commission, the Army component of which was conducted by General Hamm, the Commanding General of the United States Army-Europe, is still ongoing and is about to be completed. But I would submit, sir, that there have been many lessons, all the way from the recognition of self-radicalization within the force, which is a real threat, and how we identify that—senior Army leadership, DOD leadership, is focused on that—to how we respond in the event of a calamity like this at a local installation like Fort Hood, to include its emergency response to how we manage subsequent consequences of that.

We launched a fairly unique behavioral health response with the help of the Uniformed Services University and others, targeting subpopulations like children, like victims, family members, and other members of the community that would be affected by that. All of these have provided lessons to us.

But to your point, I have been very clear with my Command and with those who have asked, I think although, again, it is an open investigation, we all agree there are many aspects of the training of Major Hasan that we are looking at very closely. But I will stand by my earlier comments that none of his behavior, I think, would have been predictive of a mass murderer.

# ACCESS TO PRIMARY CARE HEALTH CARE

Mr. YOUNG. Well, I think your comment "lessons learned" was a good comment. I am just happy that you are really paying attention to those lessons that we have learned from this incident, which was a calamity.

Mr. Chairman, thank you very much.

Mr. DICKS. Thank you, Mr. Young. Since we are talking about Fort Bragg, there was an article in the Fayetteville, North Carolina

Observer saying that General Casey had just visited Fort Bragg and officials at the Womack Army Medical Center said they are aware of problems with access, because the number of enrolled beneficiaries at Womack has exceeded the available primary care capacity; patients have at times experienced difficulty obtaining timely appointments, largely in the area of routine and wellness care, Shannon Lynch, a Womack spokesman, said in a written statement.

How serious is this problem and what are you doing about it, General Schoomaker?

General Schoomaker. Sir, access to primary care I would say is a problem across the Army. The Chief of Staff of the Army, General Casey, and his wife, Mrs. Casey, have made this a very important focus of their leadership. For the last 18 months to 2 years, we have been working very hard across the Army with a series of initiatives, beginning with properly sizing our facilities and health-care providers to accommodate reasonably the enrolled population of soldiers and Active Duty family members. Recognizing that the Army has grown by 65,000 soldiers and has brought on many, many more beneficiaries in the form of Reserve component soldiers, this continues to challenge us at a time that the Nation is challenged to provide primary care health care.

We have a very aggressive program. We have been seeing steady improvements in overall patient satisfaction, overall ability of a patient to get to his or her primary care provider or the team. All three services have embraced the patient-centered medical home concept, which is a fundamental transformation of how we deliver care at the primary care level. And we have recently, with the help of the TRICARE Management Agency and Dr. Rice's deputy, Rear Admiral Christine Hunter in the TRICARE Management Agency, have gotten consent for standing up in 14 different communities in the Army, to include Fort Bragg, the building of and leasing of community-based primary care clinics that are going to expand the

capacity.

So we are very aware of the problems that Fort Bragg especially has. It happens to be one of the hospitals that we continue to have—because of the size of the population and growth—some of the bigger problems with, but we are seeing steady improvements across the Army, sir.

Mr. DICKS. They also mention behavioral health care to Active Duty soldiers and their families is on a space-available basis. Is

that pretty much standard?

General Schoomaker. Sir, behavioral health care across the Army, and I think almost across the services—I don't want to speak for the others—but across the Nation as well, is under challenge. We are about 86 percent of our estimated requirements for behavioral health specialists, uniformed and non-uniformed.

Admiral Robinson in his opening statement alluded to the problems they are having with social workers and psychologists. We have a problem with psychiatrists, both civilians and, of course, uniforms. Understanding that although we have doubled the amount, the capacity to train social workers and psychologists recently, the lead time for training or acquiring a psychiatrist is upwards of 8 to 10 years. So these are tough nuts for the whole Nation to crack.

I would have to say it is one of the reasons that we are really focusing a lot, as well, on building resiliency and trying to identify problems as close as possible to when they are first recognized and to use the primary care arena—our family medicine docs, our internal medicine docs, our PAs, our pediatricians—to be one of the first line of defense in treating behavioral health issues.

### SUICIDES

Mr. DICKS. One of the major issues of concern to the Defense Department and to the Congress is the suicide rate, particularly in the Army and Marine Corps. We had some discussion of this prior to the meeting. I thought some of the things that are being done we should put on the record. Dr. Rice, do you want to start on this?

Dr. RICE. Yes, sir. Thank you, Mr. Chairman. Dr. Tom Insel, who is the Director of the National Institute of Mental Health, has identified suicide as a public health problem for the Nation as a whole. There are approximately 32,000 completed suicides in the United States each year. That is a number at or slightly above the number of fatalities related to motor vehicle collisions.

In the military services for a number of years the suicide rate was lower than the population as a whole. But recently, over the last several years, that rate has gone up, so that it is now at or

perhaps slightly above the rate for the country.

The line leadership and the Service Secretary in all three Services have been very concerned about this. Particularly, I will let General Schoomaker speak in more detail about the Army's approach. But the Vice Chief of Staff of the Army is personally engaged in this issue. In fact, I am attending one of his monthly reviews of suicides in the Army this afternoon. He does this every month with the commanding generals of the various military facilities where a suicide has occurred.

He takes this personally and seriously. He identified a need for a detailed study on suicide and turned to the National Institute of Mental Health for assistance in developing a grant application. A number of academic institutions around the country responded to that application. And I am pleased to say Dr. Robert Ursano, Chair of the Department of Psychiatry at the Uniformed Services University, and his team—he is assisted by very experienced investigators from the University of Michigan, from Harvard University, and from Columbia—were the successful applicants for that grant.

Mr. Chairman, you are familiar with the Framingham study in Massachusetts, which over a number of years has contributed enormously to our understanding of the risk factors associated with heart disease. What is intended with this study is a similar longitudinal study on a large number of individuals followed sequentially over a number of years that will similarly inform us about the risk factors associated with suicide.

General Schoomaker, did you want to add?

General Schoomaker. What Dr. Rice has talked about is the program known as STARS, begun by our former Secretary of the Army Pete Geren, and is being maintained by Mr. McHugh, our current Secretary. It is a \$50 million, 5-year study which promises

to be the largest longitudinal study that examines all the factors that are relevant to suicidal ideations and suicidal behavior. It follows about a year and a half's worth of work led by Vice Chief of Army Pete Chiarelli himself to try to get inside the problem of suicide in the Army. We have seen over the last 5 to 6 years a doubling of suicide rates from what were roughly half of an age-and-sex-adjusted population rate against our civilian colleagues, to one that is on par and may even exceed the current civilian population. It is hard to tell because civilian statistics are 2 years behind the military's statistics.

General Chiarelli is really focused hard on this. About a third of our suicides are from soldiers in their first year, before they have even been deployed; often, we think, due to problems that they bring into uniform with them; and it tracks with what we know from health behavior studies that have been conducted over the last several decades where 30 to 40 percent young soldiers, airmen, sailors, will admit to bringing significant psychological problems into uniform. About a third occurred in deployment, often with a weapon, and about a third from soldiers who have been deployed in the last 2 years.

We are looking at all the factors. The one transcendent factor we see across the board is a correlation with fractured relationships—the loss of a spouse, a divorce, breakup with a girlfriend. As I explained to you, sir, before the meeting, even for marines and sailors and soldiers and airmen, the relationship they have with the service, they can forge a very close relationship with the Army and then get caught in misconduct, be administratively dealt with through the Uniform Code of Military Justice, leave the commander's office and go out and kill themselves.

So these are the things that we are dealing with. We are working very hard with the help of the STARS program to see what we can do to interrupt this.

### SUICIDE PREVENTION

Mr. DICKS. Admiral Robinson.

Admiral ROBINSON. I would like to just also say that, in addition to everything being said, taking it to the individuals in question, this becomes a leadership issue. And it is a leadership issue not only at the highest ranks but also at the lowest ranks. It has to be taken to the level of the Soldier, of the Sailor, of the Marine, of the Airman, and there has to be an awareness of the people around you and how they are doing. That comes through education and that comes through training. That also comes through destigmatizing mental health issues so that people are not afraid and do not think their career will be hindered or harmed by seeking psychological help.

It also calls for individuals to look at one another. Friends and buddies know each other better than anyone. When things aren't right, then they have to institute those programs so that they can can ask, how are you doing, how are you sleeping? They can actually look into the eyes of individuals and see who they are and see whether they are hurting. And then they can take the appropriate action by getting them to counseling, getting them to a chaplain,

making sure they take responsibility for their shipmate. I think that is another important aspect of this.

Another aspect is making sure that we have time between deployments so that we can reset from a social and a family and an emotional and psychological point of view, come back into a more regimented existence, and home, before going back into an operational and combat environment.

General GREEN. Sir, for the Air Force, we have a 14-year history of effective suicide prevention program. We were able to drop our rates below 10 per 100,000 for nearly ten years. Since 2007, we have seen our rates also edging up. And so we are reemphasizing many of the things we put in place over those years.

The newest thing is to target specific groups we have seen who are at higher risk, such as our security forces, our intel groups, and some of our aircraft maintenance, who have a much higher rate, perhaps related to operational tempo and dwell rates. Those things are not determined yet, but we are watching very closely.

Our focus is on trying to get face-to-face training for those highrisk groups and have the training and get the experience to be wingmen, if you will; someone who will watch after those who are working with them. We think, like the other Services, if we can get the leadership and the people who are overseeing these folks to know what is going on with their troops, that we can make a difference in this.

Like the other Services, we see relationship problems as number one in terms of risk factors; financial problems as a second area; and then UCMJ and disciplinary problems also can lead to issues. We have not seen any association with deployment. In fact, over the last 8 years, only two occurred while deployed. The only potential association has to do with relationship difficulties that may be caused by recurrent deployments. And so we are watching that very closely.

We do see something that is in fourth category now in terms of things that are rising. We can't yet tell you whether that is people who are depressed or who have other diagnostic categories, but we are seeing a larger number of the people who actually commit suicide who have been involved with mental health care, and we still have been unable to break the cycle that led to that impulsive decision.

General Schoomaker. If I could add real quickly to what both these gentlemen said, and especially the comment that Admiral Robinson made about the importance of small-unit leadership and fellow Soldiers, Sailors, Airmen, and Marines. You may have read a recent story of a hooch mate, a bunk mate of a soldier downrange, who knew that his fellow young enlisted soldier had just received a Dear John e-mail and was in distress. Took the firing pin out of his weapon without his knowing it. While he was out of his billets, his buddy, the suicidal one, tried to kill himself with his M-16. Of course, it didn't go off. When he came back in he said, My weapon doesn't fire. His bunkmate said, How do you know that? They got to talking about the fact that he was aware that his buddy was suffering a lot of problems. That soldier whose life was saved by his friend is still a soldier. He is continuing on Active

Duty. He has started a new relationship and he is going to be leaving sometime in the next year to marry her and start a new life.

These things that Adam talked about are very, very important.

Mr. DICKS. Thank you. Mr. Visclosky.

#### IMPLANTED STIMULATORS

Mr. VISCLOSKY. Thank you, Mr. Chairman. Gentlemen, thank you for your service.

Admiral, I usually take this opportunity to congratulate Naval witnesses on beating Notre Dame in football at home, twice. Now Mr. Moran is upset with me. But I also notice that you graduated from Indiana University Medical School.

Admiral Robinson. I did.

Mr. VISCLOSKY. You obviously know what you are talking about.

I have got to get in a plug.

Gentlemen, my understanding is the Department of Defense is doing research on implanted stimulators that would send impulses to reanimate limbs for people who have had strokes and traumatic injuries. I find the issue fascinating. If, one, you could bring me up to date as to where you are, and is there an ongoing study and is

there progress being made?

General Schoomaker. Yes, sir, real briefly. We have a very, very robust program across the Services on amputee care and extremity injury, very heavily endorsed by the American orthopedic community at large, and the Congress has been generous by providing research funds for us. We are in our third generation of prostheses. The upper arm, the upper extremity prostheses, is the most demanding for an amputee. Lower extremity prostheses—of course, the loss of any limb or extremity is a problem. I don't mean to trivialize that. But the advances in lower limb prostheses have resulted in now the ability to retain soldiers or marines or others who have lost a lower limb, especially below the knee, much more easily.

We have retained about 140 amputees in the Army on Active Duty. Forty of them we have redeployed to combat. Three of the 40 have gone back to combat, having lost their limbs not in combat, but in motor vehicle accidents or training accidents back here, and

are being deployed as amputees for the first time.

The upper extremity prosthesis is a challenge. We are in the third generation. And DARPA has been in the lead of much of this. Geoff Ling is the name associated with this, a neurosurgeon and neuroscientist who is working with linking brain thought—just as in your and my case, who have limbs—with the movement of the limb. Heretofore, we were reliant on the upper extremity prostheses to either retrain a muscle to flex and make a mechanical device in the hand or the arm move. Then we went to the advance of linking a sensor in the muscle on the remaining part of the body so when someone thought to move his thumb or close his hand, they thought, and began to move that muscle.

We have gone to now the generation that eventually will allow people to move that prostheses because of a thought in their brain.

That is the one I think that you are thinking about.

### CLINICAL AND REHABILITATIVE MEDICINE RESEARCH PROGRAM

Mr. VISCLOSKY. Is there a funding request for 2011 for that? One of the other questions I was going to address—you had mentioned DARPA—is that it was our understanding the Department was going to ask for \$125 million to DARPA for development of force enhancements. I assume that is a separate issue.

General Schoomaker. Yes, sir, I believe so. I can get back on the

details of funding for the extremity research alone.

Mr. VISCLOSKY. If you could, I would appreciate that very much. General SCHOOMAKER. Yes, sir.

[The information follows:]

Yes. For Fiscal Year 2011, the Clinical and Rehabilitative Medicine Research Program has requested, through the Defense Health Program, \$30 million for the development, evaluation and optimization of extremity orthotics and prosthetic component research. The primary impetus is on the development of arm interface technology and the further development of upper extremity prosthetics. The requested funding will support upper extremity prosthetic clinical optimization studies and subsequent optimization of the devices.

#### ORGANIZATIONS WORKING WITH WOUNDED WARRIORS

Mr. VISCLOSKY. I also understand that at a number of DOD facilities there are individual installations or not-for-profit organizations working with Wounded Warriors. Are there a fair number of these established, and how would I distinguish them from military programs for Wounded Warriors? Is there care given to make sure

there is not duplication of services?

Dr. RICE. Well, sir, there are two very prominent programs funded by Mr. Arnold Fisher and his foundation, the National Intrepid Foundation; one is at Brooke Army Medical Center at Fort Sam Houston in San Antonio, which General Schoomaker can describe; the other is under construction now at the new Walter Reed National Military Medical Center, the National Intrepid Center of Excellence, focused on traumatic brain injury and psychological health. In addition, there are a number of support activities around all military installations. USO is a good example. I am sure my colleagues can describe those in more detail.

General Schoomaker. I think all the services have very, very good relationships with a whole range of nonprofit groups out there that have leaned forward in assisting our wounded and injured soldiers, sailors, airmen, and marines in all our camps and stations where these are done. At all of those Warrior Transition units I described earlier, we have got relationships with a variety of local

and national groups.

One of the problems, I think, is how to focus and distribute those services. Recently, the USO has offered to serve as a kind of national clearinghouse to be able to provide that service for us. But I think, as Dr. Rice mentioned, we have a very large number of very generous nonprofit groups that have helped build facilities such as the National Intrepid Center at Fort Sam Houston, and is building right now the National Intrepid Center of Excellence for traumatic brain injury on the campus at Bethesda.

Another good example is the Warrior and Family Support Center that is down—attached to Brooke Army Medical Center, which was built entirely by a very large number of private donors on land that was given over by the Army. None of the donors, largely, were over about a hundred dollars apiece. So, like the National Intrepid Center, which is the amputee center down at Fort Sam Houston which was built by 600,000 donors, there has been a huge outpouring of support from the public.

Mr. VISCLOSKY. Gentlemen, thank you. Thank you, Mr. Chair-

Mr. Dicks. Mr. Frelinghuysen.

#### JOINT THEATER TRAUMA REGISTRY

Mr. Frelinghuysen. Thank you, Mr. Chairman. Gentlemen, thank you for the extraordinary work you do. Since this is a public hearing, will one of you talk about the remarkable track record of survival rate for battlefield injuries? Would one of you just mention—the statistics are very high, this is like no other war—the things that your men and women have done?

General Šchoomaker. I agree. This is a tri-service effort. It is probably best attributed to the Joint Trauma Theater System, the JTTS. It employs an electronic record, known as the Joint Theater Trauma Registry. It is maintained by the Army, Navy, Air Force, and Marines.

This is a group that, for all intents and purposes, has built a trauma system comparable to what you would have in any large metropolitan area in the country, but it has done it across three continents and 8,000 miles. They meet virtually online and by video teleconferencing at least once a week to discuss cases. And they use evidence-based practices that literally follow almost from the point of injury back through evacuation and rehabilitation back in the States to make sure that any improvements that can be made in how a case is managed are being done, and then looks for evidence for improvement. And doing that has resulted in a case fatality rate that is unprecedented in past wars.

Mr. Frelinghuysen. Would you give that rate?

General Schoomaker. It is very high. The case fatality rate is less than 10 percent, meaning that over 90 percent of casualties in combat survive. If you make it to a forward surgical team or forward Marine unit or combat support hospital or the hospital at Balad or Bagram, then your survival rate is over 90 percent.

### MEDICAL RECORDS

Mr. Frelinghuysen. All of us pay tribute to that—Medevac people, airlift people from Balad and Bagram, the hospital in the air. It truly is remarkable.

The focus of my question is sort of on medical records. Can you talk about just the issue of medical records, the integrity of the medical records? Maybe it is anecdotal, but we do hear periodically that there are issues that medical records don't often follow the patient. I sort of wondered where, generally, the services were. You do extraordinary work here, but obviously we have battlefield injuries and people are transported long distances, and done in a remarkably wonderful way, but some general comments about medical records.

We talked about this with Dr. Rice yesterday, the integrity of those records and also the susceptibility in today's world that somebody could sort of bring down the whole damn system, as evil as people are. Can we have some general comments and reaction on the medical records issue?

Dr. RICE. Happy to talk about that, sir. I bring, unfortunately, a very long perspective. I am considerably older than my colleagues here. So I was on Active Duty at the National Naval Medical Center during the Vietnam War, where casualties would come back, often 4 or 5 weeks after wounding, just because the Air-vac system was not anywhere close to what the sophistication level is today. They may have stopped at two or three hospitals along the way. And the likelihood that their record would actually accompany them back to us at Bethesda was relatively low.

I am pleased to say that that is not the case now; that almost always an accurate record of the care that has been rendered both at the forward support hospital, the combat support hospital, the theater hospitals, and in the air at Landstuhl, makes it back.

#### ELECTRONIC MEDICAL RECORDS

Mr. Frelinghuysen. Is it indeed electronic or is it sort of a combination of paper and electronic?

Dr. RICE. In some cases, it is. But by and large, it is electronic. The issue of security of the medical record is one of not just military, not just national, but actually international concern, as I know you are aware. The Department is working very hard towards our next generation of electronic health record. And the three pillars that must be there are security, stability, and scalability. The security issue is of paramount importance. We must protect the integrity of the record, and the Department is going to great lengths to make sure that that happens.

Mr. Frelinghuysen. So you think that is being well done. I know you each take pride in your service. I assume that all the

services have the same high standards.

Dr. RICE. We are taking a common approach to that across the Services, so that it will be a single system that serves all three of our Services and ultimately links with the VA system so we can seamlessly pass the relevant and important data from the DOD system into the VA.

Mr. Frelinghuysen. You said "ultimately." I know around the table we have talked about the VA at one point was sort of in a crisis. They sort of are leading the way. It was the seamlessness they have now that they didn't have. They had all the different hospitals, but records couldn't be transferred from people in the Northeast to the South. So our Services, as represented here today, how are they doing in terms of linking medical records?

Dr. RICE. We have a pilot project. Mr. Frelinghuysen. We did hear yesterday that we couldn't get I think from Walter Reed—from Bethesda to Fort Belvoir. Hope-

fully, that was an exception.

Dr. RICE. Admiral Madison commented on that yesterday. I think by and large, the ability to transfer the relevant and important data across the systems from one military treatment facility to another is a problem that we have accomplished a great deal on. We don't hear that as a major issue with our providers.

Mr. Frelinghuysen. We are counting on it. We are the resource committee. So if there is anything lacking, we would love to hear about it.

General Schoomaker. No, sir. I think across the three services, that is not an issue. Bidirectional health information flow to the major polytrauma centers, the VA, is also not a problem. My own electronic health record began in about 2002 in the Southeast. I have moved four times and my record has moved with me each time without any problems. Saved a lot of money, saved a lot of unnecessary x-rays and shots.

The one hole that we have in the electronic system is from the point of injury to the surgical site. That still is paper-dependent. We have tried electronics. We have given hand-held PDAs to medics and corpsmen. It is a problem and an issue, and we continue to try to penetrate that. Right now, it is still reliant on a hand-written record.

Dr. RICE. Sir, if I could just add one comment to that. That is not different from the civilian world. If you look in emergency rooms, even in those hospitals that have electronic records, it is the ER that still is largely paper-dependent because of the press of time.

Mr. Frelinghuysen. Thank you, Mr. Chairman.

Mr. DICKS. Thank you. Mr. Moran.

### TRAFFIC AT BETHESDA

Mr. MORAN. Thanks, Mr. Chairman. Actually, I am going to relate a little story. A few months ago, the retina in my left eye was peeling off. It is about 5:30 at night.

Mr. DICKS. Free medical advice?

Mr. Moran. No. You will see the relevancy; it is going somewhere. So I drive to Bethesda through traffic and so on. Get there about 6:30 or so. They said, You're about to lose your eyesight. This retina is going to be gone. They said, I don't know what we are going to do about it because all our folks are gone; but perhaps the best guy to do this operation is over at Walter Reed, Dr. Chun. I am going to call him. We might as well start this coordination stuff now.

So they call Dr. Chun. He was on his way home. He comes back to Bethesda. They put a couple of tables together to have me lie down at the top of it. He takes his hypodermic needle and sucked out all the liquid behind the eye, except it was probably the most excruciating thing, because there was no time for anesthesia.

Then they broke into a room that was locked and got a machine that had this gas stuff and put gas in the eye and held it down. Anyway, they saved the eye. They said among themselves, you know, had we not been able to do this together, the Navy and the Army ophthalmologist, I would have lost my eyesight in my left eye.

There was some relevance here, Mr. Chairman. So I really am a believer in this, that as we coordinate at Walter Reed—I know, as Admiral Robinson said, the Navy is also losing its principal medical care facility in terms of the public visibility, as is Walter Reed. They are both losing their identity, but we are going to have

something new that is even better, and the colocation is going to

work for a lot of people.

My concern, of course, is that both at Bethesda and at Walter Reed, the traffic is almost impossible. You know that. And I am wondering—I am not going to get into all the BRAC stuff—I am wondering the extent to which you were consulted in terms—I know it is a mundane issue, it would seem, but if your staff, if your physicians, let alone your patients, can't get in there, that no matter how good the care is, it is most if they can't get to the hospital in some reasonable period of time when there is an emergency.

So have you given any thought? Were you able to offer advice in this process of the logistics around the facility to have real ade-

quate access?

Dr. RICE. Congressman Moran, I experience this personally when I am back at the Uniformed Services University because, as you know, it sits on the Bethesda campus. I live about 10 minutes north. It is 10 minutes when I come into work at a little after 5:00 in the morning. It is considerably longer than that going home in the evening because of the traffic on Wisconsin Avenue.

Mr. Moran. It could be as much as 40 minutes just to get out. Dr. Rice. It can be as much as 40 minutes to get from Jones Bridge Road to Cedar Lane. Admiral Robinson experiences it, because he lives on the base at Bethesda. It is a complex problem, and I know a number of people have given this issue serious thought. We are hoping that DARPA will shortly come up with a transporter beam so that we could move around without vehicles.

But I think a large part of the effort that we are undertaking with the new Commander of the Naval Support Activity at Bethesda is to do everything we can to encourage staff, particularly staff and the students at the university, to use Metro to the maximum extent possible. It is a complex issue.

General Schoomaker. Congressman, first of all, we are glad to hear your eye was saved. I suspect the contributions of the soldiers involved was breaking down that door to let the Navy surgeons work.

\_Admiral Robinson. At least we have solved that break-in now.

Thank you.

General Schoomaker. Two comments I would make. First of all, many of you, after the 2007 February stories in the Washington Post about Walter Reed, came out and visited. I was then put in command of Walter Reed, and commented about whether there was reason to pause and think about the decision to close the old Walter Reed campus. My comment, in addition to the fact that we want to be in compliance with law, was that for the same reasons that you describe the problem at Bethesda, we have the same problem at Walter Reed. It is very tough to get there; patients don't like to get there; and we don't even have the benefit of the Bethesda or the National Institute of Health (NIH) Metro station.

### FT. BELVOIR

Mr. MORAN. Incidentally, you have got a similar problem at Fort Belvoir. It is a beautiful facility but there is no Metro there either. We are going to have trouble getting patients in emergency condition there.

General Schoomaker. That brings up my second point; that often overlooked is that although the most proximate demand, as Adam has pointed out, is the merger of three hospitals into two, the larger plan of 37 facilities and 400,000 beneficiaries in a greater metropolitan area, which makes up the National Capital Region, is the real motherlode here. It is how do we integrate services across the three services for over 400,000 beneficiaries.

This will be the 40th largest HMO in the country once it is completed, for 37 different military treatment facilities. Putting care close to where families and Soldiers, Sailors, Airmen, and Marines live is going to be important, which is why the Belvoir campus is

so important to us. It is much closer to where people live.

It is also why, as I said from the beginning with my colleagues here, that siting a lot of the high-intensity warrior care and accommodating their families on the Bethesda campus, which won't necessitate trans-gate traffic, is so important. If you can provide care for an injured soldier or patient and amputees and intensely injured and ill Soldiers on that campus, then you reduce the necessity to move traffic in and out of the campus.

Admiral ROBINSON. Representative Moran, I think that that is correct. I agree. I think that your comments are, we are consulted, and when I say "we," as we have the Corps of Engineers and as the Navy's NAVFAC, the Navy Facilities Command that builds, those things such as traffic loads and others are studied and taken

into account. We need to attend to how the growth goes.

I think that, as you stated, making sure that we can get staff into the hospital and—that is as important as the patients. One of the reasons we have a large number of barracks for our enlisted onboard the base, and have for years, is the fact that not only are we in a hugely expensive county, much more expensive than most of our junior enlisted can pay for, they also are within the skin of the ship, as it were. So snow days and traffic days, we can depend on those corpsmen to make sure they are with patients and doing those jobs.

So yes, we are consulted; and yes, this is a major point. No way around it.

Mr. MORAN. Thank you. Thanks, Mr. Chairman.

Mr. DICKS. Thank you, Mr. Moran. I am very glad you had a positive outcome.

Mr. MORAN. I wouldn't have shared it if it hadn't been positive. Mr. DICKS. I am glad you shared it. Thank you. Mr. Tiahrt.

# WARRIOR TRANSITION UNITS

Mr. TIAHRT. Thank you, Mr. Chairman. Welcome to the committee. I was recently in Fort Riley, where they have a Wounded Warrior transition unit that they are standing up. Even though they don't have the facilities yet, they have the program in place.

I have had the opportunity to pheasant hunt with some of the Soldiers that returned from the front lines and have suffered traumatic brain injury, and some are suffering from posttraumatic stress syndrome. They seem to have a pretty good way of helping them readjust back to life here in America.

I was wondering if you are satisfied with the progress that they are having so far and if you can explain a little bit about the

uniqueness about the unit. Because they have a pretty good rate of success; at least that is what they have told me.

General Schoomaker. Yes, sir. The Fort Riley program is one of the 29 Warrior Transition Units that are in hospitals, major health centers, and medical centers across the Army. We have about 9,000—about 7,000 Soldiers in that program and another 2,000 Soldiers in nine States that are centered around nine States—Arkansas, Utah, Virginia, Florida, and the like, and Massachusetts. These Warrior Transition Units have an Active Duty cadre made up of primary care managers, squad leaders, just like any other military unit, and nurse case managers that track the care.

A very important part of our program is with comprehensive transition planning for vocational rehabilitation; for career development; for social, medical and emotional needs. And for programs like our posttraumatic stress program, we have got a fairly high rate of return to duty for those Soldiers. Overall, the WTUs are returning about 50 percent of Soldiers back into uniform to continue service or back into the Reserves to continue service.

The campus associated with that program, the one at Fort Riley, will be our first physical campus that we are standing up with new construction on the 27th of May. That will be the first of about 20 of these campuses that will be built across the country, including the one that we are building down at Fort Belvoir.

### POST TRAUMATIC STRESS DISORDER

Mr. TIAHRT. At what point do you sort of take the temperature of people as far as trying to find PTSD or some mental capability? When they are deployed, do you test them or talk with them before they return, and when they return and how long afterwards? What is your pattern now that you shoot for?

General Schoomaker. Sir, we do it whenever it is appropriate. Frankly—I am not being coy—what we are moving away from is a kind of arbitrary surveying of people at key points. Heretofore, we did it before they were deployed; the predeployment health assessment. Immediately upon redeployment—it was called the post-deployment health assessment, and then 90 to 180 days later, it was called the post-deployment health reassessment.

What we are finding is it is more important to move in a direction of tracking the individual and their problems, because they frequently arise out of major events. For example, the last time I was in Afghanistan, there was some intense fighting on the eastern part of Afghanistan. The brigade commander told me that one of the unexpected findings was 30 to 60 days after they were deployed, some of the experienced young officers and noncommissioned officers who had deployed before and been in fights before were experiencing stress reactions to this new deployment. We didn't expect that to occur 30 to 60 days after they had arrived in theater.

So we are beginning to track longitudinally through this comprehensive program when care is provided. But, in general, what we look for most often was immediately before deployment to make sure people are sound, immediately after they return, and then the 90 to 180 days later.

The last thing I will say is that part of the program that both the Marines and the Army are doing downrange is to find both concussive events—which we think have a high correlation with posttraumatic stress disorder—and overlap with that. That is, if you have had a concussion in combat, it predicts more often than not that you are going to have posttraumatic stress later, or possibly posttraumatic stress if it is enduring. So we are trying to find those problems as close to the actual incidents as possible and begin treatment in theater.

Mr. TIAHRT. As you know, we have a lot of Guard and Reserve units that have gone forward, and they don't have access to a permanent facility like Fort Riley or Fort Belvoir. How are you dealing

with PTSD with the Reserve and the Guard units?

Dr. RICE. Yes, sir. You are exactly right. There is a challenge for the Guard and Reserve in particular as they return to areas that are remote from military treatment facilities. With the support of this committee and under the leadership of Chairman Young, we established a program at the University, the Center for Deployment Psychology, which is focused on behavioral health providers, on the peculiar types of experiences that these servicemen and -women have experienced in theater, so that they can better provide behavioral health care for them. We have educated a substantial number of civilian providers now, and I am very pleased with the success of that program.

Mr. Dicks. The gentleman's time has expired. Mr. Boyd.

## SUPPLEMENTAL FUNDING

Mr. BOYD. Thank you, Mr. Chairman. And, gentlemen, thank you for being here today.

Dr. Rice, I want to direct my question to you and talk a little bit about the budget side. Obviously, I think many of us have been concerned that over the last 8 or 10 years that we have relied on supplemental budgets for much of our funding. I wanted to pick your brain a little bit about the current supplemental that we have before us; what part of that will be for funding Active military personnel and dependents, and also what you might have in your current budget that you are talking about here today that might not be covered, we might have to cover in a supplemental later on.

be covered, we might have to cover in a supplemental later on.

Dr. RICE. Congressman Boyd, thank you. First, let me say that I am relatively newly arrived in this position, and the preparation of this year's budget happened before I got here. I do not think that any of the basic funding of the military health-care system was dependent on the supplemental budget. I think that the budget proposal that has come before you now fully funds the Military Health

System.

Mr. BOYD. Okay. Would any of the Surgeon Generals have any—do you have any knowledge about the current supplemental as it

relates to any health funding that is in that?

General SCHOOMAKER. Sir, in the past, the supplementals have helped us mainly with closing the gap in military medical construction, which had a very large hole in the program. You all very generously filled that for us, and we are building new hospitals, to include the one at Fort Riley and Fort Benning.

Mr. BOYD. But not health services.

General Schoomaker. Not direct health services, although there has been supplemental dollars attached to, for example, Army support of Grow the Army and the medical support that went into that. But I fully agree with what Dr. Rice said; that is, the President's budget in the base provides the necessary dollars for health

Admiral ROBINSON. For the Navy, as an example, I think the recent Unified Response-Haiti, there will be an additional amount of money that will be covered by the supplemental. And that is operational. I am not sure that is really in the definition of health services, but I agree, again, with what my colleagues have said.

General Green. What my financial people tell me is beginning 2010, there were dollars that were reprogrammed from previous supplementals into the baseline. The dollars for the Air Force were about just under \$35 million. About \$22 million of that was for TBI and psychological health, another \$4.5 million for OCO tasks, and about \$8.3 million for Wounded Warriors.

If your question is whether we can get by without any supplemental in 2011, we are fully funded. The trick is with ongoing contingency operations, the dollars that come in that backfill some of our deployed people, we can't absorb it; but actually a lot of that contract that fills in for care back home and ensures access does comes from OCO funds, which is part of the supplemental, if that

answers your question.
Mr. Boyd. Thank you very much. Mr. Chairman, I brought that up because, obviously, as we enter this era where we have to begin to focus on budget deficits, it is going to be really important that we understand what the requirements are going to be.

Dr. Rice, in your testimony you have laid out some very instructive information there about the rising health-care costs under your purview, both Active Duty and retirees. So I just wanted to bring that to the attention of the committee. I thank you, Mr. Chairman.

Mr. DICKS. Thank you.

Mr. Rogers.

## PRESCRIPTION DRUG ABUSE

Mr. ROGERS. On March 23, when we had Secretary McHugh and General Casey here, I brought up with them the prescription drug abuse problem that we have—and it is not limited, of course, to the military. It is a problem in the civilian world as well. But a recent USA Today article about it mentioned a Pentagon survey in 2008 which showed that one in four soldiers admitted abusing prescribed drugs, mostly pain relievers, in the 12 months prior to the survey; 15 percent said they had abused drugs in the 30 days before the survey. The records show that the abuse of prescription drugs is higher in the military than in the civilian world.

I am wondering, A, what you think about this, and what are we doing about it, and what should we be doing about it?

General Schoomaker. Well, sir, I will speak for the Army. We are very concerned about prescription drug use. As you alluded to—and you and your district are experiencing as well—there is a nationwide problem of, first of all, accidental overdose from prescription drugs now leads or exceeds deaths or complications from illegal drugs in the country. The Centers for Disease Control tell

us that. The second is that diversion of drugs—that is, prescription drugs that are used for recreational purposes, not for what they were intended—is a major problem both outside the gate and inside the uniform.

Last year, I stood up a task force within the Army for pain management oversight, working with the other services and the VA. And in anticipation of legislation that came out last year requiring that we have a DOD approach to pain management, we are starting to get our arms around the size, the magnitude of the problem of pain management, and the use of prescription pain-managing drugs. We are looking at all sources of care for pain management, to include alternative medical care practices like acupuncture and yoga and the like.

At the same time, we are, especially in our Warrior Transition Units and in other clinical settings, taking a very aggressive approach to what we call sole provider programs, where only a single physician, nurse practitioner, or PA can prescribe drugs for a patient if they are at risk for abusing those drugs, and very careful programs of counting and watching the inventory of drugs that our soldiers might have. But we are very concerned about the problems

that you address.

Mr. ROGERS. Abuse of prescribed drugs is a huge problem in my district and, as you say, across the country. It is not limited to the military, obviously. However, the Pentagon survey said that the problem is higher in the military than civilian. I am told that Army Secretary Thomas Lamont, said that a multiservice task force is examining how the Army gives pain relief pills to its soldiers. Eventually, it will outline how to limit prescription medication use and ensure that Army hospitals all use the same procedure for dispensing medicine. He said, We found every Army medical center was dealing with pain in altogether different ways, all individual, but not an Army-wide program at all. There was no consistency. Do you agree with that?

General Schoomaker. Yes, sir, that is exactly what the pain management task force that I chartered has found. That is not unique to the services. Frankly, that is a national problem. It is a problem even within the Veterans Administration. We don't have a standard kind of approach and we don't necessarily leverage all techniques, to include nonpharmacological problems. We have had a problem of acute versus chronic pain. We have pain from a variety of sources. Pain is subjective. It is not objective in the sense of

something measurable.

What we are trying to do is standardize our approaches, leverage every technique that we can, in cooperation with the other services and the Veterans Administration and leading academics in the private sector and in the academic sector who can help us. But you have identified, sir, I think a problem that we recognize as a medical system.

Mr. ROGERS. In the civilian world we have been pushing prescription drug monitoring drug programs; each State, with a grant from the Federal Government to require pharmacies, doctors, hospitals, anyone in the medical field, when a prescription is filled, to notify the central computer in our State capital so that a person will not be able to double-fill a single prescription. I think you have

what is called a Pharmacy Data Transaction Service, a similar type.

General Schoomaker. In fact, we can track every prescription across not only our military facilities but also civilian pharmacies. Any time a military prescription electronically is used and any time the military system is billed, even if it is outside in the civilian sector, we can track.

In fact, I can give you for the record a tabulation of exactly what the use of prescription drugs of various categories is right now for the entire force of 550,000 soldiers.

Mr. ROGERS. I would like to see that.

[The information follows:]

We can query the comprehensive pharmacy database of all DoD pharmacies and contracted network pharmacies (provided the service member has the DoD pay for the prescription so it is recorded in the database). We can provide a summary of how many Soldiers have current, open and active prescriptions.

Active Duty Soldier Prescription Data

(March 2010)

558,840 Active Duty Army Personnel (Includes 4,498 USMA Cadets):

—200,255 (35.8%) Active Duty Army Soldiers with any medication prescription†

-2,504 (0.4%) for combination (sleep, psychotropic\*, narcotics)

-43,578 (7.8%) for narcotics

-20,027 (3.6%) for anti-depressants -11,448 (2.0%) for sleep medications

-5,500 (1.0%) for anti-anxiety medications -5,119 (0.9%) for anti-seizure medications -2,671 (0.5%) for anti-psychotic medications

—170 (0.03%) for fentanyl patch

General Green. Sir, if I can add, the PTDS system also allows us to place restrictions, like the systems you are talking about, where people would not be able to get their prescriptions filled, even when written by another provider. So they can only get it from one source.

### PRESCRIPTION DRUG MONITORING PROGRAMS

Mr. ROGERS. I think that service works for all except medications in-theater. I think I can understand that, but explain that.

General Schoomaker. Sir, we don't have—except in selected facilities such as Balad or Bagram, where we have an electronic record available—in the average or the usual combat outpost or forward operating base where we may not have that available and where things are done out of troop medical clinics or battalion aid stations—we don't have the same oversight and ability to roll up the aggregate abuse of prescription drugs.

Mr. ROGERS. I think, Admiral Robinson, the data from ships is also not a part of this.

Admiral ROBINSON. It is not, but we have the data from ships rolled up into our SAMs program and to other electronic programs we use. But it is not a part of PTDS.

Mr. ROGERS. Well, the problem has been growing. The abuse of prescription drugs in the military is growing rather dramatically, as a matter of fact; partly, of course, because of the wars. It seems

<sup>†</sup> Does not include WT Soldiers

<sup>\*</sup>Psychotropic medications include the drugs in the following classes: anti-anxiety, anti-seizure, anti-psychotic, anti-depressant, or stimulant

to me like we are dealing with a real problem here. Do you think

it is a real problem?

General Schoomaker. Yes, sir, I think that is exactly what prompted me to charter the task force that I did for the Army, to try to get our arms around it, especially when it is related to pain use. We are doing the same thing with respect to drugs that are being given for behavioral health problems and can give you the same comprehensive tabulation of who is taking a psychotropic drug, a drug that influences mood or behavior.

Mr. ROGERS. What do you expect out of the task force, and when? General Schoomaker. Sir, I have the final draft in hand. Right now, I am reviewing that. We hope to present that to the leader-

ship of DOD Medicine very shortly.

Mr. Dicks. The gentleman's time has expired.

Mr. Rogers. Mr. Chairman, I think Dr. Rice has something.

Dr. RICE. Sir, if I may, Congressman Rogers, you have put your finger on a very complex problem. One of the challenges that we face is that for many, many years we in the medical profession undertreated pain. Through the efforts of a lot of people, including the Joint Commission, we have recognized that undertreatment, and now begun to take steps to make sure that patients are not needlessly enduring pain.

I think the challenge for us all is to know what the appropriate treatment is, and while the use has undoubtedly gone up, that increased use is entirely appropriate. Pain is the most common reason that people seek medical attention. And, therefore, paying appropriate attention to pain relief is an important part of clinical

practice.

Mr. ROGERS. Thank you.

Mr. DICKS. Thank you. Mr. Bishop.

## HYPERBARIC OXYGEN THERAPY

Mr. BISHOP. Thank you very much. Let me welcome you all back again. I would like to ask the panel to return to an issue that we visited last year, and that has to do with the related treatments for traumatic brain injury and the hyperbaric oxygen therapy.

Lieutenant General Schoomaker, I have been informed that the hyperbaric oxygen therapy equipment and the medical personnel have been contracted by DOD for a 2-year, \$20 million pilot program that was supposed to start up in January of this year. I am told that the equipment and the personnel are positioned at Camp Pendleton, Camp Lejeune, Fort Carson, and Fort Hood, but to date they haven't been used to treat any injured personnel.

I wanted to ask if you would just describe for the committee what the hyperbaric oxygen therapy is, and tell us about the situa-

tion with the equipment being available but not yet in use.

General Schoomaker. Yes, sir, I will do my best, and then I think my colleagues have even more visibility over it. But in a nutshell, hyperbaric oxygen is the delivery at a pressure above the sea level atmospheric pressure of air or oxygen, which then raises tissue levels of oxygen above the normal range. It is recognized as a treatment for a variety of things; for example, wound healing for resistant infections, especially by organisms that are sensitive to oxygen; or for reversal of complications of diving accidents, for ex-

ample, and that is where the Navy and those who work with pres-

surized environments have some experience with them.

There are some recognized medical indications for the use of hyperbaric oxygen. Its use in traumatic brain injury or for posttraumatic stress disorder is not currently recognized by the national groups that, in a sense, certify or authorize use for that clinical application. We are looking very, very hard for good scientific evidence that it adds value in those situations. We are compelled——

Mr. BISHOP. That was the status last year. I thought you told us last year that that was underway and that we would probably have

some kind of indications soon.

General Schoomaker. My understanding is that we have two or three outstanding trials right now that are just about to report and give us some early indication whether there is some utility to it. There are some recently reported nonrandomized and noncontrolled studies, meaning that patients were given the treatment, but knowing they were getting the treatment, and there was no control arm that didn't use that treatment mode to see if there was any real effect of the hyperbaric oxygen. So we are compelled to use randomized clinical trials. We have a good program now. Maybe Admiral Robinson would summarize.

Admiral ROBINSON. Representative Bishop, last year, and actually for the last couple of years, we have been—there have been a number of reports by researchers and clinicians on hyperbaric oxygen therapy. As has already been summed up, hyperbaric oxygen therapy has a usefulness with evidence-based treatments and clin-

ical protocols for a variety of different cases.

There has never been one for brain injuries and for PTSD. There have been a number of anecdotal reports, a number of anecdotal reports that people benefit from hyperbaric oxygen therapy with traumatic brain injury and with PTSD. In those reports—and this is what General Schoomaker is referring to—they were not done in a randomized fashion. They were not done so we can take evidence-based scientific study and actually produce clinical protocols that we can give to the world and say, this is based upon clear evidence of working.

Mr. BISHOP. Why have we not done that?

Admiral ROBINSON. That is what I am getting to. Over the course of the last 3 months, and we have been working on this for well over a year—but working with Colonel Scott Miller, an Army internist researcher, infectious disease expert—and I will caveat now, he has no knowledge of hyperbaric oxygen therapy, but he is a master and a professional at designing prospective studies—has in fact helped us, through the Army Research Facility, to actually put together studies that we are conducting. He has included, at Camp Pendleton, Lejeune, Carson, and San Antonio, we now have more people enrolled in those studies and actually under investigation. So those sites, the Pendleton site and the San Antonio site, are working. And for sure the San Antonio site. We have more people enrolled than ever before.

We will have a definitive result of does hyperbaric oxygen work over the course of the next 24 to 36 months. That seems like a lot of time, but in the world of research, to get that type of evidence and then to put clinical guidelines together, clinical guidelines that are going to go forward and be the standard of care worldwide, that is not too long.

Mr. DICKS. Will the gentleman yield? I may have missed this, but I think there are some situations where this is being prescribed now.

Admiral ROBINSON. There are conditions treated with hyperbaric oxygen therapy today.

Mr. Dicks. What have been the results of those?

Admiral ROBINSON. The results have been phenomenal. Wonderful. They have been absolutely unable to base it on any objective criteria that we can produce. Since oxygen therapy is a device, it is being looked at by the FDA. In fact, the FDA has stepped in and asked for some of those studies to be stopped, because they are not sure whether this would be harmful to the patients, and there has been no objective evidence in a properly controlled study to prove that it works.

General Schoomaker. I think, Mr. Dicks and Congressman Bishop, one of the frustrations we all have up here is we want the very best treatment for our people. There are far more traumatic brain injuries generated and far more posttraumatic stress disorder generated in the civilian sector every year than there is in combat—on motor vehicle accidents, on sports fields. We have had decades and decades of brain injury and posttraumatic stress disorder and have asked the field to provide good scientific evidence that it works.

We finally, as the Department of Defense, have come together and said, Okay, we can't seem to get academics to do good trials for us, so we will do the trials. And, frankly, they are getting off the ground now.

Mr. DICKS. How can the doctor, if this hasn't been vetted or whatever you call it, how can they go ahead and make these prescriptions, and do it, and find out it works very well, and how does that happen?

Admiral ROBINSON. Representative Dicks, I think that there have been all sorts of people who have sold all sorts of remedies in past years and centuries that have proclaimed the efficacy and effectiveness of things that have been really sham.

Mr. DICKS. Yeah, but this works.

Admiral ROBINSON. It hasn't been proven to work scientifically. It works according to the anecdotal explanations of patients.

General Schoomaker. Legally, a licensed physician can prescribe so-called "off label."

Mr. Dicks. That is what I want to know.

General Schoomaker. You can take a drug which is not labeled for use in a particular way and try it "off label." You are responsible for the outcome of that. But you can do that. About 90 percent of all pediatric drugs, for example, are prescribed to children "off label," meaning that there isn't a definitive trial to show its utility. It would be too expensive to do that.

In the case of hyperbaric oxygen, a licensed and certified provider can do that as a trial. The problem we have there is what Admiral Robinson says: We don't have definitive proof.

Mr. DICKS. Keep moving the trials ahead as best you can. We have to do it in a scientific way, I understand that. But there does seem to be some evidence that there are positive outcomes here.

We have a vote underway. I am trying to wrap this up. Have you got anything? Can I go ahead to Mr. Hinchey?

## MEDICAL MALPRACTICE

Mr. HINCHEY. Thank you very much, Mr. Chairman. Thank you very much. I deeply appreciate everything you are doing and we all know how important it is. It is a very complex set of circumstances also, under some set of circumstances. What I want to ask you about is the medical malpractice situation. This is something that comes about as a result of a Supreme Court decision back in 1950, which has created a whole host of problems that really needs to be addressed.

There are many cases of military medical malpractice which have been highlighted in the media recently, and a number seem to involve very preventable medical errors. One group reports 10,000 veterans were exposed to HIV and hepatitis after at least three VA hospitals failed to sterilize colonoscopy equipment. This contamination is considered a "never" event, but it is completely preventable and it should never happen. So this is a situation that I think comes about as a result of this situation of medical malpractice under a set of circumstances that is not really overseen.

My attention was drawn as a result of a former constituent of mine, a sergeant by the name of Carmella Rodriguez, who was repeatedly misdiagnosed by military doctors as having a wart when he actually had a melanoma. And that melanoma led to his death.

So I am wondering a couple of things. Do the Armed Forces keep track of how much money is wasted yearly on preventable medical errors? And how can this rate be lowered if the military is immune from liability for the harm it causes? I think that the focus of that attention has to be on this, unfortunately, Active Duty military personnel who have no legal resources in the face of medical negligence, due to this 1950 Supreme Court decision that Justice Scalia says was a mistake. This is health care that comes about not in the context of military actions but it comes in the context of just normal life. So I wonder if you could focus a little attention on that.

What do you think about that Supreme Court decision? It seems to me that Scalia is right; this is something that really needs to be dealt with. You have civilians that still have legal recourse, civilians that are members of military families. But you don't have the military personnel themselves who have the recourse as a result of that 1950 decision. Can we afford to kill and injure our own soldiers through negligent medical care?

General Schoomaker. I think you are alluding to the Feres Doctrine, which was a law passed to protect uniformed commanders and members of the military from liability for decisions made in a military setting. That has been expanded to caregivers in a practice setting, in medical practice, and surgical practice.

Just a point of information about the first cases you raised in the VA. The Veterans Administration, not being a part of the Department of Defense, I am not sure its relationship to the Feres Doctrine. But in that case—in fact, our practices in our hospitals would

have protected our patients from HIV because we do the necessary sterilization and check for it.

Mr. HINCHEY. I appreciate the focus on that. There is no question about it. But there are cases where we have documented where they come up, where they weren't paid attention to adequately.

That is the one I am mentioning.

General Schoomaker. We look very carefully at medical errors. We look at those cases that either result in a claim against it; or, even when a claim is not filed, when an error has resulted in adverse outcome for a patient, or a near adverse outcome. I am, frankly, not aware of any connection between medical liability and

improvements in medical error.

Dr. RICE. Congressman Hinchey, I have never presumed to quarrel with Justice Scalia, particularly on an issue of legal doctrine. But I think General Schoomaker is exactly right. The government is liable under the Federal Tort Claims Act for an act committed by a uniformed practitioner acting within the scope of his duties and responsibilities. As General Schoomaker has pointed out, there is a standard-of-care investigation taken in the case of any assertion of medical malpractice or an unfortunate outcome.

In my personal experience, having spent most of my career in the civilian academic world, I do not think that the threat of litigation is a particularly helpful way to improve practice. The judgment of

one's peers is profoundly effective.

Mr. HINCHEY. That is something that I am going to disagree with you on, because I think that the liability is something that is going to focus attention on the health care that people need much more effectively than it is so often. Now, almost always in the vast majority of times, it is focused appropriately and people get appropriate health care. But if you have people who don't care about it, and knowing they are not going to be held accountable as a result of it, then there can be a lot of negligence in some cases.

I think that negligence comes about as a result of the fact that there is no accountability; that they don't have to behave in the right way in the context of dealing with people who have normal health-care problems in the military. And if the people suffer as a result of that, well, they are not going to be held responsible.

Dr. RICE. Sir, I guess I would take issue with your statement that there is no accountability. There may not be accountability in a civil court, but within the military system there is a lot of accountability. The behavior and performance of a military officer delivering health care is scrutinized very carefully, and there are profound implications.

Mr. HINCHEY. I think that is right. I think that is effective. But at the same time, there are a number of other people who are not subject to accountability, and they are not subject to accountability because there is no legal accountability that they have to deal with. They don't have to deal with the legal accountability as a result of that 1950 Supreme Court decision.

Dr. RICE. I think on this one we will have to agree to disagree.

Mr. HINCHEY. All right.

General Schoomaker. I would echo that. All of our practitioners are fully accountable for their actions. Except for the Active Duty soldier who, through the Feres Doctrine, cannot raise a claim

under tort law, all family members, for example, are eligible for recourse.

Mr. HINCHEY. Family members are eligible.

General Schoomaker. I don't know any relationship between improvements in standard of care and the ability of patients to sue for that care.

Mr. HINCHEY. The families are, but the military personnel are not. And that is something that I think really has to be dealt with. Frankly, I must say, candidly, I am disappointed in the way that you feel about it because it is going to, and has, clearly diminished the likelihood of the high quality, effective quality for health care for military personnel across the board. There are some number of military personnel who have suffered as a result of this.

Mr. Dicks. The gentleman's time has expired. Ms. Kaptur.

## VETERANS CLINIC

Ms. Kaptur. Thank you, Mr. Chairman. Welcome, gentlemen. Thank you for the work that you do. In our region, we have no major bases that I represent that are Active Duty. But we have a lot of Guard and Reserve and returning soldiers. The Veterans Department has announced they want to rebuild this little veterans clinic we have in our area. If your advice—and knowing everything you know about what is occurring in theater and afterwards as these soldiers rotate out and they come back home, what would you advise them in terms of what to think about as they construct this clinic? Any considerations based on what you see happening to those in theater and in support of them compared to past wars?

Dr. RICE. Congresswoman, if you are referring primarily to guardsmen and reservists, then I think a couple of things should be kept in mind by the VA, and I know the VA does a very good job of thinking through these issues. As my colleagues alluded to earlier, the biggest challenge that our beneficiaries face is access to primary care. So I think building a robust primary care system at such a clinic and then establishing referral relationships with a secondary and tertiary care facility in the nearby region is of paramount importance.

Admiral ROBINSON. Additionally, with the comprehensive primary care, make sure that you have ready access, and I mean onsite access, to mental health capabilities—licensed clinical social workers, licensed occupational therapists that can do counseling. Psychologists, psychiatrists, of course. But it doesn't have to be only professionals; it can be a lesser person that can still give adequate and good mental health counseling.

General GREEN. The studies have clearly shown that if you establish what we call collaborative care, which is the integration of the mental health into the primary care area, that that decreases stigma, encourages use of mental healthcare, and aids the primary care folks as they take care of some of the issues that come up with veterans.

Ms. Kaptur. Your comments are very useful, because one of the challenges locally is, we have got veterans organizations, largely from past wars, they are more willing to participate than the current veterans—and one of the issues is mental health. And they are saying, We don't want to go in the same door, because when

they call our number then everybody knows—if we go down the elevator they know who we are. So we want a door built in the back of the building and we are going to drive our car back there so we are not with those other veterans. Collaborative care. I hadn't heard about that.

Admiral ROBINSON. The deployment health clinics in Navy, we have about 17 now across the United States, are based exactly on the collaborative care model. It is helping to reduce stigma in terms of getting mental health care. So your veterans groups will be pleased because you go to the deployment health center for primary care. While you are there, you can also get mental health therapy, but no one knows where you are going to in the clinic.

Ms. Kaptur. Admiral, could you send me some sort of summary of that from places where it is working? I know that you don't have responsibility for the VA. However, I have found in my career a huge gap between what happens at DOD and then when they come

home at VA. It is a huge abyss in between.
General Schoomaker. If I might, ma'am, really quickly. In fact, a lot of the behavioral health services that can be provided at a primary care site were developed in conjunction with the Veterans Administration. Durham VA, for example, was very, very active in developing a program called Respect-Mil which teaches and trains primary care providers.

Ms. KAPTUR. They probably have a big hospital there, right? When you get down to the hinterlands where you have got people

coming home, and they are only going to clinics.

General SCHOOMAKER. This is a training program that can be ap-

plied wherever it is.

The other things that I would add real quickly in terms of this clinic is dental care; a robust alcohol and drug treatment program; and because they are a younger population of veterans now, and more females, we suggest having child care available for women veterans onsite so that they can attend their appointments.

# SINGLE-PLAYER PODCAST DEVICE FOR VETERANS

Ms. Kaptur. Interesting. Thank you, gentlemen, very much.

I wanted to mention something that I saw that I will try to get to each of you, because I have ordered extras, and that is a singleplayer podcast device that is just as big as a little, tiny telephone. And what it is, the current soldiers aren't going to VFW posts and participating in veterans organizations when they are coming home. So especially where you don't have a big hospital or big base, they go out into the counties, and they are out there, and if they have mental challenges, mental illness challenges, it is likely untreated.

And I found this over at the VA in Cleveland. And working with some of the psychologists, they have developed this program that can be hand-held, where a veteran can just take it—and I don't say it is self-administered care, but it works them through questions and so forth. We are finding it to be very effective.

And so I wasn't aware if you had seen these types of devices and were using them on a regular basis. If they are out in some rural county and they have nothing, it is better than nothing. If they are not going to come into the major urban clinic, it gives them a lot

of alternatives. A lot of people working with them in the Cleveland system seem to feel it provides a new way forward. And the new veterans are all independent. They don't want to go to group sessions. A lot of them don't do that.

Have you ever seen these types of devices?

General Schoomaker. I am personally not familiar with it, but I have written it down. Maybe we can get some details.

Ms. Kaptur. We are trying to order you some cassettes.

General Schoomaker. I am going to be at the Cincinnati VA Friday or Saturday, talking to Kate Chard, one of the leading posttraumatic stress treaters. I will talk to her.

## DRUG ADDICTIONS

Ms. Kaptur. I will make sure we get one of these to her so she can give it to you. Give me your evaluation of it, if you think it is as useful as we have been told.

My final question has to do, sort of following on what Congressman Rogers was dealing with, I think about Vietnam. I remember that era and the numbers of our Soldiers that were addicted and what happened in theater and when they came home. We have got soldiers now over in Afghanistan, and we know what the primary crop in that country is.

What are you seeing? Are you seeing any evidence of additional addiction as a result of where our Soldiers are deployed, and what is happening in those circumstances and what comes to you in the health field?

General Schoomaker. No, ma'am, not that we are aware. I am not aware through the drug screening programs that are applied to all Soldiers that there has been any increase as a consequence of those deployments.

## HEALTH CHALLENGES

Ms. Kaptur. If each of you were, in summary, were to tick off a major health challenge you feel that you face in your branch or in your responsibility at the university, what would it be?

Admiral ROBINSON. Just to name a major challenge, it would be smoking.

General Green. I would say obesity. It mirrors what is going on with the country.

Ms. Kaptur. Obesity. In the Air Force.

General GREEN. Obesity with our beneficiary population, not just Active Duty. It is a problem with Active Duty, retirees, family members. Our problems tend to mimic the general society.

General Schoomaker. We have the same problem in the Army. Army statistics show the Active Duty soldier on average is at lower body mass index, but as soon as they retire—and their family members are on par with the country. So we are targeting child-hood obesity as one of the health improvement programs within Army Medicine.

Ms. KAPTUR. Thank you. Thank you very much, Mr. Chairman.

## TRICARE REGION NORTH AND SOUTH PROTESTS

Mr. DICKS. What is the basis for the protest in the TRICARE Re-

gion North?

Dr. RICE. Chairman Dicks, the General Accountability Office reviewed the contract in the North and found evidence of an undue competitive advantage. That is a public report. And the Department is working through resolution of that issue.

Mr. DICKS. UNDO competitive advantage. What does that mean? Dr. RICE. Unfair competitive advantage. The assertion is that the

winning contractor had access to inside information.

Mr. Dicks. What is the basis for the protest in TRICARE Region South?

Dr. RICE. In the South region, one of the bidders offered discounts for services. The protest was based on the fact that even though the TRICARE Management Activity had indicated that it was not going to take discounts into consideration in the award of the contract because they could not be guaranteed, the General Accountability Office found that those should have been taken into account.

So the technical evaluation of those two contracts, those two proposals, is now underway to define precisely how the proposed discounts can be factored in.

Mr. DICKS. So what is the status? Are you redoing them?

Dr. RICE. No, sir. The contracting office has reached a conclusion on those and on the one in the North, and that is now under legal review at the highest levels of the Department. We hope to be able to resolve that issue quickly. In the South, again, the technical reevaluation is underway or the technical standards are being redefined.

We will give the two proposing organizations the opportunity to refine their proposals just within those narrow technical limits. We will then evaluate those. And we hope to be able to reach a conclusion on that issue within a month to 6 weeks.

Mr. DICKS. What is the status of the award at the TRICARE Re-

gion West?

Dr. RICE. Sir, that is an agency protest that did not go to the General Accountability Office. Under the rules of competition, a health-care or managed-care support contractor can win in only one of the three regions. One of the organizations that was apparently successful in the South region lodged an agency protest in the West region so that in the event they lost in the South, they would be able to reopen discussions in the West.

Mr. DICKS. When will that be resolved?

Dr. RICE. The resolution of the West is dependent on the resolution of the South.

Mr. DICKS. So, interrelated.

Dr. RICE. Yes, sir.

Mr. DICKS. Is it possible to change the current contracts to reflect the enhancements of T3, the third-generation TRICARE contracts? Dr. RICE. No, sir. The existing TNEX contracts, which are the

Dr. RICE. No, sir. The existing TNEX contracts, which are the ones that we are operating under right now, they have run their course in the North. Where the contract has been extended with the existing contractor, that remains under the TNEX contract.

That is one of the reasons that we are eager to move ahead with the resolution of these awards, so that we can transition to T3.

In the meantime, we will very shortly begin the development of the generation of—the characteristics of the generation to follow that one, which we have, very imaginatively, tentatively named T4, which we hope to be able to take into account some of the new thinking that may help us bend the curve so that health-care costs under TRICARE do not continue to escalate as rapidly as they have.

Mr. DICKS. How fast have they been going up? What has been

the percentage per year?

Dr. Rice. Mr. Chairman, the MHS costs are projected to increase between about between 5 and 7 percent per year through the year 2015. If that growth rate remains unchecked, they are projected to approach \$64 billion in 2010 dollars in fiscal 2015. As the chairman knows, the subject of escalating health-care cost has been one that the Congress has been intently focused on for the country as a whole. The Military Health System is not immune from those same pressures.

Mr. DICKS. At least this year, you set up a budget that had all

your costs in it.

Dr. RICE. Yes, sir. The budget proposal is fully funded.

## WARRIOR TRANSITION UNITS

Mr. DICKS. How many Warrior Transition Units currently exist to date?

General Schoomaker. Twenty-nine within the uniformed system associated with hospitals and clinics. And there are nine that are based in the Adjutants General for nine different States. They are more regional; as I said, at Utah, Virginia, Massachusetts, Florida, Arkansas.

Mr. DICKS. There are nine of them?

General Schoomaker. Yes, sir.

Mr. DICKS. Not one in Washington State, I take it.

General SCHOOMAKER. Utah is the closest one.

Mr. DICKS. We have a big one at Fort Lewis at Madigan.

General Schoomaker. Yes, sir. And there is one at Fort Richardson in Alaska.

Mr. DICKS. The committee understands that the WTUs are not fully resourced. Why are the WTUs not fully resourced?

General Schoomaker. Sir, I am not aware that they aren't. In

what respect?

Mr. DICKS. Well, why don't you look into that? If you can just verify that. Our staff seems to think that there are some issues here. Are there funds in the 2011 budget to enhance Warrior Transition Units?

General Schoomaker. Yes, sir. Part of the funding is for fully funding the Warrior Transition Units.

Mr. DICKS. Okay. I was just out to the one at Fort Lewis. I was very impressed. I was also impressed by the fact that the commander of the unit was a wounded veteran, who was very impressive

General SCHOOMAKER. It may be worth noting that the Army Wounded Warrior Program, which is a part of the Warrior Transi-

tion Command that has oversight over all of these units, is going to be Lieutenant Colonel, promotable, Greg Gadson, the double amputee, who remained on Active Duty, and was the inspiration for the New York Giants to win the Super Bowl 2 years ago.

Mr. DICKS. Is the Army Medical Action Plan fully resourced?

General SCHOOMAKER. Yes, sir. The AMAP, the Army Medical Action Plan, that was stood up after an execution order in May-June of that year of 2007, was the forerunner of the Warrior Transition Unit process. That led off the whole process of transforming wounded and injured warrior care.

Mr. Dicks. How do the services differ in the provision of care in

transitioning of Wounded Warriors?

General Schoomaker. Sir, I would say that the inpatient and outpatient care is identical across the services, independent of what the color of the uniform is. What we differ in is how we administer the programs, subtleties in the support of families and nonmedical attendants and the like—and I will let my colleagues address that—but use a more decentralized process and the like. In the main, what we are all aspiring to do, and our transition into the

VA and the like, is very, very similar.

Admiral ROBINSON. I think that from the Navy's perspective, as General Schoomaker has said, the decentralized approach, all of the Warrior Transition Units and the men and women who may be there are still under the auspices of the Surgeon General of the Army; in the Navy, the Warrior Transition Units or Wounded Warrior regiments at Camp Lejeune and Camp Pendleton, and at Quantico in this particular region. The Marine Corps takes those—they are in charge of those particular units and the Marines are in control. Those units all have medical clinics or medical facilities that are with them, but we are there to provide medical care to them, but the line has control of those members.

General GREEN. For the Air Force, we have a centralized program that oversees our warrior and survivor care, all overseen by our A1, so done by our personnel community. But we do decentralize in terms of the recovery care coordinators and the community readiness consultants, et cetera, that provide support. Our Wounded Warriors are all tracked centrally, so we know exactly what is happening with each of them, but they actually can receive their care locally and then have regional recovery care coordina-

tors

Mr. DICKS. Does the budget cut provide adequate funding to take care of the Wounded Warrior Programs? As far as you know, is this fully funded?

General Schoomaker. Yes, sir.

Admiral Robinson. Yes.

General Green. Yes.

Mr. DICKS. All right. The committee stands adjourned until May 5th at 10 a.m. in H–140 when we will hold a hearing on the Missile Defense Agency programs.

Thank you, gentlemen. I appreciate your testimony.

[CLERK'S NOTE.—Questions submitted by Mr. Young and the answers thereto follow:]

Question. VA and DOD medical facilities have improved markedly over the last several years, which is good for those people who live in close proximity to them.

However, a great many National Guardsmen and Reservists live in rural communities far removed from those types of support facilities. In the past I have championed efforts to provide telephonic psychological counseling services to mitigate those types of challenges. Though accomplished at a distance, the intent of these services is to have an active medical professional manage cases over a period of time in order to both treat and diagnose psychological issues that may also appear long after a veteran leaves the service. What other things can this committee do to ensure the welfare of servicemen and women in rural areas?

Dr. Rice's Answer. The Department appreciates the Committee's support for telephonic counseling for the mental health needs of our Service members. As we review our options for best solutions, the Department will continue to work closely with the

Committee on this important issue

General Schoomaker's Answer. There are three actions I recommend to your committee in order to improve the welfare of servicemen and women in rural areas. First, continue to fully fund the Defense Health Program (DHP) budget. Eligible Reserve Component (RC) Soldiers and their Families use DHP-funded TRICARE medical and dental services before, during, and after mobilization. RC Soldiers who are issued delayed-effective-date active duty orders for more than 30 days in support of a contingency operation are covered as active duty service members and receive active duty medical and dental benefits generally from the time they receive their mobilization orders until six months after their demobilization. Eligible RC Soldiers living in rural areas use the TRICARE provider network in their local area to receive medical and dental care, and this benefit is critical to those Soldiers who lose employer-provided healthcare insurance while deployed.

RC Soldiers are also eligible to purchase TRICARE Reserve Select (TRS) and the

TRICARE Dental Program when not on active duty for more than 30 days. DHP funds subsidize a significant portion of both programs, making these plans affordable to RC members throughout the U.S. In some rural areas RC Soldiers may have few other affordable medical and dental insurance options, so your funding support

for DHP enables TRICARE to continue to offer these beneficial programs.

Second, continue to support and fund the Yellow Ribbon Reintegration Program. The Secretary of Defense initiated the Yellow Ribbon Reintegration Program to provide information, services, referral, and proactive outreach programs to RC Soldiers and their Families through all phases of the deployment cycle. The goal of the Yellow Ribbon Reintegration Program is to prepare Soldiers and Families for mobilization, sustain Families during mobilization, and reintegrate Soldiers with their Families, communities, and employers upon redeployment or release from active duty. The program includes information on current benefits and resources available to help overcome the challenges of reintegration. This program provides vital resources to rural-based Family members of deployed Soldiers as they are geographically dislocated from military installations that routinely provide similar services to Soldiers and Families in the immediate area.

Third, the Army will need your continued support as we review statutory limitations that impact the provision of telemedicine across state lines. State laws governing contract providers vary regarding licensure reciprocity and/or other sharing arrangements, while Uniformed and Government civilian providers can practice across state lines as long as they have a valid state license and are working in their Federal capacity. The Army would like to remove barriers such as this in order to provide world-class telemedicine care to Soldiers and their Families regardless of proximity to the provider. We value your support of this issue as we continue to work with our Department of Defense partners to improve access to care for all Sol-

diers and their Families.

Admiral Robinson's Answer. The Committee can continue to support psychological health outreach and support activities such as those being provided by the Navy Reserve Psychological Health Outreach Program. This program was established by Navy Medicine in 2008 to provide a Psychological Health "safety net" for Navy Reservists and their families at risk for stress injuries. Five teams consisting of two Psychological Health Outreach Coordinators and two to four Psychological Health Outreach Team Members are located at each of the five Reserve Component Commands for a total of 25 personnel. The Psychological Health Outreach Team Members provide outreach phone calls to Navy Reservists, especially those returning from mobilization, to check on their psychological health status. Additionally, they provide referrals to mental health care providers (TRICARE, VA or civilian health care provider based on eligibility) as indicated and assist in arranging follow up care as needed. Finally, the Outreach Team Members make periodic visits to each of the Navy Operational Support Centers (NOSCs) in their respective regions where they provide the Operational Stress Control (OSC) and Suicide Prevention briefings and

have the opportunity to meet with individual Reservists. As of 1 April, 2010, the Navy Reserve Psychological Health Outreach Teams have:

—Assessed over 2,000 Reservists; 975 required further services and follow-up

-Provided outreach calls to an additional 2,100 returning Reservists -Made 225 visits to NOSCs providing OSC awareness brief to over 23,400

Reservists and NOSC staff.

This program was expanded to provide services to the Marine Corps Reserves in 2009. There are six Psychological Health Outreach Teams (total of 30 licensed Social Workers) providing services to Marine Corps Reservists and their family members. General Green's Answer: The Air Force Reserve Command provides the following

suggestions:

Air Force Reserve Command (AFRC) currently has no Director of Psychological Health (DPH) positions. AFRC wants to hire DPHs who will be in charge of coordinating access to mental health services for reservists. Defense Health Program (DHP) funds have been appropriated, but because of appropriation rules this money cannot be used to provide administrative oversight positions. Recommend committee investigate how long-term funding for the AFRC DPH program can be provided. Funding of DPHs will provide recourses to assist Reserve members having difficulty accessing care and assistance, especially in rural areas.

The Air National Guard provides the following feedback: Regarding psychological health, the National Guard Bureau has contracted to have a Director of Psychological Health (DPH) in every State and Territory. These individuals are tasked with evaluating and providing case management for National Guard service members and their loved ones, regardless of their location. Unfortunately, there is only one allotted for each State and Territory. In addition, there are efforts to implement video teleconferencing for behavioral health consultation. At present, the Air National Guard has five sites where telemental health equipment

The committee could investigate the possibility of expanding the availability of DPH's at the State and Territory level. This would help ensure that service members, especially those in geographically remote areas can have rapid and convenient

access to behavioral health care practitioners.

Question: The Center for Deployed Psychology (CDP) has an excellent curriculum to train military and civilian psychologists and other mental health professionals to provide high quality deployment related service. Do you have any thoughts on how the CDP can appeal to a larger audience, to effectively expand the number of providers that are "deployment psychology" certified? Are certain incentives to attend the training the answer?

Dr. Rice's Answer: My thoughts of how CDP can appeal to a large audience is to address the three issues that currently limit participation: (1) costs in time and dollars associated with attending the programs, (2) lack of incentives making the programs a worthwhile endeavor for providers to attend, and (3) lack of awareness of

the programs.

To address these issues, we are offering certain incentives. With regard to costs, the CDP has made efforts to defray the costs associated with attending their programs (e.g., funding TDY costs for military providers, regional distribution of 1-week courses). Additional resources (i.e., TDY funds, funding for additional civilian courses, CDP staffing) would allow for larger audiences. The CDP generally offers free or low-cost Continuing Education Credits to provide incentives for attending its courses but there is some evidence that providing additional direct incentives might not attract providers who are likely to use these skills with Service members, veterans, or their families. We are considering additional incentives that target providers likely to treat these populations, such as contract providers working on mili-

tary installations.

Ğeneral Schoomaker Answer. The Center for Deployment Psychology (CDP), a tri-Service center, was established to promote the deployment-related training of behavioral health providers in support of service members and their Families. The CDP provides education to military and civilian behavioral health providers. This two-week training takes place quarterly, and is a mandated training requirement for all student interns completing their American Psychological Association Internship at every Military Treatment Facility within the Army, Navy, and Air Force. There are several ways that the CDP can appeal to a larger audience, including retaining central travel funding for attending the two-week course and not shifting this burden to the Services. When units fund the travel, they are less likely to send personnel. Also, adding programs for mobile training at Military Treatment Facilities, as well as for additional one-week civilian courses would mean CDP trainers could reach more providers. Military Treatment Facility training may be particularly important to reach contractors who can not travel as easily as military or government service personnel. An advanced CDP training course has also been suggested specifically for providers who have already attended the two-week course and then deployed. The demand is unknown and although CDP is able to develop such

a course, funding would be needed to cover additional costs.

The Army also provides additional training to our behavioral health providers including Active and Reserves Components. All providers (e.g., psychiatrists, psychologists, social workers, psychiatric nurses, enlisted mental health specialists) are mandated to receive Combat and Operational Stress Control training prior to deploying for the first time. Desirations and the latent desirations of the providers of the stress for the first time. Providers who have not deployed within the previous 24 months are also required to attend this training, and those who are re-deploying to a dif-ferent operational site are strongly encouraged to attend. This one-week training emphasizes the most current, cutting edge information, lessons-learned from combat operations, and tools to effectively deliver behavioral healthcare downrange.

Our network providers who care for service members and families also have numerous opportunities for education and training related to deployment psychology. TriWest Healthcare Alliance offers extensive education for their network providers. At this year's annual American Psychiatric Association Meeting, a number of presentations will be delivered by military and Department of Veterans Affairs (VA) providers to help civilian psychiatrists understand deployment psychology and the needs and strengths of Soldiers and their Families. In July, the Massachusetts General Hospital Psychiatric Academy is partnering with military and VA clinicians to provide an intense course on the management of complex post traumatic stress dis-

order and traumatic brain injury.

Admiral Robinson's Answer. Since 2008 Navy Medicine has coordinated closely with Dr. David Riggs and the Center for Deployment Psychology (CDP) to develop and provide evidence-based training programs for Navy mental health providers in the treatment of Post Traumatic Stress Disorder and other combat related stress illustrated the company of the provided of Navy Military Treatment Facilities. nesses. CDP training has been provided at Navy Military Treatment Facilities, Navy Psychology Internship training programs, and Navy Medicine Deployment Health Centers, with plans to expand to our growing Social Work community.

Offering Continuing Medical Education (CME) and Continuing Education Units

(CEUs) for CDP training would increase the appeal and participation in CDP

trainings

General Green's Answer. Currently Air Force psychologists, social workers, and psychiatry residents attend the Center for Deployed Psychology (CDP) during training. Adding courses/topics specific to psychiatry (e.g. medication use in Post Traumatic Stress Disorder, medication use in theater) will increase attendance by psychiatrists. We recommend advertising this to Mental Health Nurse Practitioners. In addition, we recommend CDP reach out to State and Territorial mental health departments or private sector clinicians, identifying additional clinicians treating Guard and Reserve Airmen, who would benefit from this training. We also recommend CDP certify their online educational resources for continuing education credit hours, giving providers an incentive to complete on-line trainings. We support CDP's plan to conduct an ongoing series of workshops and seminars throughout the United States in an effort to disseminate information on deployment-related behavioral health. This is especially important for our Guard and Reserve members who may not have ready access to military or veteran's medical services.

Question. Battlefield medicine has come a long way and survival rates are the highest they have ever been, yet there is still room for improvement. During the past decade, the Army Surgeon General's office has been supportive of developing the advanced life support technology known as LSTAT, which is essentially an automated life support trauma pod. It seems like promising technology and apparently lighter versions were developed, cleared by the FDA, with requests coming in from the field for them. Can you tell me why AMEDD has not fielded the FDA approved smaller versions of the system? Furthermore, can you tell me why AMEDD has stopped development of the next generation LSTAT and why it has withheld FY2009 and FY2010 Congressional dollars from the program?

General Schoomaker's Answer. The Army Medical Department has a long-standing interest along with the other Services in a portable, interoperable, and modular life support module which allows us to transfer seriously injured and ill patients from field hospitals to medical evacuation (MEDEVAC) ambulances, helicopters, and planes and through the MEDEVAC chain from far forward to hospitals in the continental United States. We have been working with industry on this for many years including current development of lighter weight LSTATS. Existing automated life support equipment demonstrates some critical deficiencies in operational testing and does not meet all functional capability requirements. The FY2010 congressional procurement funding is being reprogrammed to be used as Research, Development, Test, and Evaluation funds to further develop and improve the equipment's capability. The FY2009 procurement funding will not be expended for several months pending the result of current development efforts. If the outcome of these efforts is acceptable, we will invite vendors to compete for the procurement solicitation to provide the best currently available products to the battlefield. We are confident that this will give us the best solution and provide the Warrior and the taxpayer the best

Question. Hyperbaric oxygen treatment appears to show some promise when it comes to the treatment of brain related injuries, burns, and certain medical conditions such as cerebral palsy and autism. Can you please describe the military's position on the viability of this treatment option and how it is being assessed? Possible Follow-up: When do you expect to see results from any studies and how quickly

could treatment options become available for the vast majority of patients?

Dr. Rice's Answer. The DoD position on the viability of the Hyperbaric oxygen (HBO<sub>2</sub>) treatment is that it has shown promise in randomized controlled trials in acute severe traumatic brain injury (TBI), and anecdotally has shown promise in case reports and case series in relief of symptoms in chronic mild TBI or concussion. The results in mild TBI are not outside the realm of a placebo response, however, and attribution of the observed improvement to the HBO<sub>2</sub> cannot be determined due to the lack of rigorous scientific design. Moreover, no data on durability of any improvement has been reported.

The viability of the treatment has been assessed by the required randomized clinical trials to generate this evidence through a program of clinical studies. Three pre-liminary randomized, double-blind, sham-controlled trials within DoD are underway or due to start shortly to look at the best doses of oxygen, sham procedures, and validation of measures to assess improvement in symptoms and objective neurologic function. To date, 34 warriors with chronic TBI have volunteered in the first trial and 25 have completed all testing. A second study is actively recruiting and a third

is due to kick off soon.

We expect to see more results from these pilot trials by early next calendar year. DoD plans for a definitive trial to kick off at that time, which will take approximately three years to complete. That study will enroll approximately 300 symptomatic warriors over two years, and follow the volunteers for the durability of any

response for at least a year.

General Schoomaker's Answer. Hyperbaric oxygen (HBO<sub>2</sub>) is approved by the FDA for 13 medical conditions, but not brain injury. HBO<sub>2</sub> has demonstrated promise in randomized controlled trials in acute severe traumatic brain injury (TBI), and anecdotally has shown promise in case reports and case series in relief of symptoms in chronic mild TBI or concussion. The results in concussion are not outside the realm of a placebo response, however, and attribution of the observed improvement to the hyperbaric oxygen cannot be determined due to the lack of rigorous scientific design. Moreover, no data on durability of any improvement has been reported. In summary, there remains no randomized controlled trial evidence to support the use of HBO<sub>2</sub> for chronic TBI, and four independent reviews have failed to endorse its

use for this purpose citing lack of strong evidence.

The DoD response has been to support and to perform the required randomized The DoD response has been to support and to perform the required randomized clinical trials (RCT) to generate this evidence through a program of clinical studies, and then allow the data to guide policy decisions. These studies are in fact the only RCTs of HBO<sub>2</sub> for chronic TBI ongoing in the United States. Furthermore, the Defense Centers of Excellence for Traumatic Brain Injury, along with the Army Medical Research and Materiel Command, has been awarded an investigational new drug application (IND) to study hyperbaric oxygen, and has established an independent data monitoring board to except the court of the data and make policy. pendent data monitoring board to review the results of the data and make policy recommendations to senior leadership. Three preliminary or phase II randomized, double blind, sham-controlled trials within DoD are underway or due to start shortly to look at the best doses of oxygen, sham procedures, and validation of measures to assess improvement in symptoms and objective neurologic function. To date, 34 warriors with chronic TBI have volunteered in the first trial and 25 have completed all testing. Two additional studies are due to kick off in the next couple months. We expect some data (~100 volunteers) from these pilot trials by early next calendar year, and DoD plans for a definitive or Phase III trial to kick off at that time, which will take approximately three years to complete.

Admiral Robinson's Answer. Navy Medicine is committed to providing all available therapies to Service Members and their families as soon as there is sufficient evidence to ensure safety and efficacy of the therapy. The Department of Defense has three trials planned or in progress (two efficacy studies, one feasibility study) to assess the effects of hyperbaric oxygen therapy on the symptoms of mild and moderate traumatic brain injury. The two efficacy studies will have data available in January 2011. The feasibility study will have data available in 2014.

General Green's Answer. At the present time, Air Force research on Hyperbaric oxygen treatment (HBOT) is centered on treatment of Traumatic Brain Injury (TBI). Although anecdotal case reports and small series of trials report benefit in TBI, it is an unproven therapy and is not accepted as a standard treatment. There are several prospective randomized clinical trials underway within the DoD and civilian in-

stitutions to provide more conclusive evidence regarding use for TBI.

There are four major prospective randomized Phase II trials underway to evaluate HBOT. The first is being conducted by the United States Air Force at United States Air Force School of Aerospace Medicine and Wilford Hall Medical Center with initial Air Force School of Aerospace Medicine and Wilford Hall Medical Center with initial results expected in August 2010. The second is being conducted jointly by Defense Advanced Research Projects Agency (DARPA), the U.S. Navy, and Virginia Commonwealth University. The third is sponsored by the Defense Centers of Excellence (DCoE) and the U.S. Army Medical Research and Material Command (USAMRMC).

And the fourth trial is sponsored by Intermountain Health Care.

The definitive phase 3 clinical trial is being sponsored by DCoE and USAMRMC which will be a randomized, multi-center (DoD facilities only), double blind, definitive clinical trial to be conducted under the auspices of the Food and Drug Administrative clinical trial to be conducted under the auspices of the Food and Drug Administrative clinical trial to be conducted under the auspices of the Food and Drug Administrative clinical trial to be conducted under the auspices of the Food and Drug Administrative clinical trial to be conducted under the auspices of the Food and Drug Administrative clinical trial to be conducted under the auspices of the Food and Drug Administrative clinical trial to be conducted under the auspices of the Food and Drug Administrative clinical trial to be conducted under the auspices of the Food and Drug Administrative clinical trial to be conducted under the auspices of the Food and Drug Administrative clinical trial to be conducted under the auspices of the Food and Drug Administrative clinical trial to be conducted under the auspices of the Food and Drug Administrative clinical trial to be conducted under the auspices of the Food and Drug Administrative clinical trial to be conducted under the auspices of the Food and Drug Administrative clinical trial trial to be conducted under the auspices of the Food and Drug Administrative clinical trial trial trial to be conducted under the auspices of the Food and Drug Administrative clinical trial tration with an Investigational new Drug registration. This study will enroll 300 participants across multiple military locations where TBI affected members reside and will use the outcome measures validated in the Phase 2 studies previously conducted. This Phase 3 trial is projected to start in the fall of 2010 under the supervision of Dr. Lindell Weaver, a critical care pulmonologist, hyperbaric physician, and Professor of Medicine at the University of Utah School of Medicine, and Director of Hyperbaric Medicine at Latter Day Saints Hospital and Intermountain Medical Center, Murray, Utah.

To ensure that the data from these trials are rapidly and independently assessed, the DCoE has chartered an independent Data Safety Monitoring Board (DSMB) that will review the results of the Phase 2 and Phase 3 trials. They will ensure the safety of the study participants and will be authorized to stop the study early if it proves

to be futile or if a conclusive benefit if found.

If HBO therapy is found to be effective in the treatment of TBI, the evidence will be presented to the Undersea and Hyperbaric Medical Society for consideration as an accepted indication for use of HBO. This phase 3 study will likely take 2–3 years

an accepted indication for use of 1150. This phase 3 study will likely take 2–3 years to get results.

Question. For Admiral Robinson: In your written testimony, you mention the humanitarian missions the Navy is involved in as a "Force for Good." You specifically mentioned Haiti and the roles the USNS Comfort and Mercy have played in that tragedy and elsewhere. Such expeditionary medical capabilities seem invaluable to me, both from a humanitarian standpoint and a diplomatic one. Please tell me what long term role you see in the Navy for ships like the Mercy and Comfort. Possible Follow-up: For the other services, how do you view your expeditionary medical capabilities? Is the humanitarian assistance mission an important one?

Answer:

CNO's Sea Basing concept requires robust medical capability afloat to support the Chief of Naval Operations Maritime Strategy: A Cooperative Strategy for 21st Cen-

Both T-AHs (hospital ships) are assigned forces in DOD Forces for Unified Commands supporting their operational capability.

• Through Disaster Response and Humanitarian and Civic Assistance missions, Theater Security Cooperation is achieved with international military partners, Non-Governmental Organizations and academic institutions.

The T-AH, as a national asset, provides a unique image of national resolve in

the forward presence sea-basing strategy.
USNS MERCY (T-AH 19) and USNS COMFORT (T-AH 20) continue to provide now, and in the future, a unique and flexible capacity with up to 12 operating rooms and associated medical support. This capability of the hospital ships includes 80 beds for intensive care (including 11 isolation beds), 20 beds for recovery, 440 beds for intermediate care, and 440 beds for minimal care which allows them to treat a wide range of patients in partnership with the international community. Alliance with non-governmental organizations enhances capacity and enduring support in remote areas.

The hospital ships serve as cornerstones for Shaping and Stability operations which help to address many of the root causes of conflict. To be effective in Overseas Contingency Operations, our Combatant Commanders need tools that are not only instruments of war, but implements of stability, security and reconstruction. Operating from the sea-base, the hospital ships provide a highly visible, positive, engaged, and reassuring presence when deployed for Theater Security Cooperation or when called to respond to foreign humanitarian assistance (FHA) or Defense Support of Civil Authorities (DSCA) missions. The hospital ships are part of the Navy's

proactive influence plans and partnerships-for-peace missions.

The two hospital ships (USNS MERCY and USNS COMFORT) have a life expectancy to approximately 2020/21. Alterations to extend their service life beyond 2020, and to enhance their ship-to-shore patient transfer capabilities for shallow water coastal regions (such as larger, higher capacity, faster, and more seaworthy boats), may be considered. It is conceivable, subject to life extension studies being accomplished, that these ships might be capable of a life extension approaching 2030. Currently, there is no recapitalization plan for hospital ships, but possible smaller, more flexible alternative platforms are being examined. Continued studies are needed to define future capabilities for wartime and peacetime support and to develop an assessment of more effective, less costly, methods of providing health services support from the sea-base. Examining alternatives of sea-to-shore health services capabilities would expand the flexibility to meet a range of future missions with more agil-

ity.

The hospital ships of the past, present, and the next generation ships, have a strong role in fostering the good will stemming from the contributions of our governments are mosting the humanitarian needs of the people from other ment and citizens towards meeting the humanitarian needs of the people from other nations, and of our own nation. While serving with an enormous medical benefit to the contingency purposes of our own country in times of war and disaster response, recent missions have won the hearts of countless people, not only from those who serve on them, both military and civilian, foreign and domestic, but also with the hearts and minds of those who received care and support from those "big white American ships with the red crosses on them." Humanitarian missions are very important, and the future generation of T-AH hospital ships will remain a central con-

tributor to that civic duty of our country.

General Schoomaker's Answer. I see humanitarian assistance and foreign disaster response missions as extremely important. The Army Medical Department has incredibly diverse and robust capabilities, both in our operating force forward deployed, and in our generating force here at home. We have statutory authority under Title 10 (U.S. Code, Section 401) to support a variety of peacetime engagement projects, of which humanitarian assistance missions are a subset, principally as training missions for our forces. In addition to the training benefits, we involve our forces in humanitarian activities for several other reasons, including, of course, the moral humanitarian imperative, but also because the Army has unique capabilities, we can foster goodwill through nonthreatening engagement with foreign governments, and because there are positive public affairs outcomes that influence recruiting. Few organizations outside of the military have the capacity to move materiel, establish secure routes for aid delivery, develop command and control mechanisms, and provide direct assistance at the levels often required especially in disasters such as the earthquake in Haiti. Humanitarian operations benefit the American political process by showing other countries the diverse American population working together to achieve common goals and thus improving global public relations.

The deployment of military forces to assist with a foreign disaster is a very visible

show of support for the affected government and people. It also helps develop skills in our forces that are necessary for successful civil-military operations. The knowledge of, and relationships with, civil authorities' and non-governmental response organizations' processes, needs, goals, and constraints foster increased capabilities within the Army medical force to respond within the context of the Combatant Commander's theater engagement plans and within the scope of our federal responses to disasters within the United States. For these reasons, the Army Medical Department will continue to evolve our organizations, training, and equipment to ensure we can provide world class health care, any time, any place to meet our missions. We have to be able to apply the right mix of medical and public health expertise, knowledge and experience in civil military engagements, and cultural intelligence to successfully support the United States' expeditionary medical missions anywhere

on the globe.

Army medical forces provided support in the aftermath of Hurricanes Andrew in 1992, Mitch in 1998 and Katrina in 2005. With each of these opportunities to support our own citizens, we have evolved our processes and procedures to improve our response capabilities. Similarly, Army medical units were called on to provide disaster response medical support to earthquakes in Pakistan in 2006, and to both Haiti and Chile in 2010. The Army Medical Department is regularly engaged in Medical Readiness Training Exercises (MEDRETES) and Medical Civil Action Programs in support of the Combatant Commanders providing disease surveillance, remote clinical support and medical, veterinary and dental training. The Army Medical Department is presently involved in a MEDRETE in Honduras and is preparing for two additional exercises, one in the Dominican Republic and one in Paraguay. We have gained from our experiences some key insights about the value of these programs. We are extremely aware that creating false expectations in a foreign country is sometimes as detrimental as doing nothing. That insight led us to the awareness that building or fostering capabilities as well as capacity creates better long term impacts. By training the host country's providers, we enable them to continue programs and build medical capacity long after the Army departs.

Finally, in alignment with this goal of building host nation capacity to improve health and provide healthcare to their citizens, the Army Medical Command

health and provide healthcare to their citizens, the Army Medical Command through its subordinate Medical Research and Materiel Command has several pivotal foreign medical research laboratories—one in Germany, one in Kenya, and one in Thailand. These, in parallel with the Naval Medical Research Units in Indonesia, Egypt, and Peru, represent "intellectual power projection platforms" which foster host nation capacity and Combatant Command-centered theater health engagement.

The laboratory in Thailand (the Armed Forces Research Institute of Medical Sciences, AFRIMS), working with the U.S. National Institute of Allergy and Infectious Disease and Thai government health officials recently completed an important HIV vaccine clinical trial that for the first time demonstrated modest protection against HIV infection. In the past, AFRIMS has helped develop—in partnership with host nation scientists and health officials—vaccines protective against hepatitis A and Japanese Encephalitis 2 in Thailand; rapid diagnostic tests for malaria; work on plague in Vietnam; and other related health initiatives in the Pacific Command area of responsibility.

The Kenya laboratory (US Army Research Unit—Kenya, USAMRU–K) has done similar work with the Kenyans on malaria, leishmania, HIV, and trypanosomiasis (African sleeping sickness) and is a pivotal African regional asset for implementation of the President's Emergency Plan For Aids Relief. Further, in partnership with the President's Malaria Initiative, USAMRU–K has developed a regional center for the training of African laboratory technicians in the proper diagnosis of malaria.

General Green's Answer. Absolutely! The Air Force Medical System (AFMS) pro-

vides a Total Force contingency response capability, leveraging both our Active and Reserve (Air Reserve and Air National Guard) Components, to deliver world-class patient care on the ground and in the air. We are light, lean and are designed to move quickly to wherever needed. Our Expeditionary Medical System (EMEDS) is a time-tested and proven medical capability around which the AFMS has built its deployed operations over the past decade. It is extremely adaptive across all mission areas to include combat operations, homeland response, and humanitarian disaster relief. When linked with our highly developed patient movement system to include Critical Care Air Transport Teams (CCATT's), we are able to stabilize and move even the most critical patients within hours of injury to the highest levels of care anywhere in the world, truly a good news story for our Wounded Warriors. This 'system' of care is fast becoming the system of choice in responding to contingencies. A recent demonstration of the EMEDS success was in support of United States response to the 8.8 Chile earthquake. The United States Agency for International Development (USAID) specifically requested the EMEDS in their efforts to restore medical care and provide a temporary medical facility to the city of Angol. Within 72 hours of notification, we deployed 84 medical personnel and 67 tons of cargo to Chile and within 48 hours of hitting the ground our facility was fully a particular. Chile and within 48 hours of hitting the ground, our facility was fully operational. Over the course of the next 14 days our Air Force medics treated 276 patients, performed 38 surgeries, and integrated/transitioned the facility over to the local healthcare providers. The entire operation was well received, praised by both the Mayor of Angol and the U.S. Ambassador. We continue to perfect this expeditionary medical capability to solidify the EMEDS as the system of choice. Although the AFMS provides a vital niche capability to deploy rapidly with small modular personnel teams and equipment packages tailored to specific mission requirements, we recognize that we are still part of a much larger medical response effort that includes not only our sister Services, other U.S. governmental agencies, and coalition partners, but also a host of nongovernmental agencies specializing in providing support. Our humanitarian mission is an important one, as non-kinetic 'soft power' in the DoD arsenal to win today's fight, and through partnership and partnership capacity building to enhance stability and cooperation around the globe. In conclusion, the AFMS, as always, stands ready, willing, and able to respond to our nation's call, wherever that may be.

Question. For General Schoomaker: I enjoyed reading your written testimony about the improvements the Army has made with its Warrior Transition Units and ensuring that our wounded warriors are being properly cared for throughout the entire process. The Comprehensive Transition Plan seems like a good idea and the Army Wounded Warrior (AW2) advocates also appear to be a prudent step in giving individual attention when it comes to navigating the many decisions that need to be made by our wounded warriors. Are those advocate positions adequately manned and are there enough on hand now? Are there corresponding advocates in the VA if someone is transitioned into that system? Possible Follow-up for all services: How

effective is the transition today from DoD to VA?

Answer. Army Wounded Warrior (AW2) has 150 Advocates located at major Military Treatment Facilities (MTFs), Army Installations Warrior Transition Units (WTUs), and Department of Veterans Affairs Medical Centers (VAMCs) throughout the Continental United States, Alaska, Hawaii, 4 U.S. Territories and Germany. The current ratio of AW2 Soldiers and Veterans to Advocates is appropriately 45:1. The AW2 program has undertaken various innovative and cutting edge business protocols in an effort to continue providing its renowned first rate customer support and assistance to both the Service members and their Families. Over the past few months, the AW2 leadership has conducted a comprehensive assessment and has implemented a thorough growth management initiative that will ensure that every assigned Soldier and their Family members are adequately supported within the assigned Soldier and their Family members are adequately supported within the provisions of the AW2 program. The AW2 program is expanding its core of government personnel, who are augmented by a robust and flexible contract support vehicle. In addition to this initiative, the AW2 program has developed and is in the process of field testing new methodologies and processes for assessing, defining and managing assigned Soldiers under the Lifecycle Management Program (LCMP). LCMP allows Advocates, with the concurrence of assigned Soldiers, to more effective to the concurrence of assigned Soldiers, to more effective to the concurrence of assigned Soldiers. tively provide assistance and support based on the needs and desires of the Wounded Warriors. The general premise is—as Soldiers and Families progress back to advanced levels of independence, the frequency of Advocate interactions and involvement can be tailored to meet the needs of our Soldiers and Families. This initiative has the benefit of providing AW2 with a resource tool to measure and develop a more efficient Wounded Warrior to Advocate ratio.

more efficient wounded Warrior to Advocate ratio.

The Army and the VA have made great strides in the development and integration of sound collaborative efforts in the realm of jointly managing, supporting and assisting our severely injured and ill Wounded Warriors. The Army currently has Advocates positioned in 75 VA facilities (VAMCs or Community Based Outpatient Clinics—(CBOCs)). This relationship, like other VA/DoD joint ventures in the area of support services to Wounded Warriors, is on the increase. By the end of this fiscal local control of the strip of the of th year, it is anticipated that this collaborative effort will witness the growth of approximately 15 new Advocates sharing and supporting dually-eligible beneficiaries from VA locations. The Army and the VA will continue to reach out to each other to explore all available options that are likely to enhance our mutual support to

Wounded Warriors and their Families.

The Army and the VA have integrated several procedures to ensure Soldiers and their Families have a successful transition. Since FY2008, both organizations use Senior Advisors to ensure coordination and open communication between departments. There are 27 VA liaisons (Social Workers) currently assigned to 15 military treatment facilities to coordinate the transition of Warriors in Transition (WTs) to VA medical facilities and VA polytrauma centers. VA liaisons register and enroll service members into the VA healthcare system, coordinate care with VA program managers, coordinate with the Veterans Benefits Administration (VBA) staff to provide Soldiers with benefit information, integrate with Army staff at MTFs, and edu-

rate veterans, service members and Families about VA benefits.

To ensure severely wounded Soldiers have a plan covering all clinical and non-clinical issues, the VA has assigned 20 Federal Recovery Coordinators to major MTFs. The VA has also assigned VBA advisors (currently there are 58 VBA Military Service Coordinators assigned to WTUs and their supporting Soldier Family Assistance Centers) to educate wounded Soldiers and their Families about VA benefits and claims processing at all WTUs. VBA and Veterans Health Administration (VHA) personnel support the nine Community-Based WTUs in the same manner. There currently are 37 Vocational Rehabilitation and Employment (VR&E) counselors assigned to WTUs who provide employment, career and educational counseling to Soldiers separating from Active Duty. VBA and VHA personnel are learning about the Army's Comprehensive Transition Plan (CTP) and how the plan supports WTs. Both VR&E counselors and VA liaisons will use the CTP to better understand Soldiers and their Families.

The VA is assigning clinical and non-clinical personnel to support the ongoing Disability Evaluation System pilot at many major MTFs. At most Army installations, the VA has established "Benefits Delivery at Discharge" (BDD) sites to support the VA claims process, ensuring all Soldiers submit any necessary claims before discharge. By doing this, Soldiers can track the processing of their VA claim, and the VBA can start processing the claim before separation. In addition to the BDD sites, VA healthcare enrollment is supported at the 12 Army demobilization sites ensuring

all Army Reserve and Army National Guard Soldiers are enrolled in VA healthcare and understand VA benefit programs. Lastly, the VA is part of a team that supports the Army Career and Alumi Program (ACAP), providing a detailed benefits briefing under the Transition Assistance Program. ACAP has been a successful program in 1991 and the program of the program was to be program. since 1991, and continues to be one of the main ways to provide VA benefits to all

Soldiers separating from the Army.

Admiral Robinson's Answer. The Departments of Defense (DoD) and Veterans Affairs (VA) work in a close and unified effort in support of Wounded Warriors. Transition support within the Navy consists of medical care case managers and non-medical care managers working collaboratively and with Recovery Care Coordinators (RCC) and VA Federal Recovery Coordinators and Case Managers. This close cooperation ensures a smooth and seamless handoff of each patient's recovery needs as a member transitions between DoD care locations, or from DoD to the VA and/ or into the civilian sector.

In support of this process, Navy Medicine has increased medical care case managers to over 190 individuals and tracks acuity to ensure that adequate staffing is available to meet the case management needs of our Wounded Warrior and beneficiary population. All Navy Medicine medical care case managers receive training on Post Traumatic Stress Disorder (PTSD), Traumatic Brain Injury (TBI) and other combat-related conditions/injuries. Navy Military Treatment Facilities and VA Poly Trauma Facilities hold multidisciplinary clinical case video teleconferences to discuss patient transition and care needs and to provide follow up information on previously transferred patients.

Navy Safe Harbor has increased to 19 the number of non-medical care manager positions across a nation-wide network to facilitate close coordination during transition. Safe Harbor has also implemented the Anchor Program, assigning a Navy Reserve volunteer "near peer" mentor and senior mentor from community-based organizations such as the Navy League, Fleet Reserve Association, American Legion, Retired Affairs organizations and others, to support individual Sailors and their family members as they relocate to communities across the country. Safe Harbor non-medical care managers receive training on psychological health and traumatic brain in-

jury as part of annual programmed training plans.
General Green's Answer. The Air Force Medical Service is committed to ensuring that our wounded, ill, and injured Airmen are provided effective and efficient transition from the military to the Department of Veterans Affairs (VA). There are multiple initiatives aimed at streamlining and standardizing a service member's transitions. tion from DoD to VA. The Air Force created the Warrior and Survivor Care office (AF/1) to oversee the Air Force Survivor Assistance Program, the Air Force Recovery Coordination Program, and the Air Force Wounded Warrior program, to ensure continual contact with the wounded, ill or injured Airman and his or her family throughout the entire recovery, rehabilitation, and reintegration process. These ef forts have resulted in significant improvements in the transition process from DoD

The following are examples of DoD/VA programs and working groups to further enhance transitions and simplify processes for our warriors:

The DES Pilot

The Benefits Delivery and Discharge

The Quick Start

The Benefits Executive Council

The Pre-Discharge Working
The Disability Evaluation System Working The DoD/VA Benefits Communication Working

The Medical Records Working

The Information Sharing/Information Technology Working

The AF Survivor Assistance Program (AFSAP)

The Recovery Coordination Program
The Air Force Wounded Warrior Program

[CLERK'S NOTE.—End of questions submitted by Mr. Young. Questions submitted by Mr. Moran and the answers thereto fol-

Question. Over the past several years there has been an increasing burden on the civilian health care community to provide services to active duty members, their dependents and retirees that had previously been provided by military treatment facilities. For example, Ft Eustis, in my state of Virginia, recently closed its post hospital and now buses soldiers daily to the nearby Mary Immaculate Hospital Emergency Room to receive care. Because Tricare reimbursement rates to civilian hos-

pitals are often below the actual cost of care, these hospitals are incurring financial losses. Four areas in particular suffer the most due to a high concentration of military servicemembers: Hampton Roads, Virginia, Killeen, Texas, Colorado Springs, CO and the area surrounding Fr. Carson.

Is the Department exploring alternative reimbursement solutions to hospitals that serve a high-volume of TRICARE enrollees?

Answer. The Department is not exploring alternative reimbursement solutions to hospitals that serve a high-volume of TRICARE enrollees beyond what is already available through regulations and policy. After reviewing regulations and policies governing the TRICARE Outpatient Prospective Payment System (OPPS), we have found that the General Temporary Military Contingency Payment Adjustments (TMCPA) adequately reimburse hospitals that serve a high volume of TRICARE beneficiaries.

# [CLERK'S NOTE.—End of questions submitted by Mr. Moran. Questions submitted by Mr. Dicks and the answers thereto follow:

Question. Dr. Rice, you testified before HASC that DOD is facing a significant nurse shortage. 2010 NDAA included language (Section 525) authorizing OSD to take the lead on the establishment of an undergraduate nurse training program, and directed the Secretary to report to Congress within 180 days of passage on the plan for implementation of the program. Dr. Rice, can you talk about how you envision that program coming to fruition, and the status of the report to Congress? Do you intend to take an active role in the development of the undergraduate nursing program considering it is an OSD directive or defer it to the Services? If so, why do believe that is the appropriate course of action considering the clear congressional intent provided in Section 525?

Answer. The way I envision this program is OSD and the Services collaborating to meet our need for nurses while ensuring that we are mindful of how we are using our resources. We should also ensure that establishment of this program does not adversely affect existing Service nursing accession programs (such as ROTC and enlisted to nurse educational programs) and that the Services address this new accession source in the context of their personnel management systems. The final report to Congress, with formal Service coordination, will be submitted by July 2010.

Yes, I intend to take an active role in developing an undergraduate nursing program. For that reason, we have developed plans to establish a Tri-Service Academic Nursing Partnership program, which will meet the intent of the National Defense Authorization Act for Fiscal Year 2010, Section 525, to expand training programs aimed at increasing the number of nurses serving in the Armed Forces. We plan to establish partnerships with accredited schools of nursing near our largest military installations. The Department's Office of the Assistant Secretary of Defense for Health Affairs will have program oversight for the development of consolidated budget and reporting requirements. However, the operational aspects required to implement and maintain this program will be at the Service level.

We believe this is the most appropriate course of action because it will best sup-

port existing unique Service nursing accession programs and integration with exist-

ing personnel management programs.

[CLERK'S NOTE.—End of questions submitted by Mr. Dicks.]

## MISSILE DEFENSE AGENCY

#### WITNESS

# LIEUTENANT GENERAL PATRICK J. O'REILLY, USA DIRECTOR, DEFENSE MISSILE AGENCY

OPENING STATEMENT OF CHAIRMAN DICKS

Chairman DICKS. The committee will come to order, Mr. Young has a motion.

Mr. Young. Mr. Chairman, I move that those portions of the hearing today, which involve classified material, be held in executive session because of the classification of the material to be discussed.

Chairman DICKS. All those in favor of the motion say aye.

Opposed, no.

The ayes have it and the hearing is closed.

The committee will come to order. Today the Defense Appropriations Subcommittee will receive testimony from Lieutenant General Patrick J. O'Reilly, Director of the Missile Defense Agency. Fiscal year 2010 was a year of significant transition and high operational tempo for the Ballistic Missile Defense program, and MDA participated in several warfighter activities in support of real-world events, tested new capabilities, and delivered hardware and software to the warfighter in defense of the Nation.

MDA also restructured the test program and subsequently developed an Integrated Master Test Plan. The Agency supported the administration's development of the Phased Adaptive Approach, formerly European capability, that can be used for defense of deployed U.S. forces, friends, new allies and allies in Europe.

The fiscal year 2011 President's budget request reflects significant new policies and initiatives in homeland and regional defense, enhanced testing, and technology development to adapt and re-

spond to future threats.

Restructuring of the Missile Defense Agency's test program and plan was a significant accomplishment in fiscal year 2010. MDA worked with the services, operational test agencies, and the warfighter, represented by the Joint Forces Component Command for Integrated Missile Defense, with the support of the Director of Operational Test and Evaluation.

MDA transitioned to test objectives to verify, validate, and accredit BMDS models in simulations and collected data to determine operational effectiveness, suitability and survivability of programs. The Integrated Master Test Plan, which extended through fiscal year 2015, focuses on proving system capabilities through the collection of identified flight test data to ensure adequate test invest-

ments and a solid foundation to anchor BMDS models and simulations.

We look forward to your testimony and a very spirited and in-

formative question and answer.

Now, before I go to Mr. Young, I just want to say that I had a chance to meet with General O'Reilly and a program that our committee has been strongly supportive of, the airborne laser, has had some very successful tests, and I think is really—we really moved forward dramatically, and we are going to have a demonstration after the General makes his statement of this so that the committee members and staff can see it.

But first I want to turn to Mr. Young, the ranking member, and

our former chairman. Mr. Young.

## OPENING STATEMENT OF MR. YOUNG

Mr. Young. Mr. Chairman, thank you very much. And I want to add my welcome to yours, to our distinguished guest, General O'Reilly.

Protecting our Nation, including our troops abroad and our interests abroad, is an extremely important job, especially as rogue nations and other less-than-friendly nations develop more and more ability to attack with their missiles. We spent a lot of money on the Missile Defense Program over the years; most of the money well spent, I hope, but that can only be determined by testing.

Sometimes the committee has taken a few raps because we have supported programs that maybe weren't quite as effective as they should have been, but we are prepared to do that. We just cannot overemphasize the importance of our missile defense to our Nation.

General, your fiscal year 2011 budget builds upon your last year's transition and I commend you for some significant accomplishes. I do remain concerned, however, about our test and targets program. Continued test schedule delays or test failures due to target malfunctions only make your job and our job a little more difficult.

But as Chairman Dicks stated, you and I had an opportunity to meet at length earlier yesterday, and I found that meeting extremely interesting, and look forward to your testimony today. Again, welcome.

Chairman DICKS. General, why don't we go ahead with your statement and then we will take a look at the airborne laser tape.

# SUMMARY STATEMENT OF GENERAL O'REILLY

General O'REILLY. Good morning, Chairman Dicks, Congressman Young and other distinguished members of the committee. It is an honor to testify before you today on the Missile Defense Agency's activities to continue developing and fielding an integrated, layered, Ballistic Missile Defense System to defend the United States, its deployed forces, allies and friends.

Under the oversight and direction of the Department of Defense's Missile Defense Executive Board, the Missile Defense Agency proposes an \$8.4 billion fiscal year 2011 program that is balanced to achieve the six policy goals of the Ballistic Missile Defense Review report and the combatant commanders' and the services' missile de-

fense needs as stated in the latest U.S. Strategic Command's

prioritized capabilities list.

First, defense of the homeland against limited missile attack. The Ground-based Midcourse Defense system, or GMD, will continue to be our primary defense against raids of Intercontinental Ballistic Missiles, or ICBMs, from regional threats for the next decade and beyond. The missile fields in Alaska and California are in an optimum location to intercept missiles from either Northeast Asia or the Middle East. We continue to upgrade GMD to increase its reliability, survivability and ability to leverage a new generation of missile defense sensors. We also continue more expansive testing of GMD to accredit our simulations.

The purchase of five additional Ground-based Interceptors, or GBIs, and the production of components to support extensive reliability testing and missile refurbishment, will sustain our GBI production capability until 2016, and our critical component manufacturing beyond 2020.——

Additionally, the previous European Missile Defense program did not cover most of Southeastern Europe, which is exposed to today's ballistic missile threats. It would not have been available till 2017 and was not adaptable to changes in future missile threats to Eu-

rope.

Therefore, instead of the previous program, we plan to deploy a larger number of SM-3 interceptors in Europe over the next decade, in four phases, as the missile threats from the Middle East evolve. The first two phases, in 2011 and 2015 respectively, provide protection against short- and medium-range ballistic missiles. The third phase in 2018 provides protection against intermediate-range ballistic missiles. And the fourth phase in 2020 provides capability to intercept ICMBs from the region in which they are launched.

Third, prove the Ballistic Missile Defense System works. We have submitted a comprehensive Integrated Master Test Plan, signed by the Director of Operational Test and Evaluation, to service the operational test agencies and the Commander, U.S. Strategic Command, to ensure we comprehensively test our missiles be-

fore we buy them.

The two greatest challenges we face in developing missile defense is acquiring cost-effective, reliable targets and improving quality control in all products. Over the past year, we have initiated a new target acquisition strategy to increase competition, improve quality control, reduce costs and provide backup targets starting in 2012.

However, the precise performance of Missile Defense Systems requires stringent manufacturing standards. Until we complete planned competitions, including the greater use of firm fixed-price contracts and defect clauses, we have to motivate some senior industry management through intensive inspections, low award fees, issuing cure notices, stopping the funding of new-contract scope and documenting inadequate quality control to influence future contract awards.

Fourth, hedging against the threat uncertainty. Due to the uncertainty in the intelligence estimates of a potential North Korean or Iranian ICBM threat over the next decade, we are augmenting our current capability today to destroy 8 to 15 simultaneously launched ICMBs using our 30 GBIs in Alaska and California, with

8 additional silos. We are also completing the development of a two-stage GBI which adds several minutes to our battle space.

Additionally, in accordance with the warfighters' priorities, we are focusing our future technologies to develop more accurate and faster tracking sensors on forward-deployed platforms to enable early intercepts, to enhance command and control networks, to rapidly fuse sensor data, to handle large-scale missile attacks, to develop a more agile SM-3 interceptor to destroy long-range missiles, to enhance the discrimination of reentry vehicles from other objects, and to develop a high-energy laser technology to destroy missiles while they are boosting at great ranges.

Fifth, develop new fiscally sustainable capabilities over the long term. The Missile Defense Agency is complying with the Weapons Systems Acquisition Reform Act by establishing and managing six baselines—costs, schedule, technical, tests, contract and operational baselines—increasing service in COCOM participation and increasing emphasis on competition in all phases of a program's acquisition life cycle. We are reviewing over \$37 billion in contracts

for competition over the next 2 years.

Six, expand international missile defense cooperation. We are currently engaged in missile defense projects, studies and analysis in many countries, including Japan, Poland, the Czech Republic, Israel, Australia, the United Kingdom, Germany, South Korea, United Arab Emirates, Bahrain, Saudi Arabia, Kuwait and NATO. Additionally, Poland and Romania have agreed to host our Aegis ashore sites, and we are cooperatively developing the SM–3 2A interceptor with Japan. We also continue to support expert dialogue on cooperative efforts with the Russian Federation.

Relative to the recently expired START treaty, the new START treaty actually reduces constraints on the development of missile defenses. For example, our targets are no longer subject to START constraints, which previously limited our use of air-to-surface and waterborne launches of targets. The new START treaty also does not constrain our plans to employ ballistic missile defenses. The treaty prohibits the conversion of ICBM silos to new missile defense silos.

However, if more silos are needed in the future, they would be less expensive and more reliable if we built new silos—which are not prohibited from the treaty—than converting existing ICBM silos.

In conclusion, MDA has teamed with the combatant commanders, services, other DOD agencies, academia, industry and other international partners to address the challenges of managing, developing, testing and fielding capabilities to deter the use of ballistic missiles and effectively destroy them, once launched.

Thank you, Mr. Chairman, I look forward to answering the committee's questions.

[The statement of General O'Reilly follows:]

## **Unclassified Statement of**

# Lieutenant General Patrick J. O'Reilly, USA Director, Missile Defense Agency

Before the

# **House Appropriations Committee**

**Defense Subcommittee** 

Regarding the

Fiscal Year 2011 Budget Request Ballistic Missile Defense Programs

Wednesday, May 5, 2010

Embargoed Until Released by the Appropriations Committee United States House of Representatives Lieutenant General Patrick J. O'Reilly, USA
Director, Missile Defense Agency
Before the
House Appropriations Committee
Subcommittee on Defense
May 5, 2010

Good morning, Chairman Dicks, Mr. Young, other distinguished Members of the Committee. It is an honor to testify before you today on the Missile Defense Agency's support to the Ballistic Missile Defense Review (BMDR) and our \$8.4 billion Fiscal Year (FY) 2011 budget request to continue our mission to develop and field an integrated, layered, Ballistic Missile Defense System (BMDS) to defend the United States, its deployed forces, allies, and friends against ballistic missiles of all ranges and in all phases of flight. This budget request reflects the strategy and policy stated in the BMDR report and the prioritized missile defense needs of our Combatant Commanders and the Services as stated in the latest US Strategic Command's (USSTRATCOM) Prioritized Capabilities List (PCL).

The Missile Defense Agency has been operating in accordance with the principles outlined in last year's Weapons System Acquisition Reform Act. This includes establishment of formal baselines for the system component managers, Service participation through the USSTRATCOM-led Warfighter Involvement Process, and increased emphasis on competition at all phases of a program's acquisition life cycle. All of these steps, I believe, will maximize the return on the taxpayer's investment dollar.

Under the oversight and direction of the Missile Defense Executive Board (MDEB), chaired by the Under Secretary of Defense for Acquisition, Technology and

Logistics (AT&L), MDA proposes a FY 2011 program that is balanced to achieve the six strategy and policy goals documented in the BMDR report:

- · Defend the homeland against a limited ballistic missile attack
- Defend U.S. forces, allies, and partners against regional threats
- Deploy new systems only after effectiveness and reliability have been determined through testing under realistic conditions
- · Develop new capabilities that are fiscally sustainable over the long term
- Develop flexible capabilities that can be adapted as threats change
- · Expand international cooperation

## Defense of the Homeland against Limited Attack

The Ground-based Midcourse Defense (GMD) system forms the foundation of our homeland missile defense against limited ICBM attack today. We continue to upgrade GMD to increase reliability and survivability and expand the ability to leverage new BMDS sensors as well as test GMD to accredit our simulations. Since the beginning of FY 2009, MDA has delivered five new GBIs, upgraded Fire Control and Command Launch Equipment software, completed construction of a second GBI missile field at Fort Greely, AK, and delivered a new silo and an additional In-Flight Interceptor Communication System Data Terminal at Vandenberg Air Force Base, CA. Additionally, we are completing the missile defense upgrades to the Upgraded Early Warning Radar (UEWR) in Thule, Greenland, and we have transferred operation of the Cobra Dane Early Warning Radar and the Beale and Fylingdales UEWRs to the Air Force. We are continuing planning and design work to upgrade the Clear, AK Early Warning Radar.

We are requesting \$1.3B in FY 2011 for GMD to continue our GBI refurbishment and reliability sustainment programs to: help sustain the fleet to 2032 and support a

service life extension decision around 2027; procure an additional 5 GBIs; complete Missile Field 2 in a 14-silo configuration to accommodate a contingency deployment of eight additional GBIs; upgrade GMD Fire Control ground system software to ensure GMD leverages BMDS increased discrimination and tracking capability as sensor, data fusion and battle management network matures; and complete the installation of a second GMD command and control node at Fort Greely, AK. Additionally, we will continue operations and sustainment of the Sea-Based X-band radar (SBX) platform to prepare for transfer of the SBX operations to the U.S. Navy in 2012. Finally, we will continue development of technologies to enhance Standard Missile 3 (SM-3) variants to protect our homeland in the future by having the capability to intercept long-range ballistic missiles early in flight in the regions from which they were launched. To validate this concept, the Under Secretary of Defense (AT&L) requested the Defense Science Board independently assess the viability of developing capability for early intercept of ICBMs. Our GMD sustainment, refurbishment and test strategy gives us the flexibility to adjust to the uncertainty in the future ICBM threat. Although, we experienced a GBI vendor production break after the last procurement of GBIs in 2006, the purchase of 5 additional GBIs, and supplying "limited life" GBI components for refurbishments will sustain our production capacity until 2016 and beyond. We will conduct stockpile surveillance of GBIs by testing all limited life components as GBIs are refurbished through 2032. Data collected from future GMD flight tests, results from the aging surveillance program, and future intelligence estimates regarding the pace of ICBM growth will inform decisions on the need to procure additional GBIs.

## **Defense against Regional Threats**

Our FY 2011 budget request balances the war fighter's needs to develop new capabilities and grow our missile defense capacity. An integrated deployment of Aegis BMD and Terminal High Altitude Area Defense (THAAD) forms an effective, layered, regional missile defense. The Aegis BMD is a mobile system, designed to defeat short-to intermediate-range missiles above the earth's atmosphere, and the THAAD is a rapidly deployable system, designed to engage short- to medium-range missiles both above and within the Earth's atmosphere. Aegis has more than twice the engagement range of THAAD. Additionally, Patriot Advanced Capability 3 can add an additional layer and point defense against Short Range Ballistic Missiles (SRBMs).

We are developing regional missile defense elements that can be adapted to the unique circumstances of each Combatant Command region. For example, we plan to deploy missile defenses in Europe in four phases as missile threats from the Middle East evolve over time. The Phase 1 capability (planned to begin deployment in 2011) will provide initial protection for southern Europe from existing short- and medium-range threats using sea-based interceptors and forward-based sensors. Phase 2 (~2015) deploys the SM-3 IB interceptor at sea and at an Aegis Ashore/land-based SM-3 site. In collaboration with OSD Policy, USSTRATCOM, the Department of State, and United States European Command (USEUCOM), we are preparing to begin negotiations with Romania to locate an Aegis Ashore/land-based SM-3 site on its territory in 2015. Phase 3 (~2018) employs SM-3 IIA on land and at sea to protect NATO from SRBM, MRBM, and IRBM threats. Poland has agreed to host this Aegis Ashore/land-based SM-3 site.

SM-3 IIB, a persistent sensor network, and enhanced command and control system to intercept large raids of medium- to long-range missiles from the Middle East early in flight.

Since the beginning of FY 2009, MDA has delivered 27 SM-3 Block IA interceptors and upgraded 3 additional ships (for a total today of 20 Aegis BMD ships); upgraded the USS Lake Erie with the next generation BMD fire control software that increases the number of threat missiles that can be simultaneously engaged and more effectively uses data from missile defense sensors external to the ship. We have also delivered two THAAD batteries (the first unit is planned to be operationally accepted by the Army by the end of this year). We have separately deployed one U.S.-operated X-band AN/TPY-2 radar to Israel on a contingency basis. We have also installed C2BMC hardware and software upgrades at command and control nodes at U.S. Pacific Command, USSTRATCOM, U.S. Northern Command and USEUCOM and began C2BMC installation in the U.S. Central Command.

We are requesting \$1.6B for Aegis in FY 2011. We will continue the design, qualification, and testing of the SM-3 IB interceptor; manufacture 30 SM-3 IB test and production verification interceptors (we plan to procure a total of 436 Aegis SM-3 IA and IB interceptors by 2015), and upgrade 3 additional Aegis BMD engagement ships (two Aegis BMD 3.6.1 destroyers and one 4.0.1 destroyer) for a total of 23 BMD capable ships by the end of FY2011 and 38 BMD capable ships by 2015. We will continue development and testing of the Aegis BMD 4.0.1 and 5.0 fire control system to launch SM-3 IB and IA interceptors against threat missiles when they are beyond the range of the ship's own radar. We also will continue the co-development of the SM-3 IIA

interceptor with the Government of Japan to increase significantly the area defended by the Aegis BMD system with its 21-inch diameter rocket motors, two-color seeker, and increased kinetic warhead divert capability. We also will continue to design the first Aegis Ashore battery that will be installed for testing at the Pacific Missile Range Facility in 2012.

We are requesting \$1.3B for THAAD in FY 2011. We plan to deliver the second THAAD battery (we plan to procure 6 batteries by 2015), add a second launcher platoon to each battery to double the firepower to 48 interceptors, procure 67 interceptors (we plan to procure a total of 431 interceptors by 2015), and complete hardware and software upgrades to the communications suite to enable THAAD to use fused data from all BMDS sensors.

We are requesting \$455M for sensors in FY 2011. We plan to upgrade the AN/TPY-2 radar software to facilitate its use as a surveillance radar or as a THAAD battery fire-control radar, optimize the radar's ability to leverage assistance by external sensors, and support the contingency operations of AN/TPY-2 radars deployed in Japan and Israel. We will continue to develop a Concurrent Test, Training and Operations capability to provide operational BMDS sensors (including the UEWRs, Cobra Dane and Sea-Based X-band radars) the capability to conduct training and testing while continuing to provide on-line missile defense, upgrade AN/TPY-2 and Sea-Based X-band radar discrimination and dense track management software, and conduct ground and flight testing to support accreditation of sensor models and simulations.

We are requesting \$343M for Command and Control, Battle Management and Communications (C2BMC) in FY 2011. We plan to provide automated planners to aid a

Combatant Command's deployment of BMD assets according to its concept of operations and conduct ballistic missile defense battles according to its tactics, techniques, and procedures. Furthermore, we will develop and deploy an upgraded version of our C2BMC hardware and software to provide new battle management functions that enable shoot-look-shoot tactics between layers of U.S. and international partners' missile defense assets, control multiple BMDS radars, correlate and combine sensor data from multiple sensors tracking the same threat into one system track, provide real-time awareness of the battle as it develops in accordance with a Combatant Command's concept of operations, and enable engagement coordination among BMDS elements in accordance with regional Area Air Defense Plans.

Additionally, C2BMC will participate in and analyze results of ground and flight tests to support accreditation of models and simulations and support war games and exercises.

MDA played a significant role in the conduct of the Ballistic Missile Defense

Review. The agency provided technical analysis and data as required by the leaders of
the review to support their effort to answer the questions posed by Congress.

Preliminary analytical results were then presented to the departmental leaders,
including the Secretary and Chairman, who then made recommendations to the

President. Although MDA provided these architecture assessments, it is important to
recognize the decision to deploy the recommended European PAA architecture was not
based solely on detailed performance predictions. Rather, the decision to deploy an
Aegis SM-3-based architecture to Europe was based on the need for a flexible defense
against an evolving threat from the Middle East. First, the previously proposed

European missile defense architecture lacked a sufficient number of interceptors to

defend against the current and emerging numbers of medium-range ballistic missiles (MRBMs) being fielded by Iran. Simply put, with a notional two interceptor shot doctrine, the 10 GBI interceptors proposed for Poland would easily be overwhelmed by a raid size of 6 threat missiles launched towards European targets. Second, with the European PAA, we can deploy a missile defense capability to Europe earlier than the previous Program of Record, with GBIs in Poland and an X-Band Radar in the Czech Republic. NATO Europe is threatened by a short-range and medium-range ballistic missile threat now, so this was an important variable in the decision. Upon the completion of testing in 2011, we could begin the deployment of proven capabilities to defend against the MRBM threat. Third, by creating a re-locatable, land-based version of our most capable regional missile defense system, the Aegis Ballistic Missile Defense (BMD) system, Combatant Commanders could have the capability to adjust their missile defense architectures to address the uncertainty of future missile threats without the need to develop a new missile defense system. These systems can be deployed in any theater in a reasonably short period of time. Fourth, the increased defended areas and larger raid size capacity resulting from planned enhancements to the Aegis BMD system are expected to increase the cost-effectiveness of a European missile defense against the growing missile threat over this decade. Finally, while we currently have a limited defense system against potential Intercontinental Ballistic Missile (ICBM) threats originating in the Middle East or Northeast Asia, there is no technical reason to indicate that this system would not be further enhanced by the deployments envisioned in Phase 4 of the PAA. It is important to note that the missile defense capability needs identified in the BMDR are consistent with capability needs listed in the recently approved,

independently developed, classified USSTRATCOM missile defense Prioritized Capability List.

## **Proving the Ballistic Missile Defense System Works**

A key tenet of the BMDR is to sufficiently test the capabilities and limitations of a missile defense system before we begin procurement, or we will "fly before we buy." As such, missile defense projects are subject to production decisions by USD (AT&L). Additionally, we use the Services' standard material release and operational certification processes that also rely on developmental and operational test data prior to formally fielding initial capability. Both THAAD and AN/TPY-2 have production decisions by USD (AT&L) and Army Material Review Boards planned for this year. We are requesting \$1.1B in FY 2011 to provide targets and support to missile defense projects to test new capabilities under developmental and operational conditions, including the use of actual threat missiles, to support accrediting our models and simulations and production decisions by USD (AT&L). In collaboration with the Services' Operational Test Agencies, USSTRATCOM, and the Director, Operational Test & Evaluation, we submitted a comprehensive Integrated Master Test Plan (IMTP) in March that describes our plan through FY 2015 to conduct over 150 test events to obtain specific data necessary to accredit our models and simulations and support operational assessments. The IMTP also describes our testing to support European PAA deployment decisions. To support a Phase 1 decision in 2011, we have completed 10 Aegis BMD intercept tests of short range targets. We will conduct an Aegis BMD test against an intermediate-range ballistic missile target prior to the Phase 1 deployment. Likewise, there are system level ground tests, exercises, and simulations to test system

effectiveness and interoperability. The IMTP also describes our testing of the two-stage GBI and several GMD intercept tests against long-range targets. I concur with the January 2010 DOT&E January assessment that "if MDA can execute the IMTP as planned, successful VV&A of BMDS models and simulations should result, enabling quantitative and objective rather than subjective assessments of the BMDS capability in the future." I further agree with the DOT&E conclusion that "objective assessments of the BMDS capability are still a number of years in the future."

Our recent flight test results have been mixed. From October 2008 through today MDA achieved 5 of 7 successful hit-to-kill intercepts and a number of "firsts" in BMDS testing. In December 2008, the GMD system engaged an IRBM target launched from Kodiak Island, AK, using a GBI launched from VAFB in the most operationally realistic test to date that demonstrated our ability to fuse sensor data from five on-line sensors. Unfortunately, the target in that flight test failed to release countermeasures. In March 2009, with soldiers operating the system using tactics, techniques, and procedures developed by the U.S. Army, we conducted THAAD's first dual salvo endoatmospheric engagement of a threat-representative separating ballistic target. The Navy conducted an intercept using an Aegis SM-2 Block IV (terminal defense) in February 2009, and we conducted an SM-3 IA intercept in July 2009. In October 2009, we supported Japan's intercept test of an SRBM using the Japanese destroyer JS MYOKO.

Although we have had three intercepts out of three previous attempts using the GMD system, our newest variant of the kill vehicle, relying on data from the Sea-Based X-band (SBX) radar, failed to intercept a target in January 2010 during a flight test to

measure GMD's performance at its maximum operational intercept range. The GBI launched successfully from VAFB and the newly designed LV-2 long-range target successfully flew for the first time out of the Reagan Test Site in the Kwajalein Atoll 7,500 km away. It was a very valuable test because we collected extensive data on the performance of the SBX and GBI, the advanced exo-atmospheric kill vehicle (EKV), and the target. We discovered new failure modes for the SBX, the EKV flew more than twice the distance it had flown in previous tests, and we collected significant new data on the EKV's ability to acquire, track, and discriminate the target. The failure investigation is expected to continue for several more months before root-cause is determined and verified. It is my intent to immediately correct any deficiency and repeat the test as soon as feasible. In contrast, the most recent attempt to conduct a THAAD test last December was of no value because of a target missile failure. The THAAD interceptor was not launched and the system was not exercised. Despite the cost of more than \$40M for that test and subsequent program delays, we gained no new information on the performance of the THAAD system.

The two largest challenges to executing the U.S. missile defense program is acquiring a cost effective set of reliable targets and improving quality control. Over the past year we have initiated steps to acquire a new set of targets of all ranges, including Foreign Material Acquisitions, to verify the performance of the BMDS. Our new target acquisition strategy, initiated in FY 2009, procures targets in production lots to increase competition, quality control, reduce costs, and ensures the availability of backup targets starting in 2012. For the next three years, we must continue to rely on an intensive inspection and oversight process to motivate mission assurance.

Due to the precise nature of the operation of missile defense systems, very high standards of quality control and an enduring culture of disciplined mission assurance by the industry workforce is essential. We have had many successes in improving our prime contractor and supplier quality assurance. In each case, companies have been willing to identify shortfalls, invest in new capital assets and attain experienced leadership in changing cultures to establish the enduring discipline required to consistently deliver precision missile defense products. However, not all companies have sufficiently improved. Until we complete planned competitions, including the greater use of firm fixed price contracts, we will have to motivate greater attention by senior industry management through intensive government inspections, low award fees, the issuance of cure notices, stopping the funding of new contract scope, and documenting inadequate quality control performance to influence future contract awards by DoD.

### **Hedging against Threat Uncertainty**

Missile defense technologies must be developed to adapt and upgrade our systems to counter future changing threats. In accordance with the PCL, we are focusing our future technologies in four areas: 1) developing more accurate and faster tracking sensors on platforms to enable early fire control solutions and intercepts; 2) developing enhanced command and control networks to link and rapidly fuse sensor data to handle large raid sizes of missile threats; 3) developing a faster, more agile version of our SM-3 interceptor to destroy long-range missiles early in flight; and 4) developing discrimination techniques to rapidly resolve Reentry Vehicles from other nearby objects. Additionally, we continue to research technologies for destroying boosting missiles with

directed energy. We are developing more mature technologies for mid-term deployment decisions around 2015 and conducting science and technology experiments for far-term (around 2020) advanced capability deployment decisions.

One of the highest priority capabilities requested by the war fighter community is a persistent and precise missile tracking capability. We are requesting \$113M in FY 2011 for the Space Tracking and Surveillance System (STSS) and Near Field Infra-Red Experiment satellite operations. This space operations work will demonstrate the utility of remote missile tracking from space and reduce the risk of integrating the remote tracking data of future satellites into missile defense fire control systems. MDA launched two STSS demonstration satellites on 25 September 2009. We continue testing and operating the two demonstration satellites, including cooperative tests with other BMDS elements, and demonstrating these satellites against targets of opportunity and scheduled tests involving targets. We are also requesting \$67M in FY 2011 for a new program start, the Precision Tracking Space System (PTSS), comprised of a network of remote tracking satellites, communications, and ground stations. Key attributes of the PTSS are its limited mission, uncomplicated design, lower costs, use of mature technologies, and integration with legacy data management and control systems to provide a persistent remote missile tracking capability of the areas of the earth that are of most concern for missile defense. Lessons learned from the two STSS demonstration satellites currently on orbit will inform decisions on the development of a prototype PTSS capability by the end of 2014. After validating the prototype design in ground testing in 2014, we plan to fly the first prototypes while we have industry teams compete to produce the remaining satellite constellation for initial constellation operations by 2018.

We are also requesting \$112M for FY 2011for the development and testing of a remotely piloted vehicle (RPV) based missile tracking sensor system, or Airborne Infrared (ABIR) sensor system, to track large raids of ballistic missiles early in flight. We are completing an analysis of the optimum RPV platform and sensors to integrate into an effective early missile tracking system.

For FY 2011, we are requesting \$52M for C2BMC enhancements to develop a netcentric, Service-oriented architecture, to rapidly fuse sensor data and provide data to
distributed fire control systems to intercept enemy reentry vehicles early, optimize shootlook-shoot opportunities, and economize the number of interceptors required to defeat a
raid of threat missiles. We are pursuing enhanced C2BMC capabilities and experiments
to integrate interceptor fire control systems with ABIR, STSS, and other new sensor
technologies. We work closely with USSTRATCOM and the COCOMs to develop and
deliver the optimum C2BMC architectures in their regions.

We are requesting \$41M in FY 2011 to develop components that increase the speed of our SM-3 family of interceptors with advanced divert capability, faster boosters, and lighter kill vehicles. We are studying the use of a derivative SM-3 IB kill vehicle and derivatives of the first and second stages of the SM-3 IIA interceptor as part of the development of the SM-3 IIB long-range missile interceptor.

We are requesting \$99M for FY 2011 to conduct continued research on high energy lasers. This past year we saw the significant accomplishments of the Airborne Laser Test Bed (ALTB) as it completed preparatory tests which ultimately led to two successful and historic experimental shoot-downs of a solid rocket on February 3, 2010, and a boosting, liquid-fueled, Foreign Material Acquisition (FMA) target on February 11,

2010. We are preparing for another test against an FMA, at nearly twice the distance, later this spring. We will continue to investigate multiple high energy laser technologies to characterize their performance while validating the modeling and simulation of long range directed energy beam propagation and beam control. Additionally, we are currently supporting the USD (AT&L)/Director for Development, Research and Engineering (DDR&E) comprehensive review of all DoD high energy laser programs to establish a department wide program for developing and applying high energy laser capabilities. We anticipate this review will define the ALTB's role in the future development of high energy lasers.

### Develop New, Fiscally Sustainable Capabilities over the Long Term

MDA's preferred approach to developing new missile defense capabilities is to evolve and upgrade existing capabilities to leverage the cost-effectiveness of utilizing existing Service training, personnel and logistics infrastructures. The fiscal sustainability of missile defense systems is largely determined by the cost of operations and sustainment. Therefore, MDA executes "hybrid management" of projects with the designated lead Services by embedding "Service cells" in MDA joint project offices to make design and development decisions associated with Doctrine, Organization, Training, Leadership, Personnel and Facilities (DOTLPF) to assure MDA products efficiently align with Service processes and operational concepts.

MDA has established six baselines (cost, schedule, technical, test, contract, and operational baselines) to plan and manage the execution of missile defense projects. I approve the baselines of technology programs, but jointly approve with lead Service Acquisition Executives the baselines of MDA projects in product development. These

baselines not only assist in our cost-effective management of MDA projects, but also provide visibility to the MDEB and Congress on the progress of our execution. The baselines of all of our projects are established in spring and will be submitted to Congress in a Baseline Acquisition Report (BAR) in June. Finally, these baselines will form the basis for USD (AT&L) production decisions.

## **Expand International Missile Defense Cooperation**

As stated in the BMDR and Quadrennial Defense Review (QDR), a key strategic goal is to develop the missile defense capacity of our international partners. We are currently engaged in missile defense projects, studies and analysis with over twenty countries. Our largest international partnership is with Japan. We are co-developing the SM-3 IIA missile, studying future architectures, and supporting their SM-3 IA flight test program. In Europe, we are participating in the NATO Active Layer Theater Ballistic Missile Defense (ALTBMD) command and control program and war games, continuing technology research projects with the Czech Republic, and planning for the European PAA deployments, which include the installation of Aegis Ashore sites, one each in Romania and Poland. Collaboration with Israel has grown to involve the development and deployment of the Arrow Weapon System, which is interoperable with the U.S. missile defense system. MDA has completed and the United States is now in the final negotiation of an Upper Tier Project Agreement with Israel for cooperative development of an exo-atmospheric interceptor and amending the US-Israel Arrow Weapon System Improvement Program agreement to extend the system's battle space and enhance its ability to defeat long-range ballistic missiles and countermeasures. MDA and Israel are also jointly developing the David's Sling Weapon System to defend against shorter

range threats, to include some ranges that the PAC-3 system cannot engage.

Additionally, MDA is active in supporting the Combatant Commands through international symposiums, bi-lateral and multi-lateral dialogs, planning, and analysis with Allies and international partners to help them understand the benefits of integrated missile defense in their regions.

#### Conclusion

Missile defense is a key part of our national security strategy described in the BMDR to counter the growing threat of ballistic missile proliferation. The New START Treaty has no constraints on current and future components of the BMDS development or deployment. Article V, Section 3 of the treaty prohibits the conversion of ICBM or SLBM launchers to missile defense launchers, and vice versa, while "grandfathering" the five former ICBM silos at Vandenberg AFB already converted for Ground Based Interceptors. MDA never had a plan to convert additional ICBM silos at Vandenberg and intends to hedge against increased BMDS requirements by completing construction of Missile Field 2 at Fort Greely. Moreover, we determined that if more interceptors were to be added at Vandenberg AFB, it would be less expensive to build a new GBI missile field (which is not prohibited by the treaty). Regarding SLBM launchers, some time ago we examined the concept of launching missile defense interceptors from submarines and found it an unattractive and extremely expensive option. As the committee knows, we have a very good and significantly growing capability for seabased missile defense on Aegis-capable ships.

Relative to the recently expired START Treaty, the New START Treaty actually reduces constraints on the development of the missile defense program. Unless they

have New-START accountable first stages (which we do not plan to use), our targets will no longer be subject to START constraints, which limited our use of air-to-surface and waterborne launches of targets which are essential for the cost-effective testing of missile defense interceptors against MRBM and IRBM targets in the Pacific area. In addition, under New START, we will no longer be limited to five space launch facilities for target launches.

MDA is working with the Combatant Commanders, Services, other DoD agencies, academia, industry and international partners to address the challenges and difficulties of managing, developing, testing and fielding new military capabilities to deter use of ballistic missiles and effectively destroy them once launched. Implementing these war fighter priorities takes time, since the production time for a missile and radar is over two years and establishing and training a unit to create and deploy a military capability takes an additional year. Our FY 2011 budget funds the war fighters' near-term priorities while building the foundation of a layered defense system with our partners and friends that can provide an adaptive, cost-effective strategy to counter ballistic missile proliferation in the future.

Thank you, Mr. Chairman. I look forward to answering your questions.

#### AL&B TESTING VIDEO

General O'REILLY. I have brought a 2-minute classified video,

which I am prepared to show.

Chairman DICKS. I just want to commend you, General O'Reilly, for your approach on this competition issue and your approach to dealing with these contractors. You and I had a discussion a year or so ago, where I complained, and I have been complaining, about the performance of many of our major companies. It is unfortunate,

but the people, there is just a lack of performance.

And I think what you have done here should be a model for the rest of the Department of Defense of aggressively going after those people who are not performing and, in essence, taking away their contracts and putting them out to bid and letting other people bid who will perform. And, somehow, you know, with the amount of programs in trouble and overruns at the Pentagon, I hope this works. And we are going to be watching very closely to see if this does work, because we have got to get this under control somehow.

I am glad that you have taken this on so aggressively, and we

look forward to seeing how it turns out.

So why don't we—and I know Mr. Tiahrt will—we are going to have a little 2-minute video on the airborne laser here.

Mr. TIAHRT. Excellent.

General O'REILLY. Sir, if it is okay with the committee: I am going to project it on the wall. I would recommend some of you may want to stand in a position where you can see it. It will be very quick. ———

Chairman DICKS. Now, weren't there a lot of critics who just said

this is impossible to do?

General O'REILLY. Absolutely, sir. My background is in laser physics, and there was a lot of discussion, including previous directors of the Agency, that said this was impossible. The main difficulty I will show you is we actually fired through the atmosphere into space to destroy this missile. This is a scientific breakthrough in the area of anchoring our models and simulations, which is what some of the physicists were saying why it was impossible.

Chairman DICKS. One other thing, just one point. You will see the missile launch. And then when it breaks apart, it keeps alight, but it is only on the pieces of the thing as the debris goes away. So I would just point that out so you will understand it better.

It was quite impressive. Let us go ahead and show the start of the video. ———

So at this point we adjusted the optics and we deformed the laser, the main laser, so that when it leaves the aircraft it is unfocused. Since we now know basically the prescription of the atmosphere, kind of like my glasses. We used the Earth's atmosphere to focus the laser. When it arrives on the target it is perfectly focused. ——

Unfortunately, with the movies that have been out for the last 20 years, this doesn't impress. I show this to high school classes and others in an unclassified form. People are not reacting to it because they are saying, of course, you have got a laser beam. This has never happened before. This is the first one in history.

Chairman DICKS. It is easier to do it in Hollywood, right?

General O'REILLY. Yes, sir. It does look like what you just saw in the movies. But what you just saw was real.

It is hard to see, but that is the destruction of the missile. Now the laser is irradiating the pieces. So that is what it actually looks like for the pilots. They actually see a gigantic beam leaving the front of the aircraft.

Can you just show it one time in real-time without stopping? And what we are doing today, while this tees up again. Here is the launch. You are watching the entire flight test here. And that is the destruction of the missile. ———

We did this morning find a blemish on one of the mirrors. We are trying to clean it today. We have to change it out. It might take 2 more weeks before we do the next test.

Thank you, sir.

#### ALTB DEVELOPMENT

Chairman DICKS. Well, I want to compliment you on this, because this subcommittee was one of the steadfast supporters of this program over many years, especially when, a few years ago, there was a funding issue whether this should go forward or not.

And I must say that there were some in this body who are no longer serving here, but are serving at the State Department, who had great doubts about this. And I think the point you make about the fact that the refocusing of this laser was the critical issue: Could you go through the atmosphere and this thing, the beam, would come and hit where it is supposed to?

But I just want to compliment you because a lot of us thought this could be done, and I like your new approach to the program.

And I think it is also important to know that out at Lawrence Livermore, which has been one of the great places for the development of laser capability, there is now a—why don't you tell them about this new laser that they are developing and how it relates to the aircraft and the fact that you can have two lasers on this plane?

General O'REILLY. Sir, the Office of Secretary of Defense is executing a study right now on all high-energy laser programs. Last year there was over \$325 million in laser programs across the Agency. They are reviewing them all in order to see if we can consolidate and get a better return on investment.

But as part of that program, and under that review, they have identified the airborne laser to become the airborne laser test bed for most of these lasers. The aircraft actually has the mounting for two lasers. It had from the beginning. So you can actually put two different lasers on this aircraft.

Chairman DICKS. As I understand it, DDR&E is creating a report for Deputy Secretary Lynn on defense high-energy laser research to be completed in June. General O'Reilly, can you tell you about this report?

General O'REILLY. Yes, sir. It is the one I referred to before. Last year, in all services and the Department of Defense, we spent \$325 million on various laser programs. They are reviewing all of those programs. By June they can make a recommendation on how the Department should move forward on high-energy laser research.

I will tell you that in all the other applications, it is about 150 kilowatts. This is the only megawatt laser system or megawatt capability requirement that we have in the Department. And, sir, as you said, that will be done by the end of next month.

Chairman DICKS. The committee would like a copy of the report

when it is completed, General, if you could help arrange that.

General O'REILLY. Yes, sir. I will pass that to the Office of the Secretary of Defense.

Chairman DICKS. Thank you. Mr. Young.

Mr. YOUNG. Well, Mr. Chairman, thank you very much. That was a very interesting video, General.

Can you give us—look into the future and tell us when this system might be available to be used?

General O'REILLY. ——

Chairman DICKS. And when might we anticipate that they would be actually an IOC, where we could actually put them into the war?

General O'REILLY. Well, sir, the engineers themselves on this program have indicated they have learned so much—because this was a breakthrough technology—that if they were going to build a second aircraft, they would use what they have learned and design a different design. That is what the Secretary of Defense acknowledged last year when he said we will build one aircraft and we will test the aircraft and operate from them. ——

Mr. YOUNG. General, as you look at the world and you see so many rogue nations developing missiles of one type or another, how many airborne laser systems do you think that the United States will need to give us the type of protection that this demonstration shows that we could have?

General O'REILLY. Sir, our budget is proposing the development of several different classes of missile defense systems. I think the combatant commanders, who I work with every day, are looking at a spectrum of capabilities. Airborne laser does serve us very well in certain capabilities where you can deploy for a limited period of time, like we surge aircraft today, because they would have to be on station. It is expensive to do that, operationally difficult to do it, but it can be done.——

Mr. Young. General, one of the realistic points during the negotiations for the new START agreement had to do with missile defense. Does that new START treaty affect the airborne laser?

General O'Reilly. No, sir. I have been to Moscow seven times in

General O'REILLY. No, sir. I have been to Moscow seven times in the last 2½ years. One of the proposals we have had for cooperation on missile defense, besides sharing early-warning data and so forth, is development in laser technology with the Russians.

They have world-class experts at the University of Moscow. There are some of the best theoretical physicists and optics and such, and they can contribute a lot. Previously the Russians have not responded. ———

Mr. Young. So if they become unhappy with and withdraw from the treaty, which we have seen some suggestions that they might do that, you don't think this would be one of the reasons that they might make that decision?

General O'REILLY. No, sir. They are pursuing this technology, as we are, and as the Chinese are also.

Mr. Young. Well, as Chairman Dicks has said, this committee has been involved with and supporting airborne laser for many years, and it is pretty exciting to see the success that you have showed us here today. Thank you very much.

Thank you, Mr. Chairman.

Chairman DICKS. Thank you. Mr. Moran.

### GROUND-BASED INTERCEPTOR TESTING

Mr. MORAN. Thank you, Mr. Chairman.

I think we are all impressed by your laser capability that you showed in that video. But the General Accountability Office is less impressed with your Ground-Based Missile System and, in fact, according to the GAO—and I will quote—"The Missile Defense Agency continues to put the Ground-Based Interceptor program at risk with cost growth and scheduled delays by buying and placing enhanced interceptors before this configuration has been demonstrated in a realistic environment.

In January of this year, you attempted to intercept a target missile using the Ground-Based Interceptor with the—I will only use this full term once and then I will use the acronym—the capability enhancement 2 XO atmospheric kill vehicle. So we will just call it the CE–2. But it failed to intercept the target because of a failure of the X-Band Radar to track the target, as well as a failure of the CE–2 EKV.

But about 40 percent of the EKVs have been delivered to date, notwithstanding the fact that in the first real-world test, the CE—2 EKV failed to intercept the target missile.

What are the cost estimates for redesigning the EKV and when

will a new functioning EKV be produced and fielded?

General O'REILLY. Sir, as I testified last year and as I mentioned before, we have restructured our test program to more comprehensively test the GMD program.

In the past, we have launched our targets out of Kodiak, Alaska, launched our targets. And our interceptors have come out of Cali-

fornia. That is a 3,500-kilometer threat.

What we have gone to now is testing against ICBM ranges. Our test in January was the first test to more thoroughly test the system out. It traveled—the test was over 8,500 kilometers. We launched the target out of Kwajalein, and we launched the interceptor out of Vandenberg. That is the equivalent of a type of defense if you had to launch out of Alaska and defend Miami.

# AEGIS SM-3 PRODUCTION

Mr. Moran. Well, the problem that the GAO has, as you know, is that you were 40 percent—you had gone 40 percent of the way into production, whereas the only test showed that it was not operable as yet.

And with regard to the Aegis Ballistic Defense Missile System, the GAO said that it believes that four of the five critical technologies are immature and that there are no plans to intercept a target using a fully integrated prototype SM-3 Block 1B missile until the second quarter of fiscal year 2011. Yet production begins this year. It is not that we are not excited and we don't want to

be supportive, but our job is to ask questions, particularly when GAO raises them.

Given the fact that the SM-3 Block 1B production is set to begin before testing a fully integrated prototype in a relevant environment, what are the Department's plans to employ design changes to that SM-3 Block 1B should problems be discovered down the line? That is our concern. You have moved ahead with production, and yet the testing raises issues that seem legitimate, certainly in the mind of the GAO.

General O'REILLY. Sir, I do not agree with the characterization that the GAO made regarding the 1B because those missiles we

have in production right now are the test missiles.

We do not have a full production decision made. We are not

going to make that decision until the flight tests.

What the GAO was referring to was production of the missiles to go test them, and then we will go to a full production decision. We are following the prudent traditional path of thoroughly testing these systems before we put them into production. The GBIs in the past were not procured that way, as you said, sir. We have procured CE-2s. We are, as rapidly as we can, doing the types of tests I just referred to, but our policy from this point on is to test first and then go into production.

So, again, what we are buying right now are the test missiles to

go to production. They are not production missiles.

Mr. Moran. Okay, that is a good answer. And I won't want to take up any more time. If we get into a second round, though—and I will just prepare you—I do want to better understand why we have to pay for Europe's missile defense. But at this point I will yield to the next questioner.

Thanks, Mr. Chairman. Chairman DICKS. Mr. Lewis.

### NATO AND MISSILE DEFENSE

Mr. LEWIS. Thank you, Mr. Chairman.

General O'Reilly, thank you very much for being here. I am very much concerned about the point that Jim was just about to make, but perhaps we fall on a different side of this question. It is very clear that our European friends for some time now have been wallowing in their own resources because they spent a lot less money in defense. America, on the other hand, has been the strength providing defense for much of the world, certainly beyond the developing world.

It is very important that we be willing to make sure we carefully measure where we are going in connection with those expenditures. If America doesn't continue to commit itself to our national security

and much of the world's security, who will, is the question.

If we decide to make, Mr. Chairman, a move in the other direction and continue to fund social programs here instead of defense, and Europe is not spending money on defense, who will? It is a pretty fundamental question in terms of our future.

I am very concerned, General, about Iran and the testing that they are about and the implications of their future missile capability relative to the European theater and how that impacts our responsibilities in the world. Would you enlighten us more about your thinking relative to Iran, especially as a major target?

General O'REILLY. Yes, sir. Do you also want me to address the

question on the contribution of the allies?

Mr. Lewis. Yes. We would like to hear it. Sure, if you want to. General O'Reilly. Sir, the most effective defense is not by looking at a map and see if it is covered or not. It is actually a side view. To have effective missile defense you need at least two shots at a target. You would like them to be from two different systems, so that if you have countermeasures in something and you can spoof one, you can't spoof the other.

If each missile system has, per se, a 60 percent probability of destroying the target that it is launched at, you put those two together and you now have an 88 percent probability of killing it as it comes in. You add a third layer and you get high into the 90s.

Therefore, we want layered missile defenses.

Our proposal for Europe is the upper tier where we have the capability, and the proposal is they would provide the lower tier. The lower-tier systems, you need more of them than you do upper-tier, so their net investment actually would be greater than ours if they were going to cover Europe themselves.

Their current NATO policy is to protect their forward-deployed

forces.

They have just finished a NATO Ministerial where they are proposing to defend the soil of Europe itself with their NATO Missile Defense Systems. This proposal will go to a decision by NATO heads of state in Lisbon in November.

My understanding—and I work with this every day—is we will provide the upper-tier defense. They are going to have to provide the lower-tier defense. Why do we do it in a classified session?

Mr. Lewis. General, as you responded to Congressman Young's question about timing, when will this be available? I wasn't—maybe I missed it. I didn't quite get your response in terms of the actual time frame. You are in the process of development. You suggested, I think, that we would have this capability operable sometime near the end of the decade?

General O'REILLY.——

Mr. LEWIS. General O'Reilly, the person who said this will go unnamed, but one of my colleagues has said he never saw a four-star general with so little support behind him. Congratulations. I am talking about numbers of people in the audience.

General O'REILLY. Well, yes, sir, I am a three-star; thank you, sir.

Chairman DICKS. He doesn't need as much. Mr. Rothmans.

## COOPERATION WITH COCOMS

Mr. ROTHMANS. Thank you, Mr. Chairman.

Secretary, thank you for all your outstanding work throughout your career and in this matter in particular, and these matters in particular. Secretary Gates, it was revealed in the general press, had sent a memo back in January or February, I think, or maybe it was December, encouraging greater planning and coordination or upgrading of the planning and coordination for a military contin-

gency option against Iran should diplomacy and sanctions fail. And that got a lot of attention recently in the press.

I actually had asked him that in this subcommittee's hearing in April of 2009, in open session, and he and Admiral Mullen at the time said that they were confident they have the capabilities and were constantly working that offensive military option.

But I would imagine that part of an offensive military operation would be a defensive capability, a simultaneous defensive operation to protect the homeland or our forces in the region or our allies in the region.

Are you working, coordinated with the offensive military missile

folks, in those kinds of contingency plans, Avis Iran?

General O'REILLY. Yes, sir, we are. Both EUCOM, the U.S. Forces in Europe, under the command of Admiral Stauridis, and CENTCOM under General Petraeus are both—we are working with both of them to develop and modify and update their war plans against the protection of our assets from a strike from Iran and the offensive site. For example, our missile defense systems can, within seconds of identifying a missile being launched, determine where it came from.

So we are providing that data, we are integrating it into our offensive command and control system. So they immediately know that while the missile is still in flight, we have already launched strike attacks against the point where it came from.

Mr. ROTHMAN. And, of course, we want to make sure that there is not a conflict between our offensive and defensive systems. So have you done exercises so that your defense of launches are not misinterpreted by our offensive folks? I know in Operation Juniper Cobra—from what I have been told and read—that you had in Israel in 2009, where you coordinated that kind of information-sharing between the Israelis and the American forces so that they weren't shooting at each other's rockets, et cetera. Do we have that—have we done that with our own forces?

General O'REILLY. Yes, sir; extensively with simulations supported BY MDA with EUCOM and CENTCOM. The same commanders that are in charge of the missile defense assets that we have employed in other commands are the same commanders that have the offensive capabilities. So at the top and their staffs, they are responsible for developing both plans so it is integrated.

### COOPERATION WITH ISRAEL

Mr. Rothman. Right. And then regarding Operation Juniper Cobra, from what I understand it was at an unprecedented level of cooperation and showing of strength and commitment of resources and that it went well; but nothing goes perfectly, and that there were lessons to be learned and there is a review going on. There is some issue as to whether the U.S. is sharing the lessons learned and the mistakes with the Israelis and vice versa.

Can you comment on that?

General O'Reilly.

missile coming in, we immediately provide that data to the Israelis. Mr. ROTHMAN. Two last questions, and I will leave him with the questions, if I may, just the questions. You say one of the two big-

gest challenges you face—and this is from your written testimony—are reliable targets.

General O'REILLY. Yes, sir.

#### AEGIS INTERCEPTORS

Mr. ROTHMAN. And the last question would be, we need more of these Aegis ships and missiles. Are you comfortable with the budget for more ships and more Aegis missiles and your targets that

you say are your number one priority?

General O'REILLY. No, sir. I am not comfortable with the number of standard missiles. We need more today. It takes 2 years to build one, though. And the decision in 2008, the proposed budget, was to build a total of 105 standard missiles, total. Today we are asking for funding for 431. The problem is—

Chairman DICKS. Is that fiscal year 2011?

General O'Reilly. It starts in fiscal year 2011; yes, sir.

Chairman DICKS. Four hundred five?

General O'REILLY. I think it is 435 SM-3s and 431 THAAD missiles across the FYDP. It starts the production line. The problem

is it takes 2 years to build the first missile.

So because of the decisions made in 2008, we could use many more missiles than we have today. The Joint Staff is conducting, with all the combatant commanders in the services, a capabilities mix study. The study will determine what the ultimate number is, so that our next year's budget can have that in there. But we know we need to ramp up, and we are doing that under this budget as quickly as we can.

But, again, we need to test first and then put into production

these new missiles.

#### STANDARD MISSILE

Chairman DICKS. On this point, why don't you describe kind of in a general overall sense, how we are going to do this missile defense and where the standard missile fits into this?

General O'REILLY.

That standard missile, we made the determination it works very well on an Aegis ship. If you just take it off the ship and put it on the land, you don't have to do very much development. It is mainly the building itself and the structure. And if you put it on the land, now we have a land-based capability equivalent to a Navy capability and, more importantly, the sailors are trained. The logistics system, the worldwide logistics system, is there. There is a savings of billions of dollars to have this same missile system on the land as you do at sea.

But more revolutionary is the Joint Chiefs approved earlier this year that the Navy would be the lead service for the land-based SM-3, which will be the first time that the Navy is operating and fully responsible for a land-based weapons system. The Army fully

agreed with that.

The problem the Navy had was, with all their sailors at sea for Aegis, they did not have the type of shore assignments where they could rotate them. The Chief of Naval Operations now has land assignments and sea assignments which will help retention, it helps training, it helps across the board. So we thought that this was a

very prudent way to move forward to have land- and sea-based capability, same command and control. Where the sailors walk into a room on a land-based SM-3, it looks identical to the way it does

on a ship.

And when we have remote locations such as Guam, Okinawa, Diego Garcia, and other places in the past that have been problematic to station a ship near them, we can now permanently put one of these land-based SM-3 sites—or, as the Navy calls them, Aegis ashore—and you have now that protection. ———
Mr. Young. When will this global defense system be in place or

be available to use in the event of an attack?

General O'REILLY. Sir, the first capability is against mediumrange ballistic missiles, 3,000 kilometers or less, and that will be deployed in 2011.

Mr. Young. Is that worldwide?

General O'REILLY. No, sir. Until this budget is requested, we are requesting at least 37 ships, and, between THAAD and Aegis, about 800 interceptors. By 2015, we should have the capability now that we can start deploying around the world against MRBMs. We need the Japanese missile that we are working with the Japanese by 2018. And by 2020, we will have had many independent reviews. We believe we will have the capability to develop a missile that can destroy ICBMs from a ship or one of these forward bases

Mr. DICKS. Mr. Frelinghuysen.

# CHINA AND BALLISTIC MISSILES

Mr. Frelinghuysen. Thank you, Mr. Chairman.

Just within the last week, for the first time we have revealed a lot about our nuclear stockpile. It will be interesting to see whether the Chinese and Russians will be willing to go through the same full measure of public disclosure.

My question, sort of general question, is what do we know about the Russians' and Chinese offensive ballistic capability? Do we know how many missiles they have? I assume we have done the intel on that?

General O'REILLY.

Mr. Frelinghuysen. The view here oftentimes is what the Chinese have is crude, and often we say that about the North Koreans. But some people sort of have a different take on it. It impacts their moving fairly rapidly with the development of their missile program, particularly the Chinese. There continue to be stories circulating in the media that China is working to modify their landbased B-21 ballistic missiles.

General O'REILLY. Yes, sir.

Mr. Frelinghuysen. To potentially use against our carrier assets. Can you talk about that? I understand the idea is to have a satellite or over-the-horizon radar or maybe a UAV guide these heavy missiles towards our carrier groups at very high speeds. We have a range reportedly of about 2,000 kilometers, so that would make our fleet out there or our ships out there fairly vulnerable. And more importantly, do we have the ability to protect the carrier groups that are out there?

General O'REILLY.

Mr. Frelinghuysen. This is idiocy. General O'Reilly. We have looked at that extensively in the past, us and the Navy. It is very cost-prohibitive. It is very complex. We are not looking at using submarines to launch GBIs.

Mr. DICKS. Not offense.

General O'Reilly. I was referring to defensive missiles.

Mr. Dicks. I think what you are suggesting in the START agreement is that the number of launchers, you use some, but I know of no system that you would use off a submarine as a defensive system against-

General O'REILLY. We are not pursuing that.

Mr. Frelinghuysen. But we are limiting on the offensive side.

Mr. DICKS. Both sides are coming down. I mean, to answer the gentleman's points, any of these acts that you are talking about would be an act of war, and we have our whole, you know, strategic term that would—they are going to have to contemplate that they are going to be retaliated against, massively and overwhelmingly, if they were to launch such an attack.

Mr. Frelinghuysen. My point is that there is a degree of vulner-

ability.

Mr. Dicks. One thing that wasn't mentioned, at least for the carriers, our ships' defense systems. I mean Phalanx is not anything to write home to mother about, but it is a final system that can shoot down these missiles.

General O'REILLY. Yes, sir.

Mr. Dicks. There are limits to its effectiveness. But there are ship defense systems. General O'REILLY. -

Mr. DICKS. Mr. Visclosky.

#### PHASED ADAPTIVE APPROACH

Mr. VISCLOSKY. General, I would like to talk about the phased adaptive approach, and part of this is just to clarify the program in my mind, if I could.

You have the SM-3 block, and as I understand the relation of Block 1, Block 2, those can be launched from land or sea; am I cor-

rect? I want to make sure I am clear.

General O'REILLY. That is our proposal, sir. We have tested the standard missiles before from the land at White Sands so it is not unprecedented. But that is what we plan to develop, the land-based launchers, so we can deploy them—so you can launch the same missiles at sea as you can on the land.

Mr. VISCLOSKY. Are they launched today on land or sea?

General O'Reilly. Today they are launched at sea on destroyers and cruisers.

Mr. VISCLOSKY. And the proposal would be to have them also be adaptive-I guess that is the "adaptive" word there-on land as well.

General O'REILLY. Yes, sir. The "adaptive" word is we can move them if we find a threat changes in the future. It takes a couple of months to disassemble the whole deployment and move it to another location if we see some in the future.

Mr. VISCLOSKY. And also, obviously, there are multiple at sea. General O'Reilly. Yes, sir.

Mr. VISCLOSKY. On the Ground-Based Interceptor, that is land exclusively. That is not launching from sea.

General O'REILLY. That is correct.

Mr. VISCLOSKY. The SM-3 is for short and intermediate intercepts essentially?

General O'REILLY. Sir, there are several variances of the SM-3. The SM-3 IA is for short—which is up to 1,000 kilometers—and medium range, which is up to 3,000 kilometers.

So the SM-3 IA and IB will be to engage targets up to 3,000 kilometers, the range of the target, 3,000 kilometers. And the SM-2s would be able to handle targets of 5,000 kilometers, the IIA and the IIB ICBMs.

Mr. VISCLOSKY. So the A and the B in Block II would be modified to be long-term interceptors as well; or would it be A is short and medium, and A is long term?

General O'REILLY. The SM-3 I series is the short and medium range. The SM-3 IIA would be against IRBMs up to 5,500 kilometers, and the SM-3 IIB would be ICBMs, 12,000 kilometers.

Mr. DICKS. Are these the ones that are under development with the Japanese?

General O'REILLY. The IIA is.

Mr. DICKS. But not the IIB.

General O'REILLY. Not the IIB, sir. That is a new missile start. Mr. VISCLOSKY. That is not under development currently. It is a proposal?

General O'REILLY. We are going through the technology today of verifying the high-risk parts which we believe we have in hand, the high-risk technologies for the next 2 years for the IIB, and then we would start a formal program start after that.

Mr. VISCLOSKY. And the IIA would still be adaptable for short and intermediate intercepts?

General O'REILLY.

Mr. VISCLOSKY. And B would be long?

General O'REILLY. Yes, sir.

Mr. VISCLOSKY. There is no further development or changes proposed for, then, the Ground-Based Interceptor, which is long range? General O'Reilly.——

Mr. VISCLOSKY. What about the missile itself?

General O'REILLY. ——

Mr. VISCLOSKY. General, if I could follow up. You are not in those upgrades looking to also make it a sea-launched system, though? General O'REILLY. No, sir. We have no plans for a sea-launched GBI.

Mr. VISCLOSKY. Then the question in my mind, understanding that the Block IIB is not yet developmental—you are looking at it—why proceed with that if you are upgrading your current land-based system?

General O'REILLY. Sir, it is a quantity. A GBI costs about \$70 million apiece. The estimate for a IIB would be on the order of \$15 million.

Mr. Visclosky. One-five, 15?

General O'REILLY. One-five, yes, sir.

And the difference is the GBIs, if we are going to add a new silo—if we found out we needed more GBIs, it takes 5 years to ex-

pand a missile field. The ships at sea, we are building these new missiles so they fit in the existing launcher systems. So a cruiser has 120 launching cells on it. So we can put up to 120 missiles, four times as many as we have in Alaska-

Mr. VISCLOSKY. Short, intermediate, and long?

General O'Reilly. Yes, sir.

Mr. VISCLOSKY. On your land-based, that would also hold true, \$15 million per copy?

General O'REILLY. Yes, sir. That is the II—what we refer to as the IIB and IIA. They are about \$15 million, is our estimate.

Mr. VISCLOSKY. If you have a missile that is long-range and one copy—of course you haven't built one yet—that is \$15 million and the other \$70 million, what is the cost disparity when I am comparing apples and apples; that is, land-based IIB and the landbased GBI?

General O'REILLY.

Mr. VISCLOSKY. So the upgrade, then, to the GBI is not necessarily to increase their quantity but to make sure, as long as you have that investment in them, it is an effective investment, then you keep them effective. If you have additional quantities, you go with the IIB that you have in your proposal.

General O'Reilly. Yes, sir.

Mr. Visclosky. I know I don't have a lot of time.

If the IIB, you have not started development but obviously you have a plan for and you have a cost assessment for it, will there be a time when you need more of—will you need at some point some of the additional GBI in the interim until all of this is built?

General O'REILLY. Sir, there is a threat uncertainty. Our current plans, we are going to procure 52 missiles, GBIs, and five additional booster stacks. Now, that is what we are proposing. With those 52, we are going to be flight-testing some of them. By 2020 when we have planned on fielding the newer missile, we should have 36 GBIs at that point. If we find we need more, we are going to be in production until 2016. So we have 5 more years to continue to assess the intel and determine if we need more.

We don't want to get into the situation I am in today. Our last time we bought a GBI was 2006. Our production is stopped on most of the vendor base, and I have to restart it next year, which I am. But we are trying to make—allow decisions to be made in the future before we shut down that production line again.

Mr. VISCLOSKY. Which—industrial base would be a concern. But I know my time is up, and I thank the general and the chairman.

Mr. DICKS. Mr. Tiahrt.

# ALT B FUNDING

Mr. TIAHRT. Thank you, Mr. Chairman, thank you for your support for the Missile Defense Program. I think you have been a great visionary.

One of the things I would like to pick up on what Mr. Rothman talked about and the cooperation with Israel. They are developing great new technology over there. In fact, you can't buy a new computer today without the incorporation of some ideas that originated in Israel on processing. And I think there is a great deal of synergism that we could gain by close cooperation. So if there are any problems with that cooperation, I have got to join with Mr. Rothman in trying to smooth the bumps in the road, because I think

it gives us an advantage on defense issues as well.

There is something that happened last year that I want to point out to you. The ABL is about 12 years old. Last year, the optics needed to be recoded. It took 6 weeks to get a supplier up and running. So there was like a 6-week delay. It is an indication of how our national defense industry base is shrinking and making us more vulnerable.

While this is occurring within the United States, our own Pentagon is looking outside the United States as a supplier. You have heard a lot about the tanker program where they are trying to buy a French tanker and put an American paint job on it and call it American. And even though this is a country that I don't think we can fly over today to get our men and material to Iraq and Afghanistan, I am very concerned about this outsourcing of our national se-

We are also doing it through a program called Imminent Fury, where we are going to Brazil for aircraft which have a competitor that is made right here in America. So again, we are outsourcing our national defense base, and I think it is very ill-advised. And

this ABL program is an example.

When you are in confrontation, you can't afford a 6-week delay or 6-day delay. And we have seen this in the Gulf War, Japan disappointed us by delay. In Operation Iraqi Freedom, Belgium disappointed us with a delay in war materials. So we can't make ourselves more vulnerable. And I think the committee needs to know that by diluting our defense industrial base, we are making ourselves more vulnerable.

And I don't think any of you are going to run for reelection on the platform that we are going to increase the employment in France when we have got almost 10-percent unemployment in America; or we are going to run on the platform of increasing the employment in Brazil when we have got almost 10-percent unemployment in America. So we need to be very concerned about this outsourcing of our national security, whether it is Imminent Fury or an air refueling tanker or the ABL program.

For us to now cut back the funding on this program concerns me greatly, especially in light of all of these advancements you have

made in technology, in compressing the package carrying.

If the Department was provided with the same level of funding as last year, which would be an additional hundred million, I believe, how would that money be spent and how would we use that to progress the program and the technology?

General O'REILLY.

Mr. Tiahrt. Please explain to the committee what the 98 or 99 million will buy in 2011 that we have in program now. Is that just the one test you are talking about?

General O'REILLY. The one test, but the 1-year program. The one

major test, but we have a lot of smaller tests.

Mr. TIAHRT. The hundred million would get the smaller tests, the advanced?

General O'REILLY. Yes. And a part of that does pay for the newer laser work going on at Lawrence Livermore.

Mr. TIAHRT. ——— General O'REILLY. ———

Mr. TIAHRT. I think I want to emphasize the need for increased testing because of the versatility of this weapon. And we just are thinking, you know, how many kilometers away and all of this. But by increasing the testing, I think the capability will dramatically increase. And if you take it to—you know, using my imagination, I can imagine the capability in the back of a Humvee, and it can protect a platoon, at the platoon level, from incoming objects like a handheld rocket. So it has great potential as we compress it further, and I think that can be revealed.

Mr. DICKS. Mr. Hinchey.

## COUNTERFEIT PARTS

Mr. HINCHEY. Thank you very much, Mr. Chairman.

I think you made a very good point, as everybody else did here, but I want to express my agreement with you of the kinds of things that—what you were saying and why I think it needs to be done. So if there is anything I can do to work with you on that, I would be happy to do that.

General O'Reilly, thank you very much. Thank you for everything you are doing and the opportunity that we have to understand this situation much more clearly.

The safety and security on this planet is diminishing, and it is something that really has to be dealt with more effectively, including diplomatically. But that is another issue here that really has to be addressed.

The safety and security issue with North Korea and Iran, it is just remarkable why they would be engaging in the capabilities they are engaged in, when, if they were to do anything militarily dramatic in the context of this, it would be a disaster for them. No question about it.

And of course the safety and security issue was demonstrated in New York just a couple of days ago, and we know that kind of situation that we are likely to continue to see over time, and it is something that we have to be very, very careful about and very, very intensive about.

I wanted to ask you a technical question. It has to do with a number of things, including a company in a district that I represent, Endicott Interconnect Technologies, working with the Department of Defense.

The situation basically is this: Last year, the New York Times reported that despite a 6-year effort to build trusted computer chips for military systems, the Pentagon now manufacturers in secure facilities run by American companies only about 2 percent of the more than \$3–1/2 billion of integrated circuits that are bought annually for use in military gear. And the effectiveness of that gear, the reliability of it, is something that is obviously very important.

So recently the GAO released a report regarding counterfeit parts and the potential of such parts to potentially seriously disrupt the Department of Defense supply chain, do other things like delay missions and affect the integrity of weapons systems. The report found that the Department of Defense is limited in its ability to determine the extent to which counterfeit parts exist in its supply chain because it does not have a Department-wide definition of the term "counterfeit" and a consistent means to identify

instances of suspected counterfeit parts.

Apparently, while some Department of Defense entities have developed their own definitions of "counterfeit," these can—they vary on the context of the definitions that are being put out there. Two Department of Defense databases that track deficient parts—and they are those that do not conform to standards—are not designed to track counterfeit parts. A third database can track suspected counterfeit parts; but according to officials, reporting is low and that reporting is low due to the perceived legal implications of reporting prior to a full investigation, reporting something that you may not have all of the information about, so are you going to report it in any case before you know everything about it. Well, that is just one aspect of what is now a deeply complicated set of circumstances here. And it has to do a lot with security.

So I am wondering to what extent you may have looked into this

and may have understood this situation.

Has the MDA been impacted by counterfeit parts? Does MDA have its own definition of counterfeit? And what anti-counterfeiting

measures are being considered by MDA?

General O'REILLY. Sir, first of all, that GAO report cites us as one of the organizations that is aggressively pursuing counterfeit parts. We do have a definition of counterfeit parts, and it is both not building the part to the exact design that was proposed in our approved designs for our components of our missile systems by our prime contractors, but also built by someone different than was originally identified when we approved the design. So that is our definition of counterfeit parts: change the part or been built by somebody differently. So we hold our prime contractors accountable for that.

Yes, we have been affected. Yes, we have called in the FBI. Yes, the Justice Department has pursued them. And so yes, sir, we do

see it as a growing problem.

Mr. HINCHEY. So to what extent do we have or to what extent is the reliability of this situation increasing, do you think, over recent time?

General O'REILLY. Sir, we have been aggressively pursuing them. I have inspectors in almost every one of the plants. So does the Defense Contracting Agency. A lot of our reporting, though, of this is actually coming from our prime contractors themselves or major subcontractors. These counterfeit parts are not coming from large companies, but it is the smaller ones.

What we have added in is additional screening. So we test the first thing, to identify if something is not operating right, when you take the component. Years ago, we had—in order for acquisition reform and reducing the cost of acquisition, we had removed some of those tests. We have installed those tests back in to do more parts screening when they come in.

And second of all, it is a crime and we do pursue that.

So through inspection, making it a contract requirement, and our prime contractors themselves have been vigilant.

Mr. HINCHEY. Is it generally considered to be a serious situation where you have essentially 98 percent of the products here that are being manufactured, apparently, in places outside of the country, and the reliability of the integrity of these operations comes into question? Is the situation concerned about; is it being looked into effectively? I know you just mentioned some of the ways in which

General O'Reilly. Yes, sir. It is a concern. Screening is the first order we do to protect at the piece-part level to catch them when

they are coming in, but more is needed.

Mr. HINCHEY. Is there any potential for this operation, or is it significant enough to have it be focused in the context of being manufactured here in ways that can be seen more effectively?

General O'Reilly. Sir, that obviously is a viable solution that would solve that. Some of our counterfeit parts, though, we have found in the past some of them are from U.S. entities, and the Justice Department has taken over at that point. We have had to redesign parts of a component and go procure them from somebody else. But it is not just overseas; it is U.S. too, where we have run into this problem.

Mr. Young. Will the gentleman yield?

This is a field I have cared for for a long time. We all know the technology exists in the world to embed programs into certain types of electronics, certain types of technology that could cause a failure

or a disruption of the system.

And as Mr. Hinchey and Mr. Tiahrt have raised the issue of foreign producers or counterfeit producers, are we vulnerable to having that type of attack made against us by embedding something that we can detect but an enemy could disrupt our missile with one

of those embedded programs?

General O'REILLY. Sir, as far as a foreign component, we prohibit the use of foreign components by any of our contractors unless we provide them a waiver. And the waiver is not just the Department of Defense, but the Department of Commerce also. So we go through a process. It has to be a trusted source. We have trusted sources in the U.K. Obviously, this is something that we work very closely with the Japanese in our development with the SM-3 IIA. We do have processes to provide waivers, but without a waiver, they cannot use a foreign piece-part in any of our systems.

Mr. Dicks. Mr. Kingston.

Mr. KINGSTON. General, that just seems outrageous to me. And it would appear to me that within your Department that there would be equal outrage; in fact, that your outrage would be bigger than our outrage in terms of anybody selling counterfeit parts to a missile system so important.

Do you feel it? You don't strike me as a real emotional guy, which is good. But is anybody there pounding the desk and saying

this is—somebody has got to go to jail?

General O'REILLY. Sir, our process for that is, first of all, we turn it over to the Justice Department. Second of all, we prohibit them as a supplier to the Defense Department, immediately to MDA. We submit them to be a prohibited supplier in the future. So what we try to do is put it out of business.

Mr. DICKS. Will the gentleman yield on this point?

Has anybody been put out of business? General O'Reilly. We have—sir, I know of several incidences a couple of years ago. I can provide you the data on that.

Mr. DICKS. That would be good.

[The information follows:]

MDA has experienced several instances of counterfeit parts. For example, a counterfeit operational amplifier, which can be used on multiple MDA systems, was identified on MDA hardware during testing. The failed part was found on a circuit board supplied by a subcontractor. It was later determined that the subcontractor purchased these parts from a parts broker who was not authorized to distribute parts by the original component manufacturer. In another instance, a counterfeit microcircuit, which can be used on multiple MDA systems, was identified on MDA hardware. MDA's visual inspection showed that the part was resurfaced and remarked, which prompted authenticity testing. Tests revealed surface scratches, inconsistencies in the part marking, and evidence of tampering. These parts were purchased from a parts broker who was not authorized to distribute parts by the original component manufacturer.

MDA reports instances of counterfeit parts to the Department of Justice (DOJ) for criminal investigation and possible prosecution. In October 2009, DOJ announced that it had indicted three individuals in connection with sales of counterfeit electronic components through several distributors, including MVP Micro, Red Hat Distributors, Force-One Electronics, Becker Components, and Pentagon Components. In January 2010, one of the defendants pleaded guilty to charges of Conspiracy to Traffic in Counterfeit Goods and Defraud the United States and to the Trafficking in Counterfeit Goods. MDA also issued a formal advisory to its program offices to determine whether there had been any other parts procurements from these distributors and confirm that these entities had been removed from all Approved Vendor

Lists at the contractor and subcontractor level

Counterfeit parts are addressed as part of MDA Parts, Materials, and Processes Mission Assurance Plan which includes instructions on part selection, procurement, receipt, testing, and use of parts. MDA further has applied DOD's item-unique identification technology that provides for the marking of individual items. In addition, MDA issues formal bulletins that alert MDA staff of counterfeiting techniques and how to detect them.

Mr. DICKS. Also, what is their excuse? What do they say when

they are confronted with this?

General O'REILLY. Sir, we deal with the prime contractor. I don't know. It is a criminal act and we turn it over to the Justice Department. We then immediately find a new supplier and change the design if we have to avoid ever using those components again.

Mr. Dicks. But you are not getting a new prime. You are just

getting a new subcontractor.

General O'REILLY. Yes, sir.

Mr. KINGSTON. It would seem to me that the prime contractor would have some vulnerability.

Mr. Dicks. He is the one that selected the prime—the subcon-

tractor, right?

General O'REILLY. That is right. Sir, this is a problem that we deal with in the Department; that is the use of cost-plus contract. A cost-plus contract is intended in order to say that there is a risky technology or something we are pursuing that is not mature. And instead of the contractor absorbing the whole risk, the government, for most risky technologies, like a lot of the missile defense ones, we share the risk of them proceeding in a risky development. It was never intended, but there is no distinction in our contracts today, our older contracts, to distinguish between a legitimate development risk and negligence or a defect.

And so our new contracts that we are moving forward—and we are reviewing \$37 billion in contracts right now—our new contracts, we are aggressively using fixed-price contracts where we can; which means when you spot counterfeit parts it is on the prime contractor to pay for the impact of that.

And we are also adding in defects clauses.

#### HOMELAND DEFENSE

Mr. KINGSTON. I want to move on a little bit.

I want a Rotary Club takeaway here. When we move from agriculture to education to health care to ballistic missile defense, what would you say in terms of your number one goal, defending the homeland against a limited ballistic missile attack, where are we on the scale of 1 to 10, 10 being 100 percent secure?

General O'REILLY. Sir, we have conducted three out of three successful tests of a geometry that shows missiles being launched from North Korea and our interceptors coming out of Alaska. That is the tests where we launch the interceptor—the target out of Kodiak and we launch out of Vandenberg. We have shown it is technically viable.

The Director of Operational Tests and Evaluation has calculated that to have a statistical confidence you would need to repeat that test 17 times, and each test is over 200 million.

So I think what is more critical is when we are going to complete the testing on these systems—and that is what our integrated master test plan does—to validate our models so we can run thousands of runs in order to get a high confidence level in this capability.

We know we have capabilities, sir, but I can't quantify like I

would like to be able to of what that probability is.

Mr. KINGSTON. Two hundred million dollars just for one test?

General O'REILLY. For a GBI test, yes, sir. Again, we are now testing at greater ranges. The latest one was \$279 million. We were launching out of the Marshall Islands and the intercepter out of Vandenberg.

Mr. KINGSTON. If you were going to guess where our biggest threat is, what would you say, what could be—fast forward in the tape if you could make a prediction.

General O'Reilly. In defense, sir?

Mr. KINGSTON. Yes

General O'REILLY. ——

Mr. KINGSTON. Would it come from a rogue nation or where would it come from?

General O'REILLY. Sir, our concern is they are being sold on the arms market. So they do not discriminate. So nonstate actors do have a potential to have these.

#### NATO BMD FUNDING

Mr. KINGSTON. Okay, then I have one more question, Mr. Chairman.

I wanted to know on the European contribution, you had said they do the first level.

General O'Reilly. That is the proposal, yes, sir.

Mr. KINGSTON. And how much is that in terms of a percent of the total of their defense? What is their lift compared to American taxpayers?

General O'REILLY. Sir, our rough calculation of the value of the missile defense assets they own today, and several countries do, is about \$2 billion that they already procured.

Mr. KINGSTON. What would be the total defending Europe—and I understand it is not just defending Europe—but defending Europe, what is the total price tag for that?

General O'REILLY.

Mr. KINGSTON. I am really worried about the dollars here.

General O'REILLY. They need a lot more of them.

Mr. KINGSTON. But we are spending \$12 billion. What are we

proposing that they spend?
General O'REILLY. They would have to make a determination of what they want to protect at that lower level. And that is what is going to occur in the Lisbon Summit, between the heads of states of NATO. Today they haven't declared that they will protect territory of Europe, and that is a first step.

Then the second step-and NATO does have studies going on looking at what is the priority of what they are trying to protect

and their investment strategy

Mr. KINGSTON. At Lisbon, if they vote not to participate, what do we do with the upper tier?

General O'REILLY.

Congresswoman Kilpatrick.

#### STRATEGY BALLISTIC MISSILES

Ms. KILPATRICK. Interesting discussion. I think I am trying to visualize.

Let me ask you this: What missile system is the strongest defense system in the world? What countries?

General O'Reilly. For missile systems?

Mr. DICKS. Are you talking about offensive or defensive?

Ms. KILPATRICK. How can you separate them?

General O'Reilly. Offensive, the threat missiles, if you remove the United States

Ms. KILPATRICK. I don't want to remove them.

General O'REILLY. The country that has the most missiles today is Russia; the second country is the United States; and the third is China.

Ms. KILPATRICK. Do you base my question on the number of missiles they have or the best defense system that there is?

General O'Reilly. Our intelligence estimates look at the effectiveness of the threat. So it is the most egregious threats are the ones that have the most potential.

Ms. KILPATRICK. So which is the best system of the three that vou named?

General O'Reilly. -

Ms. KILPATRICK. So U.S. in that regard.

General O'Reilly. For offensive strategic accurate weapon.

Ms. KILPATRICK. And Russia would be how in that same sce-

General O'Reilly. -

Ms. KILPATRICK. And Russia is now our friends. We work with them. They are one of our allies, are they not?

General O'REILLY. They are not an ally, but we do work with them. We have agreements that we do surveillance on each other's systems. So we do know—and they do inform us and they have done that—every time they move their systems.

Ms. KILPATRICK. So we have a working relationship, say, not al-

lies. What would they be to us? We use their parts.

We meet with them. We discuss the security thing. General O'REILLY. We have an ongoing open dialogue for years, going back to the original STARTs. We exchange data back and forth on our systems.

Ms. KILPATRICK. I am trying to move to Iran and North Korea and all of them.

Is Iran—you didn't name them in that top three. Do they have the capability that the other three that you mentioned have?

General O'Reilly. No. They are pursuing it, is our intelligence estimate. So are the North Koreans. But, no, they don't today.

Ms. KILPATRICK. Okay, so that is good. They are still in testing, then. They are trying to get there.

General O'REILLY. They are trying to get there.

Ms. KILPATRICK. So between Syria, Iran, China, North Korea, we have better offensive and defensive missile defense systems than they at the current time?

General O'Reilly. Yes.

Ms. KILPATRICK. If we use some of our other partners—I guess Russia would be one of those—does Russia have the same relationship with Iran and North Korea that we have? Are they in that realm? They agree on some things and some things they don't, or are they like our country?

General O'Reilly. They do have ongoing dialogues and relationships with both North Korea and Iran.

Ms. Kilpatrick. Then on the video that we saw, the laser. Does it operate in bad weather, in clouds? Is any of that interrupted?

General O'REILLY.

Ms. KILPATRICK. How much is it going to cost to develop that testing? We want to get you what you need. Is it in addition to in our Congress, everyone wants to cut the Defense budget because it is the money that we need to secure, and I am for securing as much as we need.

Is the phase-in 2014 that you mentioned, 2015, going to mean that we can reprogram some old money, or is it all new money that we are talking?

General O'REILLY. It is all new money that we are proposing in this budget. However, there are two reprogramming actions on the Hill here today right now; one to complete the missile field in Alaska to provide us the eight additional silos to give us some additional hedge for the future; and the other is to upgrade more Aegis ships to BMO capability sooner. So those actions are on the Hill today.

## STANDARD MISSILE-3 IIB DEVELOPMENT

Ms. KILPATRICK. I commend you for your knowledge, and the physics background that you have obviously helps that.

Lastly for me, if there was one thing that you would ask this committee to do or support in your capacity as Director of MDA, what would that be?

General O'REILLY. I believe it is the support for the SM-3 IIB missile. And the reason for that is that regardless of the intelligence estimates, my concern is these technologies are out of the box. People are aggressively working on long-range mobile missiles and they have shown over and over again they are willing to sell them to anybody who will buy them.

So it may not be this decade, but it would be hard to say it wouldn't be the next decade that we could face threats from all directions. We have to convince these people it is not worth even pursuing. And therefore having missiles like an SM-3 II8 that could shoot down a missile over a country that is launching the missile would deter them and persuade them, like we have done with their air forces, to stop investing in these missiles.

Ms. KILPATRICK. Thank you very much.

Thank you, Mr. Chairman.

Mr. DICKS. Now I want to recognize Mrs. Granger, and I notice that she has an apple there.

And General, can you tell us why that apple is there?

General O'REILLY. My mother taught me to always bring an apple and give it to your teacher. And believe it or not, I don't know what the odds are of missile defense, but the odds here are pretty high.

Should I say how long ago it was, ma'am?

Mr. DICKS. That is one thing you don't. Strike that from the

record. If you were both much younger.

General O'REILLY. A few years ago I was briefing Congresswoman Granger and she asked me where I was from, and I informed her I was from her district. And then she asked me where I went to high school and where my parents lived. And it became quickly apparent that we have known each other many years ago when I was 16, and I don't know how old she was.

Mr. DICKS. But she was the teacher, right?

General O'REILLY. Yes, sir. Congresswoman Granger was my high school English teacher, I believe my junior year in high school.

Mr. DICKS. You told us that she vigorously corrected your papers. General O'REILLY. You may think I am worried about these questions that committees ask. I am worried about having my former English teacher correcting my grammar.

### ARROW-3 DEVELOPMENT

Ms. Granger. When you were talking about the defense of Europe and you said, "We are going to have to propose," and so I was going to come back to you and say, Does that mean they haven't decided not to? Then you told us about the Lisbon Summit, so we will watch that very carefully.

I want to ask you to go back to something that we have talked about, you and I talked about, and that is the critical importance of the relationship with the U.S. and Israel. And I want to ask you about the Arrow-3 program and how that is progressing and the

challenges it presents and how we are coming along with the project agreement.

General O'Reilly. ——

So we have a program laid out with them that very systematically monitors their progress, and we do assist with them, and U.S. companies like Boeing are participating with them on this program.

Ms. Granger. I was aware that it was more costly and going to take more time, but they are absolutely committed to it. So I thank

you.

I would suggest to anyone—I did, because I am his former teacher, and because I wanted more information. You gave me a briefing that was very helpful just generally on all of these missile programs and what they do. And it was very helpful to me in understanding and be able to then zero in on particular issues.

Mr. KINGSTON. Was he still trying to get extra credit? Is that

what this was about?

General O'REILLY. When I briefed her, she gave me a gold star at the end. I was hoping there was no homework.

#### PHASED ADAPTIVE APPROACH

Mr. DICKS. Mr. Rogers.

Mr. ROGERS. General, some people are concerned that the new Nuclear Posture Review weakens our missile defense efforts. In 2009, the administration scrapped the planned missile defense systems in Poland and the Czech Republic, coincidentally turning its back on two very staunch allies in the effort to, I think, appease Russia. Am I correct on that?

General O'REILLY. No, sir. When I was advising the Secretary of Defense and others in this, our primary concern with the other program is it takes 5 years to build the missile field. And if we found we didn't have enough missiles, we would be vulnerable for 5 more

years until you can upgrade the missiles.

So the concern was not enough missile defense. We needed to procure or pursue a system that was more affordable, that could in fact—because GBI cost 70 million apiece, the missiles we are proposing now are between 10 to 15 million apiece. We project we are going to need hundreds—instead of 10, hundreds of interceptors in Europe if the threat emerges, as some of the intel predictions are.

Mr. ROGERS. Why did we scrap Poland and the Czech Republic? General O'REILLY. Sir, I was part of the—Under Secretary Tauscher and Under Secretary Flournoy and I went to Poland the

day the President made the announcement.

When we landed at the airfield in Warsaw, the first thing we saw was a London Financial Times telling us how the meeting went that we hadn't even held yet. There was a complete fabrication on what had occurred in the announcement. I was one of the three that announced this to the Polish Government.

We listened for an hour respectively, as they were very upset that we had left them hanging. And at the end of the hour, we then explained to them we still want to put an intercepter system in Poland; and they looked at us and said, But that is not what we were

told.

And myself and Secretary Flournoy and Secretary Tauscher said, "We are here on behalf of the President. We do want to have missile defense here. We are continuing our agreements on the deployments of Patriot and to put the command and control system we had before." And frankly, instead of having 10 interceptors in Poland, they could have as many as a hundred and-

Mr. Rogers. Where do we stand now? Are we going to have mis-

siles in Poland?

General O'REILLY. Yes. And they have agreed to that, sir.

Mr. ROGERS. And effectively, what will those missiles defend against and whom?

General O'REILLY.

Mr. Rogers. Well, again, the question is why are we paying for the protection of Europe, especially those areas where we do not have troops of our own or installations that we need to protect? Why are we doing this? Are they going to help us with the costs, the Europeans?

General O'REILLY. Sir, that, again—NATO is reviewing that right now, and the first step is to agree to protect themselves. That

is the Lisbon Summit.

But, second of all, once you have this separate tier protection for ourselves, it does have zones of about 2,000 kilometers. With Article 5 and NATO, if we have a capability to defend NATO, we must under the article launch our interceptors to defend NATO, which is part of the indivisability of NATO that goes back to the very beginning.

Mr. ROGERS. Well, will we be pushing NATO and/or the Euro-

peans to help pay the costs of these deployments?

General O'REILLY. Yes, sir. Two weeks, ago, I spent 4 hours, privately, with the Secretary General of NATO. He came to Colorado, and we showed him all of our demonstrations and our simulations and so forth, and we had very long discussions on what would be the cost to NATO and what would be the changes in the command and control and so forth, for them to have an Integrated Missile Defense System.

Mr. Rogers. So the Lisbon Summit will, hopefully, decide the European defense posture; correct? Who pays for it, where the mis-

siles will be?

General O'Reilly. Yes, sir. Without their agreement to protect themselves, and it is a U.S. commitment only, or bilateral, with each of the countries.

Mr. Rogers. Well, in September of 2009, the President introduced what is called a Phased Adaptive Approach for missile defense in Europe. What is that and what does it have in relation to the Lisbon Summit?

General O'REILLY.

The second step, then, would be the Phased Adaptive Approach. As we are developing new missile capabilities with the SM-3 and the THAAD and our forward-based radars, we will deploy the capability, as they are being tested and proven and accepted by the services, first deployment in 2011, the second deployment in 2015. And these deployments are geared by our intelligence estimates of what range the Iranians can reach if, in fact, they are successful in the development of their own systems.

Mr. ROGERS. So this will be a NATO-run program, do you think? General O'REILLY. ——

#### ALTB CONCEPT OF OPERATIONS

Mr. ROGERS. Now, in closing, a wholly different subject. In the video, what is the planned protocol for stationing the aircraft, the laser-armed aircraft, in a defensive situation? Obviously the plane has to be fairly close to the launch phase, right? How would you have those planes deployed on a routine basis?

General O'REILLY.

Mr. ROGERS. Well, on a worldwide mission, you are going to need

a lot of planes.

General O'REILLY. Sir, that is why this would be a great capability to surge. That is why we are proposing to have many different missile defense systems so that the combatant commanders that I am working with today put the appropriate system against the appropriate threat.

Chairman DICKS. Would the gentleman yield?

Mr. Rogers. Yes.

Chairman DICKS. A possibility would be you would have planes off of North Korea.

General O'REILLY. Yes, sir.

Chairman DICKS. Or off of Iran as a possibility. So if tensions rose, we had some indication that they might do something, then you could deploy these airplanes and you could attack a missile in boost phase.

Mr. ROGERS. Well, that is what I am talking about. And, like Iran, where to get close to a launch site that might be inside the middle of Iran, I don't know how you would be able to patrol close

enough to—

General O'REILLY. Well, again it is what we call goal-tending from hockey. If you know where the threat missiles are coming and you know what you are trying to defend, and you have a mobile defense, you can put the defense and put the aircraft between where they are being launched and where they are going.

So we have an idea. We know what trajectories they would have to use if they were going to threaten the United States. So we are in their path, and we let them come towards us as well as shooting

them. That would be part of the strategy.

But, again, this would be more applicable to a system where, when tensions rise, like many of our defense systems, we surge them into an area and then you have, for a limited time, a very high capability.

But to deploy them globally, constantly, we do not do that with

any of our defense systems because of affordability.

Mr. ROGERS. But I assume you would, for the moment. You would be patrolling around Iran and North Korea, would you not,

if you had the capability?

General O'REILLY. Sir, that is why we work with the combatant commanders, and they would determine that capability because of training and other things. That is why we went with an Aegis ashore, where you can have a semipermanent protection and then you have mobile systems, both sea and aircraft. They are not to act as—our proposal is they are not to act as a permanent defense.

They are surged when they are needed because it would be cost-

prohibitive to keep them there constantly.

Mr. ROGERS. Final question. In your realism talk, what do you think the distance, the range, will finally be of the airplane-borne laser capability?

General O'REILLY.

Mr. ROGERS. Got you. Thanks, General.

Chairman DICKS. Mr. Rothman then has a final question.

Mr. ROTHMAN. Yes, sir, thank you, Mr. Chairman. I appreciate it.

It is a two-part question. It is regarding the airborne laser and part one is, how high will it fly? My concern is countries objecting, certain countries to our overflying their territory, albeit at 400 kilometers out. But what countries would those be, and are they all friendlies who would permit to us overfly their countries, and how high would they be?

Mr. ROTHMAN. Right.

General O'REILLY. And you could actually use the defensive systems of Japan in order to assist our aircraft. So it really does depend on geometries, but what we are working for is to give the combatant commanders this capability so that they can determine the best use.

Mr. ROTHMAN. And so you build in—the SAMs will have a longer range in the future,

General O'REILLY. Yes, sir.

Mr. ROTHMAN. So at 50,000 feet we don't care about overflight

General O'REILLY. Yes, sir, we do. And that is an issue that we have today. But usually this is used in a time of war and when tensions have risen and those are—we are given those rights—

Mr. ROTHMAN. We have already identified those countries, the

racetracks?

General O'REILLY. No, sir. We actually work with that all the time. We have recently received overflight rights from the Russians but it is a continual diplomatic dialogue.

Mr. ROTHMAN. Thank you, General. Thank you,

Mr. Chairman.

# THAAD TESTING/PRODUCTION

Chairman DICKS. Let me just go through, give us a little update on THAAD. How is THAAD doing?

General O'Reilly ——

The next two big decisions for THAAD is, number one, that the Army formally accepts it and it will be transferred, the first unit to the Army, and the Army will operate it, not MDA at that point. That will occur in January; it is scheduled upcoming January.

Chairman DICKS. 2011.

General O'REILLY. 2011. That will be the Army's first fully operational THAAD unit. ———

I am requiring that they solve that before, in fact, we go to our first full-rate production decision. The United Arab Emirates have put in a request to purchase two THAAD units and a forward THAAD-based radar at the cost of \$6.9 billion, and their request is to have a THAAD unit by 2014.

Chairman Dicks. Who is the contractor on THAAD?

General O'REILLY. Lockheed Martin is the developer of the missile and the whole system, and Raytheon develops the fire-control system and the radar.

Chairman DICKS. How is Raytheon performing?

General O'REILLY. In the Raytheon area, they have performed very well with their radar and their fire-control system on this.

### PAC-3 INTEGRATION

Chairman DICKS. Okay, what about PAC-3?

General O'REILLY. Sir, I currently do not have responsibilities for PAC-3. That is an Army program. The Army is looking at, in discussions today, and has been asking us about a possible transfer of PAC-3 back to MDA. And that is a decision that they are discussing at this time.

Chairman DICKS. What is the reason for that?

General O'REILLY. The approach to MDA used to be, back 5 years and beyond, was that we would develop the technologies and develop systems ready for production, and then we would hand them off to the services and we would produce the systems. The decision has been made since then, over the previous administration and this administration, is that due to the constant need to upgrade our missile defense systems as the threat keeps changing, I am now responsible for the lifetime of the systems, for the Navy systems, for all of them, and PAC–3 had just matured early, or matured at the point where it was transferred to the Army. Today it wouldn't have been transferred to the Army; just like Aegis and THAAD, stay with the Missile Defense Agency.

So because of that, they are going back and looking at should they revisit the decision on moving PAC-3 possibly back to MDA so that the Army then gets the benefits of the rest of our national effort that I lead.

Chairman DICKS. How do you feel about it?

General O'REILLY ———

Chairman DICKS. So who in the Army—this will go up to General Casey?

General O'REILLY. Yes, sir—and the Secretary of the Army are currently reviewing this. At their request—it was their initiative, not MDA's, to retook this decision.

#### SBX TESTING

Chairman DICKS. We have discussed a lot of things today, but is there anything on the radars, again, that stands out in your mind that we need to—

General O'Reilly ———

When you are dealing with a solid rocket motor, it actually, what we call chuffs, it produces bits and pieces that are burning still, that come out of the back end of the missile and produce a lot of fiery hot objects, that are just part of the debris that comes out of the back of a missile, a solid missile, as it burning.

And as we said, the Iranians are working on a solid rocket motor missile, so we need this capability for the future, sir.

Chairman DICKS. Okay. Well, thank you very much.

The committee stands adjourned until May 13 at 10:00 a.m., when we will hold a hearing on the United States Pacific Command and U.S. Forces-Korea.

Thank you, General. You did a great job.

[CLERK'S NOTE.—Questions submitted by Mr. Dicks and the answers thereto follow:]

### PRECISION TRACKING SPACE SYSTEM (PTSS)

Question. Another new program in the FY2011 budget request is PTSS which is intended to track a missile after boost phase and cue Aegis. This is a follow on program to STSS however is still a demonstration satellite

How is this new demonstration satellite different that STSS that was launched

on September 25, 2009?

Answer. The Space Tracking Surveillance System (STSS) was designed from preexisting work on the Space-Based Infrared System (SBIRS) program and will accomplish the following objectives:

· Provide critical data on how a space-based sensor could be used to track missiles and their released mid-course objects to close the fire control loop from space;

• Assess space layer performance in Launch-on/Engage-on Remote scenario of

an intercept of a ballistic missile in flight;

- · Measure latency of BMDS communications and weapon system/Command and Control, Battle Management, Communications (C2BMC) integration and interfaces;
- Assess user/warfighter (i.e., CONOPS gaps) in operating a Low Earth Orbit (LEO) space constellation in support of BMDS operations;

Familiarize the warfighter with precision space tracking;

 Collect LEO based phenomenology, atmospheric and environmental data; and

· Conduct observations and monitoring in support of other missions, not nec-

essarily related to BMDS tracking.

The objective of the Precision Tracking Space System (PTSS) program is to address the ascent-phase, midcourse tracking challenge facing the joint warfighter. PTSS is a simplified system with the minimum necessary functionality to cost effectively provide midcourse tracking data and is an integral part of the extended Aegis fire-control system and early intercept capability—a key focus of the Missile Defense Agency (MDA). PTSS will leverage high Technology Readiness Level (TRL) space system components and improvements in BMDS Command and Control, Battle Management, and Communications. This approach will minimize the need for new technology development that may drive up costs and increase development

MDA is incorporating lessons learned from the STSS demonstration satellites to inform our decisions on the development of PTSS, specifically in the areas of phenomenology and fire control. STSS phenomenology data (i.e., infrared scene collections such as atmospheric GC 611 315 lot backgrounds, clouds, earth limb observations, etc.) will be used to anchor models essential to the missile tracking mission. In the case of PTSS, this category of collections is planned to be used in payload design, and validate the selection of optics, focal planes, wavebands of interest and data processing. STSS uses on-board processing to autonomously generate missile target tracks and pass that data to the ground control system. The PTSS program will analyze STSS processing performance to determine the level of on-board processing required, from a system-wide perspective for PTSS. PTSS program goals are to:

• Develop an operational, end-to-end, missile tracking capability from space

focusing on regional ballistic missiles;

- Develop and test a space system prototype and integrated ground system with BMDS to precisely track missiles with sufficient accuracy and low enough latency to provide sensor data to BMDS interceptors to defeat large raids from regional threats;
- Establish the technical and programmatic foundation for procuring the operational system;
- Develop space qualified technology to hedge against future missile threat growth; and Fully integrate PTSS space and ground systems into the BMDS architecture

Question. Why is MDA pursuing another demonstration satellite that will not have the appropriate capabilities?

Answer. The objective of the Precision Tracking Space System (PTSS) program is to address the ascent-phase, midcourse tracking challenge facing the joint warfighter. PTSS is an integral part of the extended Aegis fire-control system and early intercept capability, which is a key focus of the Missile Defense Agency (MDA)

Challenges and problems associated with past satellite development programs in-Challenges and problems associated with past sateline development programs indicate that a stable baseline and risk reduction is necessary to improve development timelines. To that end, the Missile Defense Agency (MDA) will establish Precision Tracking Space System (PTSS) requirements baseline upfront and early and discourage future growth without operational necessity. The MDA also intends to leverage heritage, high TRL space system components for the PTSS. This approach focuses on component reuse and integration and minimizes the need for new technology development and custom design which will drive costs up and increase development. nology development and custom design which will drive costs up and increase development timelines.

Developing prototypes prior to making production decisions will ensure that proper Technology Readiness Levels (TRL) are achieved, thereby improving our development timelines. The PTSS acquisition strategy is to develop a prototype system with Johns Hopkins University's Applied Physics Laboratory before awarding production development contracts to industry. Additionally, we will award contracts to several industry participants during concept development and exploration to insure the prototype can be readily produced by industry. Industry engagement during the prototyping phase will greatly improve the level of understanding by the contractors and reduce risk for PTSS production. This partnership between industry and the scientific community will ensure our understanding of requirements before we award production development contracts.

The crawl-walk-run approach to space system development has shown great success in prior programs, such as the efforts that led to the Global Positioning System program.

Question. How are the mission requirements different than those for STSS?

Answer. The Precision Tracking Space System (PTSS) plan calls for simplification of STSS as much as possible and takes advantage of several improvements in capability over the past decade. PTSS will utilize MDA's Command and Control, Battle Management, Communications (C2BMC), significantly reducing the requirements on PTSS for command, control, battle management, and communications as compared to those levied on Space Tracking Surveillance System (STSS). In addition, PTSS will receive missile launch cues from Overhead Persistent Infrared systems, reducing the sensor requirements on PTSS, again, as compared to those on STSS. PTSS will also be integrated as part of space layer leveraging external space systems with a common ground processing node that is interfaced to the battle manager.

Question. Will PTSS have mid-course tracking capabilities?

Answer. Yes. The requirement for Precision Tracking Space System (PTSS) is to enable mid-course tracking closing the fire-control loop, and enabling early interpretations.

enable mid-course tracking, closing the fire-control loop and enabling early intercept.

# TARGET ACQUISITION

Question. MDA is also addressing the need to have more reliable and less costly targets. The new target acquisition strategy, initiated in FY 2009, streamlines a set of target classes to increase quality control, account for intelligence uncertainties, control costs, and ensure the availability of backup targets.

Since it takes about two years to build and deliver a high quality target, when

do you expect to complete the new target acquisition strategy?

Answer. Request for Proposal (RFP) was issued for the Intermediate Range Ballistic Missile (IRBM) targets in the second quarter of FY10. The draft RFP for the InterContinental Ballistic Missile (ICBM) target is anticipated for release 4QFY10. The IRBM contract award schedule is dependent on the volume/quantity of proposals received, but award is planned for 1QFY11. The ICBM contract award is planned for 4QFY11.

Question. What is the timeframe the new strategy will be realized?

Answer. Over the past year, the Agency has initiated steps to implement the new target acquisition strategy. The initial step was to streamline the current Lockheed Martin contract to provide the near term IRBM targets with the LV-2. Secondly, two classes of new targets are to be procured.

• The IRBM class of targets is being acquired through the release of an RFP in 2QFY10 with contract award 2QFY11 and first target delivery milestone in 2QFY14.

The ICBM class of targets is being acquired by release of RFP in 4QFY10 with contract award 4QFY11 and first target delivery milestone in 3QFY14.

Question. What types of targets will you be acquiring?

Answer. In accordance with the Targets and Countermeasures Acquisition Plan (3 November 2009), MDA will acquire targets in the following classes:

• Intermediate Range Ballistic Missiles (3000–5500 km or 1620–2970 nm)

InterContinental Ballistic Missiles (greater than 5500 km or 2970km)

#### GMD FLIGHT TEST DELAYS

Question. GMD has planned 11 flight tests and 14 ground tests in fiscal year 2011. Many previous tests have been delayed or cancelled. This test schedule contained 9 additional tests compared to FY2010.

The Committee understands that many test events scheduled in previous years

Answer. In 2005 the Missile Defense Agency (MDA) Director established a Mission Readiness Task Force (MRTF) to address all issues contributing to flight test mission preparedness and strengthen systems engineering and quality. The new processes that were adopted greatly improved the success of Ground-based Midcourse Defense (GMD) testing. The attached "GMD Flight Test Delay History—EV06 to EV10" chart shows each flight test incoursing delay size. EV2002 at 1.12 FY06 to FY10" chart shows each flight test incurring delay since FY2006 and the

reasons for the delay.

In Fiscal Year 2009, MDA transitioned from an architecture-based approach to a Models and Simulations (M&S) Verification, Validation, and Accreditation parameters-based test objectives approach. The Integrated Master Test Plan (IMTP) is used to evaluate research and development milestones, technology maturity levels, and coverage and performance analysis. The IMTP establishes and documents test requirements of the GMD element with specific focus on collecting data needed for the Verification, Validation, and Accreditation (VV&A) of missile and threat models and simulations. Models and simulations permit repeated assessments of performance and provide a statistical determination of effectiveness of GMD capabilities. Ground tests using these high fidelity models and simulations test GMD capabilities across a range of threats and environments that cannot be affordably replicated in

flight tests.

The Missile Defense Agency remains committed to successfully executing and completing the IMTP. The development and testing schedule within the IMTP is realistic, accounts for the possibility of testing anomalies, and is updated semi-annu-

ally. The next update is expected to be complete by July 30, 2010

Question. Can you explain primary reasons behind the rescheduling of prior year

Answer. In Fiscal Year 2009, MDA transitioned from an architecture-based approach to a Models and Simulations (M&S) Verification, Validation, and Accreditation parameters-based test objectives approach. The Integrated Master Test Plan (IMTP) is used to evaluate research and development milestones, technology maturity levels, and coverage and performance analysis. The IMTP establishes and documents test requirements of the GMD element with specific focus on collecting data needed for the Verification, Validation, and Accreditation (VV&A) of missile and threat models and simulations. Models and simulations permit repeated assessments of performance and provide a statistical determination of effectiveness of GMD capabilities. Ground tests using these high fidelity models and simulations test GMD capabilities across a range of threats and environments that cannot be

affordably replicated in flight tests.

The Missile Defense Agency remains committed to successfully executing and completing the IMTP. The development and testing schedule within the IMTP is realistic, accounts for the possibility of testing anomalies, and is updated semi-annu-

ally. The next update is expected to be complete by July 30, 2010.

Specific challenges in the Ground-based Midcourse Defense (GMD) flight test program include acquiring a cost effective set of reliable targets and Ground-Based Interceptor quality control issues. MDA has taken action to address both of the chal-

For example, as a result of a Short Range Air Launched Target (SRALT) failure during a THAAD flight test in December 2009 MDA issued a Cure-Notice and directive to cease air-launch operations to repair program deficiencies. This resulted in a delay to the BMDS test program impacting cost and schedule of multiple major BMDS weapon systems and capability delivery to the Warfighter. To bridge the time between the delivery of these targets and our new competitive target procurements next year, the MDA initiated a limited procurement of Air Launched Targets through its existing Lockheed Martin contract. Lockheed Martin is evaluating the target options to satisfy MDA's requirements and have not made a final target solution decision. As with all of our target providers, MDA fully expects Lockheed Martin to select and deliver a target solution that meets the performance specification

thresholds within the cost and schedule parameters.

Over the past year MDA also initiated steps to acquire a new set of targets for all ranges, including Foreign Material Acquisitions, needed to verify the performance of the BMDS. Our new target acquisition strategy, initiated in FY 2009, procures targets in production lots to increase competition, quality control, reduce costs, and ensures the availability of backup targets starting in 2012. Accordingly, MDA issued a Request for Proposal (RFP) for the Intermediate Range Ballistic Missile (IRBM) targets in the second quarter of FY10; a draft RFP for the InterContinental Ballistic Missile (ICBM) target is anticipated for release 4QFY10 with contract award planned for 4QFY11; the IRBM contract award is planned for 1QFY11, but the contract schedule is dependent on the volume/quantity of proposals received. Nevertheless, until backup targets are available starting in 2012, we will continue to rely on an intensive inspection and oversight process to enhance mission assur-

Quality issues are also a primary driver and a high focus area for GMD. Built-in-test software and test silo quality issues caused delays in 2005. Challenges in Exoatmospheric Kill Vehicle (EKV) development, hardware quality, and target availability and target development issues drove test schedule delays in 2007–2009 affecting flight tests FTG-03, FTG-04, and FTG-05.

MDA is committed to improving missile defense acquisition to overcome signifi-

and flight test delays, target and interceptor failures, cost growth, quality control, and program delays we have encountered in the past. Moving forward, MDA is implementing the Weapon Systems Acquisition Reform Act of 2009, including provisions related to contract competition, and it is our intent to use greater firm fixed price contracts and defeat clauses as we complete planned competitions. We are in price contracts and defect clauses as we complete planned competitions. We are increasing emphasis on competition at all phases of a program's acquisition life cycle to ensure the highest performance and quality standards are sustained throughout development.

However, until we complete planned competitions we will have to motivate some senior industry management through intensive inspections, low award fees, issuing cure notices, consideration of pending quality concerns during funding decisions for new contract scope, and documenting inadequate quality control performance to in-

fluence future contract awards by DoD.

Question. What issues remain to be resolved to reschedule delayed test events? Answer. There are no current delayed test events that have not been rescheduled or are in the process of being rescheduled. FTG-06a is being added as an incremental step in correcting the shorts comings of FTG-06. FTG-06a scheduling is in work. FTG-09 is being deleted and the objectives are transitioning to FTG-08.

FTG-06 was conducted on January 31, 2010 and resulted in a failed intercept. A Formal Independent Failure Investigation Team (FIT) was established to conduct Missile Defense Agency investigations into the failures to meet test objectives. The scope of the FIT included investigating all potential target, interceptor, ground systems, and any other area deemed relevant in the determination of root cause and contributing conditions associated with the failure; recommending corrective actions to preclude the reoccurrence of a similar event on future missions; and identifying design, integration, test, and readiness deficiencies discovered during the investigation that did not directly contribute to the failure. The FIT results will aid decisions on future GMD flight tests.

The FTG-06 Failure Investigation Team final report and its effect on possible courses of action to ensure a successful FTG-06a follow-on flight test are driving final planning activities and the overall GMD test schedule. Decisions on the FTG-06a test design and schedule are expected in June 2010. The Integrated Master Test Plan is under semi-annual review and will be updated to capture all GMD test planning changes as well as other BMDS test planning.

Question. How will this impact the current test plan for GMD? Answer. The FTG-06 Failure Investigation Team (FIT) final report and its effect on possible courses of action to ensure a successful FTG-06a follow-on flight test are driving final planning activities and the overall GMD test schedule. Decisions on the FTG-06a test design and schedule are expected in June 2010. The Integrated Master Test Plan is under semi-annual review and will be updated to capture all GMD test planning changes as well as other BMDS test planning.

FTG-06a is an incremental step in correcting the short comings of the FTG-06 mission. Once the FIT final report is complete modifications to the Ground Based

Interceptor will be incorporated as needed.

Question. How will the test plan review change the way MDA tests?

Answer. In FY09, MDA transitioned from an architecture-based approach to a Models and Simulations (M&S) Verification, Validation, and Accreditation param-

eters-based test objectives approach. This new test approach focuses on collecting data needed for the Verification, Validation, and Accreditation of the BMDS Models and Simulations and identifies the specific data to be gathered and the circumstances in which to measure them. For example, Critical Engagement Conditions of the Condition of the BMDS Models and Simulations and identifies the specific data to be gathered and the circumstances in which to measure them. For example, Critical Engagement Conditions of the Condition of the BMDS Models and Simulations and identifies the specific data to be gathered and the circumstances in which to measure the conditions of the BMDS Models and Simulations and identifies the specific data to be gathered and the circumstances in which to measure them. tions (CECs) and Empirical Measurement Events (EMEs) will examine the accuracy of GMD and BMDS models and simulation by measuring key factors affecting a kill vehicle's ability to see a target and adequately maneuver in time to collide with it. Key factors include: solar and lunar backgrounds; low intercept altitudes; timing between salvo launches; long times of flight; high closing velocities (ICBM-class targets); correcting for varying booster burnout velocities; and responding to countermeasures. This test approach will establish confidence that the M&S used to evaluate the BMDS represents real world behavior and enable simulation based performance assessment to verify system functionality. DOT&E and the operational test communities are key partners in this effort. The Integrated Master Test Plan describes each CEC and EME and is updated semi-annually. The next update is expected to be completed by 30 July, 2010.

#### TESTING AND LACK OF SUFFICIENT NUMBER OF TARGETS

Question. One of the key limiting factors of MDA's test program has been the lack of sufficient number of missile defense targets and the inventory of foreign assets. Do you currently have a sufficient amount of targets to execute your testing program? For the current fiscal year? For fiscal year 2011? Does the FYDP provide for sufficient number of targets?

Answer. Yes, we have sufficient quantity of primary targets on contract for the current fiscal year (FY10) and FY11; however, we do not have a sufficient number of spare targets in case of a target failure or other processing problems. Spare targets will be available starting in FY12. MDA plans to update the Integrated Master Test Plan (IMTP) twice a year ensuring executability within budget controls. For the remainder of the FYDP, we currently have the required targets on contract to support tests scheduled in FY12. The new Targets Acquisitions to be awarded in FY10 and FY11 will provide the remainder of the targets required across the FYDP in support of the IMTP Version 10.1, which was delivered to Congress in March

Question. If not, what can we do to improve the number of targets?

Answer. We have sufficient primary targets to support the PB11 program, but due to the 18–24 month lead time to produce a target, there is no opportunity to improve the availability of spare targets till FY13.

Question. Would additional funds in this area be helpful? Answer. The Targets and Countermeasures acquisition strategy for the new target procurements provides the opportunity to acquire flexible threat representative target configurations. The President's budget request represents an appropriate balance of risk given competing priorities for resources.

Question. Would having a procurement account be beneficial? Answer. No. The Targets and Countermeasures program will require RDT&E funding to perform non-recurring engineering activities associated with target development in the MRBM, IRBM, and ICBM classes against our new acquisition program in FY10 and FY11. Additionally, several on-going development activities in countermeasures along with improvements in existing target configurations require RDT&E funding. If procurement funding were provided it would be applied to the fixed price hardware Contract Line Item Numbers (CLINs) for targets procured on the new acquisition contracts only. The remaining CLINs for engineering services, modeling and simulation activities, or other related engineering activities would still require RDT&E funding.

[CLERK'S NOTE.—End of questions submitted by Mr. Dicks.]

## TESTIMONY OF MEMBERS OF CONGRESS AND OTHER INTERESTED INDIVIDUALS AND ORGANIZATIONS

## AMERICAN MUSEUM OF NATURAL HISTORY/OHIO STATE UNIVERSITY

#### WITNESSES

WARD WHEELER, Ph.D., CURATOR AND CHAIR, DIVISION OF INVERTE-BRATE ZOOLOGY, AND PROFESSOR, RICHARD GUILDER GRADUATE SCHOOL, AMERICAN MUSEUM OF NATURAL HISTORY

DAN JANIES, Ph.D., ASSOCIATE PROFESSOR, THE OHIO STATE UNI-VERSITY, DEPARTMENT OF BIOMEDICAL INFORMATICS, COLLEGE OF MEDICINE

## Introduction

Mr. Dicks. The committee will come to order. This morning the committee will hear testimony from witnesses outside of the executive branch. The committee is finishing its hearing process for the fiscal year 2011 period, and we have heard from all the Secretaries and Chiefs of each service.

The committee held hearings regarding the military's personnel programs, medical programs, intelligence programs, acquisition programs, the missile defense program. Now we are turning our attention to hear from 17 different public organizations which will highlight issues that the committee should consider as work continues on the 2011 base appropriations bill that we will fund in support of our men and women in uniform over the next year.

This hearing will allow the committee to understand the unique capabilities that outside entities can contribute to the needs of our servicemembers. The committee is aware that many of you have an existing relationship with the Department of Defense as it relates to medical research in support of the unique needs of our

The structure of today's hearing will follow a format that ensures all witnesses will have an opportunity to highlight their key points on the record. Further, each of your prepared statements will appear in full in the published hearing volume.

We ask that you summarize your testimony in 5 minutes or less. Because President Calderon is speaking at 11 o'clock, the hearing has to end, so at 5 minutes you are going to hear the gavel. We don't have the clock, do we?

I would like to express my gratitude to each and every one of you for the work you do on behalf of our Armed Forces. We look forward to your testimony, and I now yield to Mr. Frelinghuysen for any comments that he would like to make.

Mr. Frelinghuysen. I join the chairman and welcome you all this morning, and I commend him for having this hearing. Thank

you very much.

Mr. DICKS. Our first witness is Dr. Ward Wheeler, Ph.D., curator and chair, Division of Invertebrate Zoology, and Professor, Richard Guilder Graduate School, American Museum of Natural History; and Dr. Dan Janies, Ph.D., associate professor, the Ohio State University, Department of Biomedical Informatics, College of Medicine.

We will start you at 5 minutes to 9:00. You may proceed. We will

put your statement in the record.

Mr. Wheeler. Good morning. Chairman Dicks, my name is Ward Wheeler, and as chair of the Invertebrate and Zoology Division and Professor at the American Museum of Natural History, it is a pleasure and honor to testify before you about the global spread of emergent infectious disease and human health implications of viral evolution. With me today is Dr. Megan Cevasco, a research scientist who is actively involved in the project.

The recent emergence of a pandemic influenza and SARS has shown that new diseases can affect human populations without warning, presenting critical threats to our troops, public health and our economic welfare. Rapid genomic sequencing of these pathogens has become the primary method by which we understand,

fight and infer their spread.

Analysis of these data, however, is difficult, requiring new algorithmic approaches and high-performance computation. To provide an important basis for forecasting these outbreaks, the AMNH has been working over the past several years to apply our research expertise in evolution, geography and computation to the problems of

the emergence and spread of pathogens.

Recognizing the potential of this work to aid the Department of Defense in its goal to prepare for and respond to the full range of threats, the AMNH seeks \$3.5 million in fiscal year 2011 to continue contributing our unique resources to the advancement of research in this area. By increasing the Nation's capacity to infer where disease outbreaks might occur, and to effectively monitor disease-causing agents and their global spread, this research works directly to combat bioterrorism and to protect both troops in the field and civilian populations at home.

While the AMNH has been a recognized leader in education, educating the public on complex scientific issues, many people may not realize that we are also an active research and training institution, much like a research university, with major innovative research programs that are positioned to advance the Nation's capacity to

prepare for and respond to security threats.

AMNH research staff, who number over 200, publish nearly 450 scientific articles each year and enjoy a success rate in competitive peer-reviewed scientific grants that is approximately double the national average. AMNH is also the only American museum authorized to grant the Ph.D. degree. Our Richard Guilder Graduate School encompasses both a doctoral program in comparative biology and long-standing graduate training partnerships with such universities as Columbia, Cornell and NYU.

As our research on infectious disease requires biomedical expertise, as well as evolutionary and computational expertise, AMNH

has bonds with Dr. Dan Janies of The Ohio State University Medical Center in these efforts. Dr. Janies is here with me today and

will testify in just a moment.

First I would like to tell you what we have been able to accomplish with DOD support thus far. In fiscal year 2005, DOD and the AMNH launched a multifaceted research partnership via DARPA that leverages the AMNH's unique expertise and capacity. The first phase of this project focused on the development and application of a high-performance computational system to study the complex conditions that underlie the evolution and spread of infectious diseases, specifically analyzing genetic and functional changes in hosts and pathogens across time and space.

Concurrently we develop methods to visualize these data by projecting an evolutionary tree onto a virtual globe, such as Google Earth or NASA Whirlwind, and the resulting visualizations are akin to weather maps that show the spread of pathogens and their key mutations over time, space and various hosts. These maps provide not only situational awareness, but also diagnostic and infer-

ential power.

We are now able to track the global spread of any pathogen and can identify for any geographic region sources, destinations, mutations and host shifts by pathogens.

Mr. Dicks. You have got 2 minutes left, so if you are going to

share any time here, it is 5 minutes for the both of you.

Mr. Wheeler. We continue work, particularly in influenza. And I appreciate the opportunity to speak to you today. I will now give

the floor to my colleague Dan Janies.

Mr. Janies. Mr. Chairman, members of the subcommittee, I, too, am honored to have been invited to testify today. My name is Daniel Janies, and I am an associate professor of biomedical informatics at Ohio State. I bring biomedical expertise to the project. My efforts have focused on meeting deliverables, ensuring that the tools are highly interoperable, and communicating our results to military planners, public health scientists and policymakers.

We have engaged in a variety of outreach programs. We have conducted workshops and symposia, have published results in peerreviewed scientific journals, results that have been covered by journalists in many media. We have testified on pandemic influenza before the U.S. Senate Committee on Homeland Security and have

been invited to present our research to DHS.

We have also worked with the Department of State on efforts to build capacity in public health abroad to foster data sharing. We have discussed the evolution of drug resistance and pandemic influenza with the White House Office of Medical Preparedness. Throughout our partnership, DARPA program managers have supported the AMNH's work and made our research known to other DOD-supported scientists, have invited scientists from the AMNH and Ohio State to participate in today's conferences for research, planning and force protection.

Our work moves forward. We plan to continue our outreach efforts and plan to hold workshops and symposia annually, as well as to rapidly respond to requests for information, consultations and

briefings.

As you know, the committee has supported our work over the last several years. Should the committee fully support our fiscal year 2011 requests, the AMNH will be able to advance to the next phase of the project, focusing on more complex pathogens and the host side of the infectious disease problem.

Mr. DICKS. Thank you very much. We will take this under very sorious consideration

serious consideration.

[The statement of Mr. Wheeler and Dr. Janies follows:]

# Testimony of the American Museum of Natural History presented to the House Appropriations Subcommittee on Defense

## May 17, 2010

It is an honor and a pleasure to have the opportunity to testify before you about the global spread of emergent infectious disease and the human health implications of viral evolution.

The recent emergence of a pandemic influenza (H1N1) has shown that new diseases can come from nature to infect human populations without warning--presenting critical threats to force protection, to public health, and to economic welfare. As demonstrated by the coordinated international responses to both H1N1 and to Severe Acute Respiratory Syndrome (SARS), rapid genomic sequencing of these pathogens has become the primary method by which we understand, fight, and predict their spread. Analysis of these data, however, is very difficult, requiring new algorithmic approaches and high performance computation. Furthermore, we have only begun to understand how animal pathogens adapt to new hosts and travel to cause outbreaks in human populations.

To understand and predict outbreaks of infectious disease, we must better understand these processes over space and time. To provide an important basis for forecasting such disease outbreaks, the AMNH has been working to apply our research expertise in evolution, geography, and computation to the problems of the emergence and spread of pathogens. By increasing the nation's capacity to predict where disease outbreaks might occur and to effectively monitor disease-causing agents and their global spread, this research works directly to combat bioterrorism and to protect both troops in the field and civilian populations at home.

Recognizing the potential of this work to aid the Department of Defense in its goal to prepare for and respond to the full range of threats, the AMNH seeks \$3.5 million in FY11 to continue contributing its unique resources to the advancement of research in this area of science so closely aligned with DOD's research and defense priorities.

## About the American Museum of Natural History

The AMNH is one of the nation's preeminent institutions for scientific research and public education. Since its founding in 1869, the Museum has pursued its mission to "discover, interpret, and disseminate—through scientific research and education—knowledge about human cultures, the natural world, and the universe."

While AMNH has long been a recognized leader in educating the public on complex scientific issues, research, and events, many people may not realize that we are also an active research and training institution—much like a research university—with major innovative research programs in such areas as biocomputation, comparative genomics, and evolutionary and conservation biology—programs that are positioned to advance the Nation's capacity to prepare for and respond to security threats.

The AMNH research staff numbers over 200, with tenure track faculty carrying out cutting-edge research in fields ranging from molecular biology to astrophysics. Museum scientists publish nearly 450 scientific articles each year and enjoy a success rate in competitive (peer reviewed) scientific grants that is approximately double the national average. This robust scientific enterprise, with a century-plus record of leadership in field science, theoretical science, and the professional training of scientists, provides the foundation for a wide range of public outreach and educational initiatives for learners of all ages, backgrounds, and levels of preparedness.

These initiatives include professional development for teachers, out-of-school programs for pre-K-12 students, permanent halls, temporary exhibitions and space shows (which travel both nationally and internationally), public programs, major conferences, and special seminars and symposia.

In 2006, the Museum was authorized by the New York State Department of Education as the first American museum authorized to grant the Ph.D. degree. With this, the Museum launched the Richard Gilder Graduate School, which embraces both a new doctoral program in comparative biology and maintains the Museum's longstanding graduate training partnerships with such universities as Columbia, Cornell, New York University, and City University of New York. The Ph.D. program in comparative biology has now admitted two classes of students and is fully accredited.

As our critical research on infectious diseases requires biomedical expertise as well evolutionary and computational expertise, the Museum has partnered with Dr. Daniel Janies of Ohio State University Medical Center (OSUMC) in these efforts.

## History of the Partnership

The Department of Defense (DOD) ensures the nation's security and its capacity to understand and respond to threats in this new era of complex defense challenges. DOD is committed to the research, tools, and technology that will achieve these goals, and in FY05, DOD and the AMNH, launched a multi-faceted research partnership via DARPA that leverages the Museum's unique expertise and capacity. Since that time, our research has increased understanding about the sources, distribution, and spread of agents of infectious diseases. This, in turn, increases our capacity to predict where disease outbreaks might occur and to effectively monitor disease-causing agents and their global spread.

The first phase of this project focused on the development and application of a computational system to formulate and test hypotheses for the complex conditions that underlie the evolution and spread of infectious diseases. A novel approach was taken to integrate information from genetic and functional changes in hosts and pathogens across time and space using the tools of the field of evolutionary biology, the retrospective analysis of biological change, and adaptation over time. We also leveraged high-performance computing to understand mutation and recombination events associated with the emergence and spread of pathogenic and drug resistant strains of viruses. As the analysis of datasets from next-generation sequencing requires large processing power, we

advanced development of highly interoperable software and hardware to systematically address alignment and phylogenetic analysis.

Concurrently, we developed methods to visualize large amounts of these genetic, functional, and geographic data by projecting an evolutionary tree into a virtual globe (such as Google Earth or NASA Worldwind). The resulting visualizations are akin to weather maps that show the spread of pathogens and their key mutations, over time, space, and various hosts. These maps provide not only situational awareness but also diagnostic and predictive power. We share compelling visualizations via social media and hypothesis-driven research in academic journals to enable and encourage global collaboration on infectious diseases.

We are now able to track the global spread of any pathogen, and can identify, for any geographic region, sources, destinations, mutations, and host shifts by pathogens. In light of the H1N1 pandemic, we continue to work particularly on influenza and to share our results with a broad group of users. It is important to note, however, that the research has investigated progressively more complex systems, moving to viruses such as those that cause hemorrhagic fevers, and to the study of bacteria such as those that infect wounded soldiers.

#### Communication of Results

We have engaged in an array of outreach programs with the goal to actively and vigorously share project results with those integral to fighting emergent infectious disease, including public health specialists, scientific researchers, and policy makers.

We have conducted workshops and symposia; have published results in peerreviewed scientific journals—results that have in turn been covered by journalists in
many media. We have testified on the H1N1 pandemic before the U.S. Senate
Committee on Homeland Security and Governmental Affairs, and have been invited to
present our research to such government agencies as the Department of Homeland
Security. We have also briefed the Department of State on how to foster international
data sharing, and have discussed the pandemic H1N1 with the White House Office of
Medical Preparedness. Throughout our partnership, DARPA program managers have
supported AMNH's work, have made the research known to other DOD-supported
scientists, and have invited AMNH and OSUMC scientists to participate in conferences
for research planning and force protection.

As the work moves forward, we plan to continue such outreach efforts, and plan to hold workshops and symposia annually, as well as to respond to requests for information, consultation, and so forth.

## The Future of the Research

As you know, the Committee has supported our work over the last several years. Should the Committee fully support our FY11 request, the Museum will be able to advance to the next phase of the project—focusing on more complex pathogens and the host side of the infectious disease problem. Such outbreaks are the result of an evolving complex of pathogen genomes and hosts (e.g., SARS-CoV in bats, small carnivores, and humans; or influenza A in birds and mammals), whereby pathogens evolve (mutate and

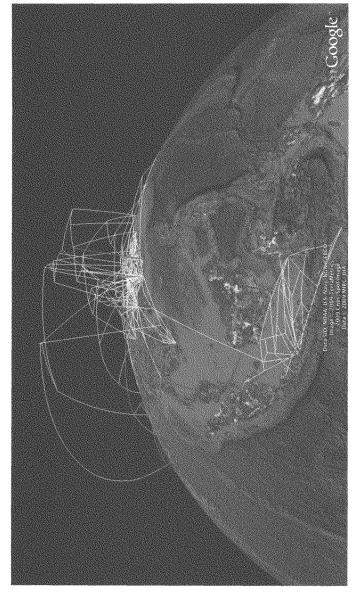
exchange genetic material) and adapt to various hosts, causing the hosts to become infected or to alternate between infected and non-infected states.

Moving forward, we plan to focus on analysis of large evolutionary datasets comprised of genomic data from pathogens and migratory patterns of hosts and other geospatial data. This work will allow us to connect complex systems—both those existing within the organism and those involving multiple organisms and the environment—so as to develop predictive hypotheses for the emergence of disease.

In this new phase of the research, we will use analytical techniques from the field of biogeography to study the evolution and spread of host-pathogen complexes. Specifically, we will use large datasets of genetic sequences and geographic data for hosts and pathogens to predict hotspots for the emergence of diseases.

With continued DOD support, AMNH will be able to continue to draw on its unique research, training, and education capabilities to advance goals critical to DOD and our national preparedness and security.

Thank you for your time and for the opportunity to speak before you today.



Screenshot from a study of avian influenza using SUPRAMAP. Orange lines represent the spread of drug-resistant strains, while white lines indicate the spread of drug-susceptible strains,

w

Mr. DICKS. Mr. Frelinghuysen.

Mr. Frelinghuysen. No comment.

Mr. DICKS. Thank you.

THURSDAY, MAY 20, 2010.

## **HEART OF A CHAMPION**

#### WITNESS

## STEVE RIACH, FOUNDER AND BOARD MEMBER, HEART OF A CHAMPION FOUNDATION

Mr. DICKS. Next is Mr. Steve Riach, founder and board member, Heart of a Champion Foundation.

Mr. Riach, welcome.

Mr. RIACH. Good morning.

Mr. DICKS. You have 5 minutes. You understand the drill.

Mr. RIACH. Chairman Dicks and distinguished Members, thank you. It is an honor for me to be here and provide testimony this morning regarding military families and the unique challenges that they face, and the unique challenges that we face in terms of educating our military families, and the role that character-development programs can play, such as our very successful Heart of a

Champion Program, in meeting those challenges.

We know that 1 million military-connected students today are living in what is called a "new normal" environment, dealing with multiple wartime deployments, lengthy parent-child separations, mental illness, injuries and even death. These unique stresses can create chaos in the lives of affected students and negatively impact their motivation, their grades, their behavior, their peer relations, family life and graduation rates in military-impacted schools and districts. And while each of our Nation's military services has made strong covenants to assist families and students, much greater support and specialized programs are needed to follow those military students into DOD, DEA and non-DOD public school systems. Our research has proven that an important part of the solution must be character-development programs taught in these schools.

During the past 9 years our Nation has been at war, DODEA schools have had to deal with special significant challenges to teach our military children. But more than just our military bases, schools in districts such as the Killeen Independent School District, which, of course, serves Fort Hood, Texas, where Active Duty military enrollment can be as much as 80 percent of that population,

they struggle to meet those challenges.

It is my view that character-development programs such as ours can be a vital, in fact, necessary, tool to help these young children of our servicemen and women deal with the many unique stresses

they face on a daily basis.

When we launched Heart of a Champion 14 years ago, started by business leaders around the United States who had a desire to impact the lives of children in any kind of environment, it was our goal to create the finest character-development program around that would deliver measurable results. We spent 4 years researching with educators around the United States to determine what would create the most efficient and effective program. And now, since 2001, we have deployed our program in 24 States, to reaching about a half a million young people in any kind of environment you can imagine, public schools, after-school programs, partnering with people like the Big Brothers/Big Sisters, Boys and Girls Clubs, and in juvenile justice facilities, where we impact students who are or young people who are the most hard-core teen offenders in the United States, as well as those who are in the probation system, and redirecting them out of the juvenile system.

So we know that this program works and character education, character-development programs work to create change in the lives of young people in any type of population. We know it can be the same in the population of military families.

We have seen results that are dramatic. We have seen not only attitudinal behavioral changes, we have seen increased graduation rates, in some cases as many of 100 percent of students in some areas graduating; decreased truancy; decreased dropouts; decreased drug and alcohol use, in some cases as much as 40 percent; increased grade average; increased test scores.

We know that what has occurred is in changing the heart of the student. We have seen students perform better. We have seen them

make better life choices.

Mr. Dicks. The gentleman has 1 minute to summarize, or if you want us to ask a question or two.

So how do you work this with the school? Are you doing this with the DOD schools?

Mr. RIACH. Currently not in DOD schools; in public schools.

Mr. Dicks. But you just do it in public schools that are near the

Mr. RIACH. Correct.

Mr. Dicks. How do you get organized? How do you work it out with the local school district?

Mr. RIACH. We work directly with the local school district and the individual schools. We train their teachers. Those teachers deploy the program in the school. We certify them. They deploy it during the class day, in class during the school day. And we work with them. We pre- and post-assess and deliver measurables, empirical data showing the results that I mentioned earlier.

Mr. Dicks. And do they do after school, too? Is it after school as

Mr. RIACH. Absolutely. Worked with Big Brothers/Big Sisters, Boys and Girls Clubs, a number of after-school programs, both on school campus and in the community.

Mr. DICKS. Any other questions?

Thank you very much. If you want to summarize.

Mr. RIACH. Thank you.

I just, in conclusion, would say that if there is anything this committee can do to look at the critical need with these families and these students, and the deployment of a character program that actually works and changes their hearts and helps them make better decisions, we will see a decrease in suicides, drug and alcohol use and those things that are plaguing young people who are military family members in this current day.

Mr. Dicks. Thank you very much.

Mr. RIACH. Thank you.

[The statement of Mr. Riach follows:]

## STATEMENT OF MR. STEVE RIACH FOUNDER AND BOARD MEMBER HEART OF A CHAMPION FOUNDATION

## BEFORE THE HOUSE APPROPRIATIONS COMMITTEE DEFENSE SUBCOMMITTEE

## ADDRESSING THE UNIQUE CHALLENGES OF EDUCATING CHILDREN OF MILITARY FAMILIES DURING WARTIME THROUGH CHARACTER DEVELOPMENT PROGRAMS 20 May 2010

Chairman Dicks, Congressman Young and distinguished members of the Subcommittee: It is an honor for me to provide testimony to you today on the unique challenges of educating the children of our military families and the role character development education, such as our very successful "Heart of a Champion" program, can play in meeting those challenges. I wish to thank each of the Members for spending your time to hear our concerns today on so many topics dealing with support for our great military and particularly the men and women that serve our country so valiantly and selflessly. And I specifically thank you for allowing me to discuss my passion for better supporting the unique needs of military-connected children in schools around the world and their families.

Last summer I was asked to testify before other Congressional committees to discuss successes the Heart of a Champion program has achieved across the country in our public schools, after-school programs, and juvenile justice settings. I am thankful now for the opportunity to tell this committee of our proven record of success, the results of which have been independently verified and qualitatively measured. It is my view that character development programs like Heart of a Champion's can be a vital tool for helping the young children of our service men and women deal with the many, unique stresses they must face on a daily basis.

To better understand what character education is and can provide, let me begin by introducing you to the Heart of a Champion Foundation. We are a nonprofit organization founded in 1997 by a group of business leaders and sports team owners who shared a common concern for the nation's youth and sought to find a way to make a positive impact on their culture. As we began to conduct extensive research, it became apparent that one of the most significant areas of need was for quality, effective character development programs that would instill character and ethics into young people.

Our board and staff spent nearly four years researching and collaborating with educators from across the country, the Department of Education, and other agencies, to understand the landscape of character education in the U.S. These efforts provided us with answers to questions of efficacy

regarding content, presentation and delivery of a successful character program. We came to the following five conclusions:

- In terms of demographics, the greatest area of need is at the middle school and junior high level. This was confirmed by the vast majority of educators with whom we worked, as well as the three-year study conducted by the United States Secret Service in the aftermath of the rash of school shootings in the late 1990's.
- Most character education programs lack the ability to engage students, particularly with this generation that we have called the "sight and sound" generation.
- Most programs lack substantive content content that would not only teach concepts, but also teach application of those concepts in a relevant way.
- 4) Most programs lack a delivery model that was consistent and deployment that was long-term.
- 5) Most programs have no mechanism to determine their efficacy.

The Under Secretary of the Department of Education at that time made it clear to us that any program which could effectively address these deficiencies had a substantial chance to be successful in actually producing behavioral change.

In 2001, after nearly four years in research and development following those guidelines, we launched the Heart of a Champion program in Plano, Texas and Brooklyn, New York, with two very diverse populations. One involved upper middle class students while the other involved underserved and predominantly minority students. The results in both cases were nearly identical in terms of attitudinal and behavioral change. The data validated that we had indeed achieved what we had been asked to deliver.

Since 2001, we have deployed the program to a total of 24 states with similar, measurable results.

Approximately a year ago, while developing a strategy for expanding further on our success, we learned of a situation in my home state of Texas where military families stationed at Fort Hood with parents deployed in war zones in Iraq and Afghanistan were being supported by an outpouring from the entire civilian community to help them deal with the day-to-day rigors of family separation, frequent moves around the world, and loved ones serving in harm's way. Local families were helping with after school transportation, Boy Scout campouts, even prom night preparations. This spontaneous effusion of local support for and recognition of the rigors of a military lifestyle helped us

to recognize what the Killeen community saw: that these military-connected children were at greater risk if not provided with additional support.

As we learned more about the day-to-day lives of military families, it became clear that while the stresses facing America's military dependent children are profoundly and distinctly different from the general population, the tools for responding to them are much the same as those Heart of a Champion has been teaching to help school children across the country deal with family violence, homelessness, single parenting and more. We have come to recognize that new targeted programs, training, and funding sources are needed to help support the hundreds of schools that serve military dependent students and their families.

Living in a "new normal" environment describes the circumstances of one million military-connected students who are dealing with multiple wartime deployments, lengthy parent-child separations, mental illness, injuries, and death. These unique stresses can create chaos in the lives of affected students and negatively impact motivation, grades, behavior, peer relations, family life, and graduation rates in military-impacted schools and districts. While each of our nation's military services has made strong covenants to assist families and students, much greater support and specialized programs are needed to follow military students into DODEA and non-DOD public school systems. Our research has proven that an important part of the solution should be a character development program taught in schools.

While the Department of Defense Education Activity does offer a menu of character programs for its schools to choose from, they are unfunded – that is, these programs must compete for funds with core curricula; there is no requirement for data collection on these programs to determine efficacy; and there is no similar program offered, with funding, for non-DODEA schools supporting heavy concentrations of military-connected students.

During the past 9 years our nation has been at war, DODEA schools have had to deal with the special, significant challenges that teaching our military dependent children bring. But more than just on our military bases, schools in districts such as the Killeen Independent School District serving Fort Hood, Texas, where active duty military dependent enrollment can be as high as 80% of the student population struggle to meet these challenges as well. In both cases, teaching these students presents many different and challenging requirements for teachers and counselors that are often not anticipated or adequately funded by federal, State, or local education agencies. Extremely high student turnover, large percentages of geographically single parents, and extraordinarily stressful family dynamics caused by combat deployments are among the stresses that can make education and discipline far more challenging for these military populations and the public schools they attend. The Heart of a Champion Foundation has proven that character development programs that strongly reinforce positive student character traits and decision-making skills through real-world, poignant examples that are easily

understood and identified with by today's sight and sound generation can actually help our military families deal with these challenges. All of the empirical data we have collected in large cities and small towns, from troubled youth in correctional facilities to middle class families in public schools across America; it all points to a requirement to teach our youth, in ways that they can identify with, how to make right choices.

In addition to filling a significant requirement for military-connected families, Heart of a Champion has learned over the years that students overwhelmingly desire character development help. At the genesis of our program we collaborated with two Members of Congress in our home state of Texas on Safe School Summits. At each of these summits 500 secondary school students convened to discuss school safety issues. The data derived from the students amazed even the Members.

At both of these Safe School Summits, the students told us that when they go to school on a daily basis, they don't feel physically unsafe. The vast majority expressed feelings of emotional insecurity. Many felt there was no one they could trust, that they were not accepted, or that they couldn't connect.

When students were asked what elements would make them feel safer on campus, their answers corresponded to this revelation. When asked about security guards, hall monitors, surveillance cameras, and metal detectors 11-23% of students said each of these items would make them feel safer. Yet, when they were asked about the consistent deployment of a character program on campus, 74% of these students said this would make them feel safer.

In post-survey focus groups, students summarized issues addressed at the Safe School Summit by explaining that only by changing the heart of the student sitting beside them could you create a safe school; thus, the impetus for us to create the Heart of a Champion character development program.

It was clear to us that students recognized that the heart of the problem was itself a heart problem. Physical safety is a byproduct of emotional safety.

Much has been said and written about social and emotional intelligence over the past few years, but based on our work over the past 8 years, we believe that this is clearly the key to addressing the many challenges facing our military-connected families. Rather than focus on symptoms, the focus of any program must be on root cause behaviors to create any substantive and enduring change. We have seen this play out from the program's inception. Not only do character development programs help our children in failing schools choose the path to succeed, they can help our military dependent families face the severity of family life during wartime and help supplement the parenting skills diluted by the rigors of military life.

Our assessments have produced empirical data which demonstrates that students who participate in the Heart of a Champion program realize significant attitudinal and behavioral change. In addition, our data also demonstrates a decrease in violent behavior, a decrease in drug and alcohol use, a decrease in referrals and in bullying incidents, and an increase in grade point averages. Each of these behaviors are of significant concern to the deployed service member and have the potential for impacting combat readiness in profound and measurable ways. By supplementing classroom curricula with a program that addresses behavioral root cause issues and providing training in social and emotional intelligence, we are seeing proven, measureable change which we believe will have a profound effect on the entire family, and thereby positively impact readiness of deployed forces.

The Heart of a Champion program is a comprehensive three-year curriculum, designed for implementation throughout a student's entire middle or junior high school experience. The program is taught throughout each nine-month school year, focusing on nine different core character traits each month: Commitment, Leadership, Perseverance, Teamwork, Respect, Integrity, Responsibility, Self Control or Compassion.

Under each of these traits the curriculum highlights real people who have exemplified these attributes, and details the consequences of their actions. Rather than telling students what not to do, the Heart of a Champion program provides them with examples – or role models if you will – of those who have made good choices, and allows them to learn about, and discover first-hand, the results of such choices. The curriculum includes some recognizable individuals from sports and entertainment industries, such as Indianapolis Colts head coach Tony Dungy and musician Bono from the band U2. Some lesser known individuals, like Louis Daniels – a homeless student who ended up receiving a scholarship to Yale – are also highlighted in the program. There are service men and women in our materials as well and even a few members of Congress.

The men and women profiled in the program serve as models for the students and give them an ideal to shoot for and an idea of what they themselves can achieve. They are role models that teach lessons through their life stories in contexts with which today's youth can readily identify.

In the Heart of a Champion program, during each month, students work through a curriculum workbook focusing on one of the specific traits mentioned earlier. Each workbook contains weekly lessons delving deeply into a different aspect of that trait. With video segments, posters, online applications, critical thinking and decision-making exercises, and rewards and reinforcement elements being utilized on a weekly – and sometimes daily basis – students learn about character with the same frequency they do in any of their core subjects. With this degree of emphasis and consistency, students intuitively see that society values their depth of character as much as their level of performance in the classroom.

Heart of a Champion directly trains and certifies teachers, helping them to deliver the program as a normal part of their daily classroom activities, and proving to enhance the relationships that teachers have with students. Many have said, "I feel like I am more than just a teacher now, I feel like I am making a greater impact in my students' lives."

The program's impact is not only seen through such anecdotal data such as this, but also through empirical data derived through pre and post program assessments. This is a vitally important point that should be addressed by any character development program utilized by our Department of Defense education programs. It is vital that the pulse of the target audience be taken at regular intervals to determine both the efficacy of the program and to help it adapt to the needs of the audience. Beyond ROI, a company that is a leader in diagnostic and measurement services with organizations across the U.S., provides complete pre and post measurements and data reports for our programs. The data has demonstrated significant attitudinal and behavioral change in students participating in the program and has helped us maintain this efficacy year after year. Moreover, this data collected has also proven that the program is also delivering critical, measurable results such as reduced referrals, reduced alcohol and drug use (as much as 40%), 92% increase in self-esteem, decreased violent behaviors including bullying, and increased grade averages - as much as 47%.

Another venue that has been exciting for us has been our intervention programs outside of schools. We are not only seeing these tremendous results in public schools in the 23 states we now deploy the program, but also in after-school outlets such as the Boys & Girls Clubs, and in juvenile justice facilities such as Rikers Island prison in New York, a maximum security facility that houses the most violent teen offenders in New York, ages 16-18. Heart of a Champion is also deployed to the Gainesville State School in North Texas, another maximum security facility which houses the most violent teen offenders ages 13-19. In fact, Warden Edmund Duffy at Rikers Island emailed me recently to tell me that the guards who oversee the unit where the Heart of a Champion program is deployed were asking him "what have you done to these kids? They are changing."

Regardless of the population – schools, after school or juvenile justice - the program continues to produce similar results. It is changing the "hearts" of the students. As it changes the "heart", changes in attitude, behavior and performance result. As it changes the "heart" it enables the child to better cope with the stress of military family life and the warfighter to better focus on defending our nation.

Heart of a Champion has been labeled a model program by the populations we are serving and for that we are appreciative. However, we are most grateful that it is working. We strongly believe that this model of character

development is urgently needed in the schools that serve our military-connected children.

Again, I thank you for your leadership and for the opportunity to come and share with you this morning what we have learned. I am happy to discuss with any of the Members or your staff how character education programs in general, or the Heart of a Champion program specifically, can be used in DODEA schools and public schools that serve large, military populations; or to provide advice on what actions could be taken through future legislation to make it easier for school districts to adopt effective character development programs like Heart of a Champion.

Thank you.



## **Educators Comments on Heart of a Champion**

We are thrilled with the response from our members who are going through the Heart of a Champion program at the Boys & Girls Clubs of Greater Dallas! It provides a consistent message that all kids need to hear as much as possible; and that is the importance of good character and personal responsibility.

Misti Potter VP, Boys and Girls Clubs of Greater Dallas

As an educator for over 45 years, I believe the Heart of a Champion Foundation has truly created a quiet revolution wherever it is given an opportunity to support young people in thinking about their lives and how they want to live out their dreams.

Pat Orlowski Kansas City Public Schools

I've been in public education for 37 years now, and I've seen every character program available. This is the very best character program I have seen.

Marilyn Brooks Assistant Superintendent, Plano ISD

What an awesome way to impact students in the things that matter most in life – building good citizens for our society.

Sara Bonser Principal, Hendrick Middle School

The teachers were by the fourth or fifth week coming to me and saying, 'This is good. I like this,' and were having fun with it. They were starting to learn a lot about their kids that they would have never learned just through their normal classes.

Charles Pickitt Principal, North Junior High

The program is very useful because of the lifelike situations that our members can use to keep them out of trouble but also empower them to be responsible citizens.

Kevin Foster Boys and Girls Clubs of Tarrant County



## Sponsor Comments on Heart of a Champion



Heart of a Champion has proven themselves to be in invaluable partner in our community program. The curriculum they provide is first rate, not only in terms of content, but also in terms of the way the materials are delivered. The professionalism of HOC has also manifested itself in the construction of collateral materials supporting our program, and in the framework they customized that enables the execution of our program. HOC is a crucial and respected partner in one of our most strategic and important initiatives.

Ben Lawson Director of Bottler Sales and Marketing Coca-Cola North America - Southwest Region



We consider Heart of a Champion to be our flagship program in character development. The Heart of a Champion material is perhaps the most substantive program in character education and we are proud to serve the Houston community in this manner."

Robert McNair Chairman, Houston Texans



We consider Heart of a Champion's character education program to be a significant investment in the children of the communities we serve. HOC engages this critical generation of young people by providing valuable lessons about integrity, perseverance, commitment and teamwork. We have been honored to bring this unique and effective program to Kansas City.

Clark Hunt Owner, Kansas City Chiefs



We believe in the ability of the Heart of a Champion Foundation to positively and powerfully impact America's youth. Together, we can develop and influence positive character traits that will enrich their future.

Robert A. Funk Chairman & CEO, Express Employment Pros





October 19, 2004

## To Whom It May Concern:

Many character education programs come to me through direct mail, email, and telephone solicitations. I've reviewed more than a dozen during the past few years without finding one which truly met my expectations for a character education program for Plano ISD middle school students.

Heart of a Champion caught my attention at once with both presentation and content. After sharing the program with our district middle school principals, who shared my enthusiasm, we began using the program three years ago.

The program is well-planned and attractively packaged to appeal to both teachers and students. It is a valuable addition to our middle school instruction.

Because of the modular components, each school has been able to tailor the program to fit its scheduling and staffing. Schools use the colorful Heart of a Champion posters and other materials to keep strong character education messages in front of their students.

Working with the Heart of a Champion organization is a delight. They have taken feedback from teachers and administrators and continued to improve the content of an already strong program.

In my opinion, Heart of a Champion is the best character education program I have seen. The people associated with the program are easy to work with and responsive to our needs. They are committed to young people and to working with educators to provide a quality character education program for our children.

 $\mbox{I'm}$  proud that Plano ISD middle school principals have chosen to embrace and support Heart of a Champion.

Sincerely,

Marilyn Brooks

Marilyn Brooks,
Associate Superintendent
For Curriculum and Instruction



#### Arizona

East Valley High School (Mesa) Chino Valley High School

#### **Arkansas**

Pine Bluff Schools Watson Chapel School District Dollarway Public Schools Whitehall Public Schools

#### California

Miracles Program (San Diego) Miracles Program (San Jose) University Charter Middle School (Camarillo) South Junior High (Anaheim) Savannah Schools (Anaheim)

## Florida

Lely High School (Naples) Nova Middle School (Davie) Broward County Public Schools

## Georgia

Miracles Program (Atlanta)

## Idaho

Midway Middle School (Rigby)

## Illinois

Miracles Program (Chicago)

#### Kansas

Youth Leadership Foundation (Manhattan) Central Middle School (Kansas City) Regional Prevention Center of Kansas (Girard)

## Maryland

Hope Worldwide (Baltimore) Newport Mill Middle School (Kensington)

#### Michigan

CA Frost Middle School (Grand Rapids)
Grand Rapids Montessori
Martin Luther King Middle School (Grand
Rapids)
Sherwood Middle School (Grand Rapids)
Southwest Community (Grand Rapids)
Alger Middle School (Grand Rapids)
Burton Middle School (Grand Rapids)
Ford Middle School (Grand Rapids)
Ford Middle School (Grand Rapids)
Harrison Middle School (Grand Rapids)
Riverside Middle School (Grand Rapids)
Westwood Middle School (Grand Rapids)
West Junior High (Traverse City)
East Junior High (Traverse City)

#### Minnesota

Saint Paul Public Schools

## Missouri

Belton High School (Belton)
Center Middle School (Kansas City)
Campbell Middle School (Lee's Summit)
Grandview Middle School
Pleasant Lea Middle School (Lee's Summit)
Summit Lakes Middle School (Lee's Summit)
Smith-Cotton High School (Sedalia)

## Nevada

Andre Agassi Preparatory Academy (Las Vegas, NV)

## **New York**

Grace Faith Church (NYC)
IS 152 (NYC)
City College Academy of the Arts (NYC)
Riker's Island (NYC)

#### Oklahoma

Belle Isle Middle School (OKC) Jackson Middle School (OKC) Jefferson Middle School (OKC) Rogers Middle School (OKC) Roosevelt Middle School (OKC) Webster Middle School (OKC) Classen Middle School (OKC) Taft Middle School (OKC) Douglas Middle School (OKC) John Marshall Middle School (OKC) Centennial High School (OKC) Northeast Middle School (OKC) SeeWorth Academy (OKC) About Face Academy (OKC) Western Heights Middle School (OKC) Independence Charter Middle School (OKC) Millwood Middle School (OKC) Crutcho Middle School

#### Pennsylvania

Wissahickon Middle School (Ambler)

#### Texas

Thomas Middle School (Houston) EO Smith Middle School (Houston) Woodson Middle School (Houston) Welch Middle School (Houston) Dowling Middle School (Houston) Cullen Middle School (Houtson) Morton Ranch Junior High (Katy) Beckendorff Junior High (Katy) Rescue Youth Mentoring Program (Humble) Boys and Girls Clubs of Houston The Briarwood School (Houston) Wunderlich Intermediate School (Klein) Parkview Intermediate School (Pasadena) Tannahill Intermediate School (White Settlement) Rockwall Independent School District Tarrant County Juvenile Justice Program Fossil Hill Middle School (Keller) Lorena Alternative School Parkhill Junior High (Richardson) Union Bower Center for Learning (Irving) Royse City Middle School (Texas) Murphy Middle School (Plano) Mabank Middle School Miracles Program (San Antonio) Miracles Program (Dallas) Mansfield Select Athletics Highland Park Middle School (Dallas) Gainesville State School Boys and Girls Clubs of Greater Dallas Boys and Girls Clubs of Fort Worth Lena Pope Home (Fort Worth) OL Slaton Middle School (Lubbock) Dunbar Middle School (Lubbock) Atkins Middle School (Lubbock)

Burnet Middle School (Burnet)

#### Virginia

Chesapeake Alternative School Norfolk Christian (Norfolk) Smith High School (Chesapeake)

#### Washington

McIlvaigh Middle School (Tacoma) Kopachuck Middle School (Gig Harbor) Harbor Ridge Middle School (Gig Harbor)

## House Appropriations Committee Defense Subcommittee

## Witness Disclosure Form

Clause 2(g) of rule XI of the Rules of the House of Representatives requires nongovernmental witnesses to disclose to the Committee the following information. A non-governmental witness is any witness appearing on behalf of himself/herself or on behalf of an organization other than a federal agency, or a state, local or tribal government.

Your Name, Business Address, and Telephone Number:

STEVE RIACH  14:2APT OF A CHAMPION  99 MAIN, SVITE 100  COLLEGIVILLE, TX 76034  BIT-427-4621
Are you appearing on behalf of yourself or a non-governmental organization? Please list organization(s) you are representing.  HEALT OF A CHAMPION FOWOARON
<ol> <li>Have you or any organization you are representing received any Federal grants or contracts (including any subgrants or subcontracts) since October 1, 2007?</li> <li>Yes No</li> </ol>
3. If your response to question #2 is "Yes", please list the amount and source (by agency and program) of each grant or contract, and indicate whether the recipient of such grant or contract was you or the organization(s) you are representing.
Signature: Date: 5/18/10
Please bring this original form on the day of your testimony.

Thursday, May 20, 2010.

## LUNG CANCER ALLIANCE

#### WITNESS

## LAURIE FENTON-AMBROSE, PRESIDENT AND CEO, LUNG CANCER AL-LIANCE

Mr. DICKS. Laurie Fenton-Ambrose, president and CEO, Lung Cancer Alliance. Welcome, Laurie.
Ms. Fenton-Ambrose. Thank you, Mr. Chairman.

Mr. DICKS. You have 5 minutes. We will let you know when you have 1 minute so you can summarize.

Ms. Fenton-Ambrose. Thank you very much.

Dave Hobson also says hello, who I also had the pleasure of seeing this morning. So he wanted me to say hello.

Mr. DICKS. Thank you.

Ms. Fenton-Ambrose. I am delighted to be here, Mr. Chairman, members of the subcommittee. My name is Laurie Fenton Ambrose, and I am president and CEO of the Lung Cancer Alliance, which is the only national organization that is providing patient support and advocacy to those either living with or at risk for lung cancer.

And it is my great privilege to be here to talk with you about a program that we had the great pleasure of working to see established, along with our former board chairman Admiral Phil Coady; and our current board members, former Secretary of Transportation Norman Mineta, who is a lung cancer survivor, and along with Joe Lopez; and certainly with the late chairman John Murtha, who saw the need to create this program to help our military men and women who are at greater risk for the disease.

To summarize, lung cancer is a public health epidemic. It is the leading cause of cancer deaths among men, among women, in every ethnic group, and in our military, conservatively speaking, is at a 25 percent higher risk for this disease not just because of smoking, but because of exposures to toxins, battlefield fuels and the like. It is a disease that, even with this proportion of deaths, has received the least amount of Federal funding. What we are doing today is to try to ensure that a very comprehensive plan of action is brought to bear on all of those who are either living with or at risk for this disease.

It is important to note that today, based on CDC surveys, 60 percent of those with this disease are former smokers, most who quit decades ago. Another 20 percent are those who have never smoked at all. So what we are faced with is the fact that today, tomor-

Mr. DICKS. Is that a different kind of cancer; is that a different disease for the people who don't have—who have never smoked?

Ms. Fenton-Ambrose. I wish I could say we knew. There are many variations to this disease. We don't have enough research to understand why, for example, men and women have differences in the type of diagnosis and progression with the disease. But it is lung cancer.

So if you think about the fact that 80 percent of those with this disease today, tomorrow and decades to come do not have the research to support earlier intervention or certainly to have a robust treatment pipeline, no doubt we need tobacco control and prevention strategies, but that alone will not address those who actually heard the message and quit their addiction to ensure that we find it early or then have treatments best to manage it.

This brings us really to why we are here today. Even last week the President's Panel on Cancer produced a report about the environmental risk factors that highlighted among our military expo-

sures that are putting them at greater risk.

Lung Cancer Alliance has been advocating strongly and persistently for a greater focus on our military men and women who are at great risk. Whether it is Agent Orange, whether it is battlefield fuels, whether it is smoking, our military men and women do not deserve to have this disease, and we have worked to establish a program within the CDMRP that is focused on an early intervention program to help our at-risk military.

Chairman Murtha was so quick to recognize the need. We are grateful that he helped us to establish this in 2007. This is a program not intended to duplicate, but rather supplement, the research programs under the National Cancer Institute. This has a particular focus on the patient and patient outcomes rather than

the basic science which has been the purview of NCI.

This patient-oriented, mission-oriented program, if properly implemented, will have an immediate impact on our high-risk military and quickly lead to other earlier detection and improvement of treatments for the entire civilian population.

I have attached supporting documents—

Mr. DICKS. Thank you.

Ms. Fenton-Ambrose [continuing]. I am happy to present for you today.

Mr. DICKS. Thank you.

[The statement of Ms. Fenton-Ambrose follows:]



888 16th Street NW Suite 150 Washington DC 20006 202-463-2080 lungcanceralliance.org

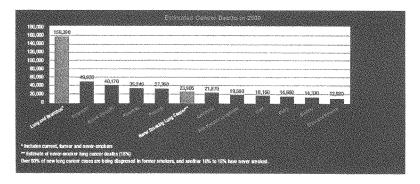
# Laurie Fenton-Ambrose President and CEO of Lung Cancer Alliance Testimony Before the House Appropriations Subcommittee on Defense May 20, 2010

Chairman Dicks, Ranking Member Young, Members of the Subcommittee: My name is Laurie Fenton Ambrose. I am President & CEO of Lung Cancer Alliance, the only national organization providing patient support and advocacy exclusively to those either living with – or at risk for lung cancer.

It is my great privilege to be able to testify before the House Appropriations Subcommittee on Defense on the Lung Cancer Research Program within the Congressionally Directed Medical Research Program in the Department of Defense.

It was our great honor to play a role in establishing this program through the efforts of our late Chairman of the Board, Admiral Phil Coady, and our current Board members: former Transportation Secretary and lung cancer survivor, Norman Mineta, and Admiral Joe Lopez. We are deeply grateful to the late Congressman John Murtha for his recognition of the need and his support for an accelerated, patient-oriented, mission-oriented research program focusing on lung cancer among high risk military men and women.

Lung cancer is a public health epidemic. Lung cancer is the number one cancer killer in among men and women and in every ethnic group, yet most people are not even aware of the statistics.



The fact is that lung cancer is taking more lives each year than the next four biggest cancers - colon, breast, pancreatic and prostate cancers - combined. When President

Nixon and Congress launched their "War on Cancer" in 1971, lung cancer's 5-year survival rate was 13%. Today, almost 40 years later, the 5-year survival rate is 15%.

In 2001, the Progress Review Group's report to the National Cancer Institute bluntly warned that lung cancer was being funded "far below its massive public health impact." Yet it continues to be the least funded in research dollars per death of all the major cancers.

A series of papers published in 2008 in the Journal of the National Cancer Institute indicate that lung cancer is the most costly cancer in terms of healthcare dollars spent, productivity losses, the value of lives lost and Medicare costs. Predictions published in the Journal of Clinical Oncology in 2009 indicate that the number of people who will be diagnosed with lung cancer will increase by 52% over the next 20 years.

Lung cancer is also the only cancer blamed on the patient and routinely portrayed as a "self-inflicted" disease that smoking cessation alone will cure. LCA recognizes the horrible impact of smoking and fully supports tobacco control and prevention efforts, including the regulation of tobacco by the Food and Drug Administration. LCA has been actively engaged for many years and has filed amicus briefs in the still ongoing federal RICO lawsuit against Big Tobacco.

But the facts about lung cancer present a more complicated picture. According to a 2007 Centers for Disease Control and Prevention survey, 60% of new lung cancer cases are former smokers, many of them people who were initially hooked as young as eight or nine, who have already taken the difficult steps to break their addiction. Another 18% never smoked at all, which would make lung cancer among non-smokers the sixth biggest cancer killer, ahead of leukemia, liver, ovarian, bladder and brain cancers.

The President's Cancer Panel last week issued a report entitled "Reducing Environmental Cancer Risk" which listed forty categories of cancer-causing contaminants, ranging from radon to asbestos to pesticides. Over half of them were specifically associated with lung cancer, the majority of them strongly associated to lung cancer. No other cancer was so frequently cited or so strongly implicated. One entire chapter of the report was devoted to the military-related environmental exposures.

Lung Cancer Alliance has been advocating strongly and persistently for greater focus on our military men and women who are at higher risk for lung cancer. Studies have cited their higher smoking rates during active duty and their greater exposure to known carcinogens and have indicated that not only is incidence higher, but survival is lower than in civilian populations. For the record, attached is Lung Cancer Alliance's Veterans and Lung Cancer Fact Sheet, which outlines the scope of the problem. I would like to include it in the record.

In 2008, the late Chairman Murtha, with his steadfast compassion and support of our military men and women, moved rapidly to provide resources for those at risk via the Lung Cancer Research Program with an emphasis on early detection. The fact is that only 16% of all lung cancers are being diagnosed at an early, curable stage.

As the report language for the FY09 and FY10 appropriations indicated, this pipeline was established to fund the integrated components of early intervention research for at risk military service men and women. In this respect the lung cancer research program is more specific to military men and women than other CDMRP programs.

It is intended to supplement, not duplicate, research programs under the National Cancer Institute, with a particular focus on the patient and patient outcomes rather than on basic science which has been the purview of NCI. This patient-oriented, mission-oriented program, if properly implemented, will have an immediate impact on our high risk military and quickly lead to earlier detection and improved treatments for the entire population of those living with and those at risk for lung cancer.

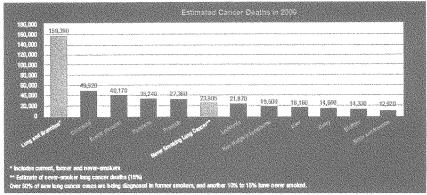
We thank the committee for its support for this program and urge the committee to appropriate additional funding for FY11.

## **VETERANS AND LUNG CANCER**

"Lung cancer is an urgent priority among veterans. Not only is the incidence higher, but the survival is lower than in civilian populations."  $^{1,2}$ 

## Scope of the Problem:

Overall the toll of lung cancer deaths in the United States exceeds that of the next four major cancers combined. On average 448 people a day will die of lung cancer..



Surveillance, Epidemiology and End Results Program: http://seer.cancer.gov http://seer.cancer.gov/csr/1975 2006/index.html

Studies have indicated higher rates of lung cancer incidence and mortality among veterans than among non-veterans.

## **WORLD WAR II AND KOREAN WAR VETERANS**

According to a study looking back on 33 years of cause of death data for people born between 1920 and 193939, the mortality rate for lung cancer among veterans has been nearly twice that of civilians. 2,000,000 World War II and Korean War veterans died an average of 11.1 years sooner than their civilian counterparts, making the toll of premature deaths in terms of "years of life lost" greater than that of all combat casualties from both wars. In addition to higher smoking rates, veterans of these wars were exposed to asbestos which was widely used in submarines, Navy ships and as plumbing and heating insulation.

## **VIETNAM WAR**

A 1987 study of the death records of 52,000 veterans of that era showed that Marine ground troops who served in Vietnam died of lung cancer at a 58% higher rate of lung cancer than veterans who did not serve there.

<sup>&</sup>lt;sup>1</sup> Harris RE, Hebert JR, Wynder EL. Cancer risk in male veterans utilizing the Veterans Administration medical system. Cancer 1989;64:1160-8

<sup>2</sup> Campling BG, Hwang WT, Zhang J, et al. A Population-based Study of Lung Carcinoma in

Pennsylvania: Comparison of Veterans Administration and Civilian Populations. Cancer. 2005; 104(4)

In 1991 Congress directed the National Academy of Sciences (NAS) through its Institute of Medicine (IOM) to carry out comprehensive reviews and periodic updates of the scientific and medical information on the health impact of Agent Orange and other herbicides. Every report since then has cited the association of lung cancer with Agent Orange.

In 1994 the VA agreed that all veterans who served in-country Vietnam between 1962 and 1975 (including those who visited Vietnam even briefly) and who have lung cancer are automatically entitled to full compensation and disability compensation with no limit on the time since service.

(It should be noted that studies carried out by the Australian VA found a 47% higher rate of lung cancer among its veterans who participated in the Korean War and double the rate of lung cancer cases among Australian veterans who served in Vietnam. These veterans also had lung cancer mortality rates 79% higher than expected.)

## **GULF WAR VETERANS**

In 1998, again at the direction of Congress, the IOM began studying the health impact of the Gulf War exposure to depleted uranium, the residue left after nuclear grade uranium is extracted. Because it is even denser than lead, depleted uranium has been used in defensive armor plating and in armor-piercing projectiles, such as SCUD missiles. Like radon, which is the second leading cause of lung cancer, depleted uranium can give off radioactive products of decay that can be carcinogenic. While the first IOM report in 2000 found insufficient evidence of a definite link to lung cancer, the 2008 update now assigns "high priority" to continued review of the link with lung cancer. IOM has also been reviewing the impact of exposure to fuel exhausts, smoke from burning oil wells, kerosene cookers and heaters in enclosed tents and other battlefield emissions. The "strongest finding" was the association of combustion products and lung cancer.

## **SMOKING AND THE MILITARY**

Until 1976, cigarettes were routinely included in K-rations and C-rations and for decades sold at deeply discounted prices in commissaries and exchanges. Tobacco products are still sold at discounted prices on military exchanges and commissaries (except for Navy and Marine commissaries). Military induced smoking accounts for a significant percentage of the higher lung cancer rates, perhaps as high as 50-70% of the excess deaths. The percentage of active duty military who ever smoked was highest during the Korean and Vietnam Wars (75%). Currently overall 32.2 % of active duty military personnel smoke versus 19.8% of adults in the civilian population and 22.2% of veterans.

## OTHER RISK FACTORS

Other risk factors include Agent Orange, radon, asbestos, depleted uranium used in weapons and armor shielding, beryllium, fuel exhaust and other battlefield emissions.

## **DEPARTMENT OF ENERGY AND LUNG CANCER**

Munitions plant workers exposed to uranium, beryllium and other carcinogens have been routinely screened for lung cancer under the Worker Health Protection Program funded through the Office of Environment, Safety and Health of the Department of Energy. The program is being expanded to more plants in FY10.

## DEPARTMENT OF DEFENSE AND LUNG CANCER

Since its initiation in FY92, the Congressionally Directed Medical Research Program under the Department of Defense has funded over \$5 billion in research programs with more than half of the funding earmarked for breast, prostate and ovarian cancer research programs. In FY09 Congress established a Lung Cancer Research Program with an initial appropriation of \$20 million to focus on high risk military. Lung Cancer Alliance is strongly advocating for additional funding for FY10.

## **LEGISLATIVE HISTORY**

In the 110th Congress, the House of Representatives (H.Res. 335) and the Senate (S.Res. 87) unanimously passed resolutions urging that lung cancer be declared a public health priority that required an urgent and coordinated public health response. In this Congress the first legislation ever to authorize a comprehensive lung cancer research program was introduced in both Houses of Congress. The bipartisan bills (H.R.2112 and S. 332) require the Departments of Health and Human Services, the Department of Defense and the Department of Veterans Affairs to develop a coordinated strategic plan for reducing lung cancer mortality by 2016.

## **UNMET NEEDS OF VETERANS AND LUNG CANCER**

Lung cancer is a stealth disease that usually takes decades to develop and fails to show obvious symptoms, such as bloody sputum, until it has already spread beyond the original site. In the general population only 16% of lung cancers are being diagnosed at an early localized stage when it can be treated and cured. Cancers with widely used screening methods (such as mammograms for breast cancer, PSA testing for prostate cancer and colonoscopies for colon cancer) have high survival rates. Currently the 5-year survival rate for breast cancer is 89%; for prostate cancer 99% and colon cancer 66%.

The 5-year survival rate for lung cancer is still only 15%, reflective of the persistent lack of adequate research funding and the pervasive blame associated with the disease. **Neither is appropriate in addressing the unmet needs of veterans who by virtue of their service are at higher risk.** 

Rapid advances in imaging technology have now given those at high risk for lung cancer an option for detection at its earliest, most treatable and curable stage. Fifteen years of observational studies in the United States and abroad have demonstrated that cancers detected by CT screening are highly likely to be cured.

Randomized controlled trials to assess the impact on mortality are also underway in the United States and abroad, but none of these trials are focused on the military or veterans. It is urgent that the unique impact of lung cancer on veterans be researched.

Lung Cancer Alliance has consistently stated that those at high risk for lung cancer should speak with their doctors abut the risk and benefits of a CT scan, and to only have it done at centers experienced in lung cancer diagnosis.

Late stage lung cancer is twice as costly to treat as early stage cancer. Even conservative estimates place the cost of lung cancer to the VA at \$1 billion a year. A study published in the April 29, 2009 *Journal of Clinical Oncology* predicts that the incidence of cancer overall will increase by 45% over the next 20 years, while the incidence of lung cancer specifically will increase by 52%. It is imperative that the VA initiate a pilot early detection research program targeting high risk veterans.

## SOURCES

Harris RE, Hebert JR, Wynder EL. Cancer risk in male veterans utilizing the Veterans Administration medical system. Cancer 1989;64:1160-8.

Campling BG, Hwang WT, Zhang J, et al. A Population-based Study of Lung Carcinoma in Pennsylvania: Comparison of Veterans Administration and Civilian Populations. *Cancer. 2005;* 104(4)

Jeffrey E. Harris MD PhD. Cigarette Smoking Practices, Smoking-Related Diseases, and the Costs of Tobacco-Related Disability Among Currently Living U.S. Veterans. Report Commissioned by the Department of Veterans Affairs, Revised September 15, 1997

Stuart Bondurant and Roberta Wedge. Combating Tobacco Use in Military and Veteran Populations, , Editors; Committee on Smoking Cessation in Military and Veteran Populations; Institute of Medicine 2009. http://www.nap.edu/catalog.php?record\_id=12632

Adam A. Powell, PhD, MBA,\* Ellen M. Schultz, MS, Diana L. Ordin, MD, MPH, et al. Timeliness Across the Continuum of Care in Veterans with Lung Cancer. CHEST. 2008; 133: 1167-1173

Kelly Bedard and Olivier Deschenes. The Long-term Impact of Military Service on Health: Evidence from World War II and Korean War Veterans. *American Economic Review*. 2006; 6:(1): 176-194

Committee to Review the Health Effects in Vietnam Veterans of Exposure to Herbicides (Seventh Biennial Update), Institute of Medicine 2008, <a href="https://www.nap.edu/catalog/12662.html">https://www.nap.edu/catalog/12662.html</a>

Gulf War and Health Volume 3: Fuels, Combustion Products, and Propellants Committee on Gulf War and Health: Literature Review of Selected Environmental Particulates, Pollutants, and Synthetic Chemical Compounds Board on Health Promotion and Disease Prevention, The Institute of Medicine, The National Academies Press, 2005 <a href="http://www.nap.edu/catalog.php?record\_id=11180">http://www.nap.edu/catalog.php?record\_id=11180</a>

Gulf War and Health: Updated Literature Review of Depleted Uranium, Committee on Gulf War and Health, The Institute of Medicine, The National Academies Press, 2008. http://www.nap.edu/catalog.php?record\_id=12183 Stuart Bondurant and Roberta Wedge, Editors. Combating Tobacco Use in Military and Veteran Populations. Committee on Smoking Cessation in Military and Veteran Populations; Institute of Medicine 2009

Australian National Service Korean Veterans and Vietnam Veterans: Mortality and Cancer Incidence Studies: <a href="http://www.dva.gov.au/aboutDVA/publications/health-research">http://www.dva.gov.au/aboutDVA/publications/health-research</a>

Centers for Disease Control and Prevention, Cigarette Smoking among Adults, Morbidity and Mortality Weekly Report, November 14, 2008 57(45);1221-1226

Benjamin D. Smith, Grace L. Smith, Arti Hurria, Gabriel N. Hortobagyi, Thomas A. Buchholz. Future of Cancer Incidence in the United States: Burdens Upon an Aging, Changing Nation. *Journal of Clinical Oncology*. 2009; 17(1): 2758-2765

Wilson, M.. Prevalence of tobacco abuse in a United States Marine Corp Infantry Battalion Forward Deployed in the Haditha Triad Area of Operations, Al Anbar, Iraq. CHEST. 2008;134: s53001

# Cost of Care for Elderly Cancer Patients in the United States

K. Robin Yabroff, Elizabeth B. Lamont, Angela Mariotto, Joan L. Warren, Marie Topor, Angela Meekins, Martin L. Brown

J Natl Cancer Inst 2008;100:630-641

Table 6. Aggregate 5-year costs of care for the cohort of elderly Medicare cancer patients diagnosed in 2004\*

	Wome	n	Men				
Tumor site	No. of patients in United States	5-year costs, million \$	No. of patients in United States	5-year costs, million \$	Total 5-year costs, million \$		
Brain and ONS	3223	141	3173	152	293		
Female breast	77 008	1375	O	0	1375		
Cervix	2369	73	0	0	73		
Colorectal	44838	1571	41 788	1530	3101		
Corpus uteri	15131	340	0	0	340		
Esophagus	2392	104	5896	282	386		
Gastric	5912	248	8512	376	624		
Head and neck	5231	176	10338	317	492		
Leukemia	7923	300	9712	395	695		
Liver	2908	107	5042	171	278		
Lung	54665	2038	61646	2200	-4238		
Lymphoma	16112	663	15408	687	1350		
Melanoma of the skin	7981	53	14404	129	181		
Ovary	9088	507	0	0	507		
Pancreas	11 758	429	9565	343	771		
Prostate	0	0	118369	2294	2294		
Renal	7750	278	11250	407	685		
Urinary bladder	11304	256	31892	767	1 023		
All other tumor sites	38954	1113	45 585	1304	2417		
Total	324 546	9771	392581	11353	21 124		

<sup>\*</sup> All cost estimates discounted by 3% annually and reported in 2004 dollars. ONS = other nervous system. Data sources were 17-registry Surveillance, Epidemiology, and End Results (SEER) data (cancer incidence in 2004) and 13-registry SEER data (survival) and SEER-Medicare (net costs by phase of care).

# Productivity Costs of Cancer Mortality in the United States: 2000–2020

. Cathy J. Bradley, K. Robin Yabroff, Bassam Dahman, Eric J. Feuer, Angela Mariotto, Martin L. Brown

J Natl Cancer Inst 2008;100:1763-1770

Table 2. Site-specific present value of lifetime earnings (PVLE) among adults 20 and older in 2010

Cancer site	PVLE, \$US	Percentage of total cost	Deaths	PVLE/death, \$US
Total (all cancers)	142373887175	100.00	657005	216701
Lung and bronchus	38 953 476 028	27.36	185 202	210330
Colon and rectum	12802283437	8.99	67928	188 468
Female breast	10878840020	7.64	48776	223 037
Pancreas	7058015604	4.96	35474	198963
Leukemia	5879620378	4.13	24 459	240387
Brain and other nervous system	5851151373	4.11	14894	392.853
Non-Hodgkin lymphoma	5755042326	4.04	26 230	219407
Liver and intrahepatic bile duct	4638204280	3.26	16041	289 147
Ovary	2944996275	2.07	16700	176347
Kidney and renal pelvis	3632633377	2.55	14246	254993
Head and neck	.3 630 391 776	2.55	12109	299809
Prostate	3537601571	2.48	37819	93 540
Stomach	3453510837	2.43	14774	233 756
Melanoma of the skin	3298014331	2.32	8871	371 775
Urinary bladder	1976965144	1.39	14794	133633
Cervix uteri	1807797110	1.27	4666	387 440
Corpus and uterus	1101322676	0.77	7896	139479
Hodgkin lymphoma	828 691 758	0.58	1523	544118
Testis	471 622 615	0.33	372	1267803
All other sites	23873706259	16.77	104231	229046

# Estimates and Projections of Value of Life Lost From Cancer Deaths in the United States

K. Robin Yabroff, Cathy J. Bradley, Angela B. Mariotto, Martin L. Brown, Eric J. Feuer

J Natl Cancer Inst 2008;100:1755-1762

Table 1. Age-adjusted mortality rates (per 100 000) in the United States by sex and tumor site, 1999–2003\*

	Mortality rate	e (per 100 000)
Sex and tumor site	<65 years	≥65 years
Men		
Lung	21.9	440.5
Prostate	2.0	216.6
Colorectal	6,6	146.7
Pancreas	3.9	69.3
Leukemia	2.9	60.0
Lymphoma (non-Hodgkin)	3.0	57.5
Esophagus	3.0	40.6
Urinary bladder	1.1	51.7
Liver	2.9	34.9
Kidney	2.3	32.5
Gastric	1.9	35.4
Head and neck	2.5	28.1
Brain and ONS	3.2	21.7
Melanoma of the skin	1.8	18.2
Lymphoma (Hodgkin)	0.3	2.2
Testis	0.3	0.3
All cancers	69.6	1446.5
Women		
Luna	13.9	228.6
Breast	13.3	113.4
Colorectal	4.6	102.4
Pancreas	2.5	56.1
Ovary	3.7	44.8
Lymphoma (non-Hodgkin)	1.8	- 38.3
Leukemia	2.0	32.0
Corpus uteri	1.4	22.9
Brain and ONS	2.1	14.4
Gastric	1.0	17.8
Liver	1.0	17.2
Kidney	0.9	15.5
Cervix	2.0	7.1
Urinary bladder	0.4	15.4
Esophagus	0.5	10.4
Head and neck	0.6	9.7
Melanoma of the skin	0.9	7.4
Lymphoma (Hodgkin)	0.2	1.4
All cancers	60.2	883.7

Rates are age adjusted to the 2000 US Standard Population (19 age groups. Census P25-1130).

Table 2. Person-years of life lost (PYLL) due to cancer deaths in the year 2000 by sex and tumor site\*

	М	en	Wo	men
Tumor site	<65 years	≥65 years	<65 years	≥65 years
Lung	610855	635 080	488915	576102
Breast			526508	267 769
Prostate	49602	219714		
Colorectal	196931	184506	172303	224 298
Pancreas	113170	94461	87697	130226
Ovary	arem.		140152	109080
Leukemia	118013	74 698	97 195	70818
Lymphoma	99986	73 154	70133	86679
(non-Hodgkin)				
Esophagus	87829	59460	18211	24476
Urinary bladder	31 591	58293	13539	32320
Liver	92 689	49053	36485	40056
Kidney	68986	44 248	35353	36315
Gastric	58741	45301	39245	39 282
Head and neck	73 641	40617	23830	22982
Brain and ONS	123302	32733	97110	36459
Cervix			88979	17692
Corpus uteri	****	-	50962	54898
Melanoma of the skin	59723	24394	39860	17343
Lymphoma (Hodgkin)	15346	2991	12575	3241
Testis	12660	411	The state of the s	and a
All cancers	2148725	1883620	2331853	2084256

<sup>\*</sup> Tumor sites are listed from highest to lowest sex-specific age-adjusted mortality rate. — a not available or not applicable to this population; ONS = other neurologic sites. To estimate PTLL the number of deaths for each tumor site was calculated from age-and sex-specific nontality rates and age-and sex-specific population projections. For each death, cohort life tables were used to compute the remaining life expectancy had the person not died from cancer.

Tumor sites are listed from highest to lowest sex-specific age-adjusted mortality rate. ONS = other neurologic sites.

Table 3. Value of life lost due to cancer deaths in the year 2000 by sex and tumor site in billions of dollars\*

	M	en ·	Wo	men	
Tumor site	<65 years (billion \$)	≥65 years (billion \$)	<65 years (billion \$)	≥65 years (billion \$)	
Luna	66.1	82.3	50.1	72.3	
Breast			51.3	33.9	
Prostate	5.5	29.3			
Colorectal	20.7	24.1	17.2	28.8	
Pancreas	12.1	12.3	8.9	16.6	
Ovary	-	-	13.9	13.8	
Leukemia	10.7	9.8	8.4	9,1	
Lymphoma (non-Hodgkin)	10.0	9.6	6.8	11.1	
Esophagus	9.4	7.7	1.9	3.1	
Urinary bladder	3.4	7.7	1.4	4.2	
Liver	9.6	6.4	3.6	5.1	
Kidney	7.2	5.8	3.4	4.6	
Gastric	6.1	5.9	3.8	5.0	
Head and neck	7.8	5.3	2.4	2.9	
Brain and ONS	11.5	4.2	8.6	4.6	
Cervix			8.2	2.2	
Corpus uteri			5.2	6.9	
Melanoma of the skin	6.0	3.2	3.8	2.2	
Lymphoma (Hodgkin)	1.4	0.4	1.1	0.4	
Testis	1.7	0.1	<u> </u>	nurn	
All cancers	222.4	245.8	227.9	264.5	

<sup>•</sup> Tumor sites are listed from highest to lowest sex-specific age-adjusted mortality rate. — = not available or not applicable to this population; ONS = other neurologic sites. Value of life lost was estimated using a previously published value of 1 year of life (\$150000) applied to the person-years of life lost estimate for each tumor site. All value of life lost estimates were discounted by 3% annually and reported in real dollars.

Table 4. Value of life lost due to cancer deaths in the years 2000 and 2020 by tumor site in billions of dollars\*

	Value of	life lost	
Tumor site	2000 (billion \$)	2020 (billion \$)	% increase in value of life lost
Lung	270.8	433.4	60.1
Female breast	85.3	121.0	41.8
Prostate	34.8	58.4	67.6
Colorectal	90.9	140.1	54.3
Pancreas	49.9	77.9	56.2
Ovary	27.7	41.0	48.1
Leukemia	38.0	55.4	45.9
Lymphoma (non-Hodgkin)	37.4	56.5	51.0
Esophagus	22.0	34.9	58.6
Urinary bladder	16.7	26.7	60.2
Liver	24.6	37.2	51.4
Kidney	21.0	32.6	54.9
Gastric	20.8	31.6	51.5
Head and neck	18.4	28.7	56.3
Brain and ONS	28.9	40.5	40.1
Cervix	10.5	13.5	28.7
Corpus uteri	12.1	18.5	52.4
Melanoma of the skin	15.1	21.6	42.8
Lymphoma (Hodgkin)	3.2	4.3	31.0
Testis	1.2	1.3	13.6
All cancers	960.7	1472.5	53.3

<sup>•</sup> Tumor sites are listed from highest to lowest sex-specific age-adjusted mortality rate. ONS = other neurologic sites. Value of life lost was estimated using a previously published value of 1 year of life (\$150,000) applied to the person-years of life lost strate for each tumor sits. All value of life lost estimates were discounted by 3% annually and reported in real dollars.

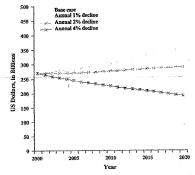


Figure 1. Projected value of life lost due to lung cancer deaths in the United States. The most recent years of data (ie, from 1999 to 2003) were used to calculate sex-and age-specific lung cancer mortality rates for the base case mortality rate projections. Sensitivity analysis scenarios included annual 1%, 2%, and 4% declines in lung cancer mortality.

Published Ahead of Print on April 29, 2009 as 10.1200/JCO.2008.20.8983 The latest version is at http://jcc.ascopubs.org/cgi/doi/10.1200/JCO.2008.20.8983

#### JOURNAL OF CLINICAL ONCOLOGY

#### Future of Cancer Incidence in the United States: Burdens Upon an Aging, Changing Nation

Benjamin D. Smith, Grace L. Smith, Arti Hurria, Gabriel N. Hortobagyi, and Thomas A. Buchholz

ABSTRACT

From the Radiation Oncology Flight Wilford Hell Madical Center Leckland
Air Force Base Department of Radia-uon Oncology, The University of Texas
M. D. Aixberson Cancer Center, Housion, 14 and the Department of Medica Oncolugy, City of Hope Cancer Center Duarte, CA

Submitted Novembar 3, 2008: accented February 13, 2009 published online ahoad of punit as when yelloo orgion April 29, 2009

Presented in part at the 22nd San Anto-nio Brassi Cancer Symposium in Discember 10-14, 2008

Authors inschoures of potential con itios of interest and author contribuconsulted found at the end of this arcket

Corresponding author Benjamin Smath, MD, 2200 Bergouist Dr., Sie 41. Lack-knd AF8, TX 78206, e-mail bensomth® alumni rice adu

© 2009 by American Society of Clinical Oncology

0733-1807/09/2799-1/\$20.00 DG1 10.1209.JCO 2008 20.8963

By 2030, the United States' population will increase to approximately 365 million, including 72 million older adults (age ≥ 65 years) and 157 million minority individuals. Although cencer incidence varies by age and race, the impact of demographic changes on cancer incidence has not been fully characterized. We sought to estimate the number of cancer patients diagnosed in the United States through 2030 by age and race.

Current demographic-specific cancer incidence rates were calculated using the Surveillance Epidemiology and End Results database. Population projections from the Census Bureau were used to project future cancer incidence through 2030.

Results
From 2010 to 2030, the total projected cancer incidence will increase by approximately 45%, from 1.6 million in 2010 to 2.3 million in 2030. This increase is driven by cancer diagnosed in older adults and minorities. A 67% increass in cancer incidence is anticipated for older adults, compared with an 11% increase for younger adults. A 99% increase is anticipated for minorities, compared with a 31% increase for whites. From 2010 to 2030, the percentage of all cancers diagnosed in older adults will increase from 61% to 70%, and the percentage of all cancers diagnosed in minorities will increase from 21% to 28%

#### Conclusion

Demographic changes in the United States will result in a marked increase in the number of cancer diagnases over the next 20 years. Continued efforts are needed to improve cancer care for older adults and minorities

J Clin Oncol 27. @ 2005 by American Society of Clinical Oncology

One of the most defining sociodemographic changes ongoing in the United States is the dramatic increase in the number of older adults and minorities. Specifically, the number of adults age 65 years or older increased from 25 million in 1980 to 35 million in 2000, and is further expected to increase to 72 million by 2030 as the baby boomer generation ages (Figs 1A, 1B) 4-3 Similarly, the number of minorities increased from 46 million in 1980 to 83 million in 2000, and is further expected to increase to 157 million in 2030 (Figs 1C, 1D). 4-3 As cancer occurs more commonly in older adults, the aging of the United States' population is expected to markedly increase the number of cancer diagnoses.' The increase in minorities is also likely to impact cancer care, particularly as prior evidence suggests that certain minorities have higher cancer incidence rates and lower cancer survival rates as compared with white people.5 In addition, minorities and older adults represent important populations that may be particularly vulnerable to suboptimal cancer care, because both groups have been under-represented in cancer clinical trials<sup>6</sup> and are also subject to disparities in can-cer treatment.<sup>7,8</sup>

These demographic shifts in our society are thus expected to exert a substantial stressor on the health care system, and they highlight the need to address shortcomings in concer clinical trials and disparities in cancer care. Quantifying the projected number of cancer cases in older and minority patients is fundamental for defining the expected societal burden of cancer, and, accordingly, guiding research and health policy priorities. However, to the best of our knowledge, specific long-term incideuce projections for cancer in the United States have not been fully quantified. To address this need. we used data from the Surveillance Epidemiology and End Results (SEER) project and the United

#### Smith et al

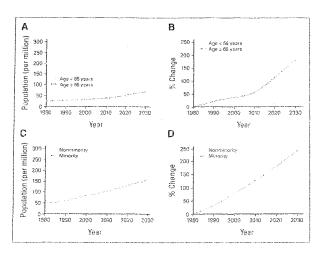


Fig 1. Population trands in the United States by age and incallorgin. 1980 to 2030 Data for 1980 and 1990 are derived from the United States Census for these years. <sup>1,3</sup> Data from 2000 onward are derived from the 2000 Census and projections for population growth thersafter.<sup>2</sup>

States Census bureau to project the anticipated number of cancer cases by age, sex, race, and origin through 2030.

in August 2008, the United Status' Census Bureau released updated projections for population growth through 2050, "which were detired from current data regarding birth rates, death rates, and immigration parterns. The projections reported the astimated number of individuals for each age from 9 through 100 years add stratified by sex, race, and origin. Race categories in-ducided which busikes, water, before Islander, haveries in individuals Particus, and multiractal. Origin categories included within 21.0 retains in combinations of line and orbifolia.

and multiracid. Origin zetegonies included either non Hispanic or Rispanic. Thus, there are 12 potential combinations of rate and origin. Our entage, sex., noc., and origin-specific current incidence rates were calculated for the United States population using the SEER-17 database, which represents approximately 29% of the United States population and includes the following: Connecticut, New Iersey, Atlanta, Rural Georgia, Kentudoy, Louisians, Datroit, Iowa, New Mexico, Utah, Los Angeles, Sun Practisco-Caldand, Sun Jose-Monterey, Greater California, Seattle, Alaska Native Temor Registry, and Havaña. \*Incidence rates were calculated from 200 through. 2005. which are the three most present reads or which data is available. Cancer. 2005, which are the three most sevent years for which data is available. Cencer sizes included all investive cancers combined (excluding normalements cole-ticous cancer), 23 individual cancer sizes, and in situ breast cancer. For incidence calculations, age categories included: 0 years, 1 to 4 years, 5 to 9 years, 10 to 14 years, and so on through 80 to 84 years, with patients age 85 years and older in a single group. Race categories included white, biase, Asian/Pedific Islander, and American Indian/Alaska Mative. Origin categories included non-Hispanic and Hispanic. Calculated incidence rates were adjusted for delayed reporting according to the method of Clegg et al. <sup>10,13</sup>

Cance incidence projections through 2000 were calculated by multiply-ing the age-, sex-, race-, and origin-specific population projections by the age-, sex-, race-, and origin-specific conver incidence rates. To account for differences between the census projections and the SEER-based cancer incidence rates, the population projections for Asians and Pacific Islanders were colleged into a single group. In addition, because SEER does not report cancer

incidence rates for multiracial individuals, these individuals were assumed to have a cancer incidence rate equal to that of the forst population not adjunct for race. For the purposes of this report, we used the US Census Bureau defutition of minority, which was defined as non-vehite race or Hispanic origin of any race.2

The assumption surderlying this method for cancer incidence projection is that the assemption sometying ever immort of tender between the projection is that the age, saw, never, and origin-specific cancer incidence rates unreaged over the years 2003 through 2005 will remain constant through 2030. Recent epidemiologic data suggests that this is a reasonable assumption, as the American Ducor Socially reported that the age-adjusted unicidence of nation from all sites combined has remained relatively constant for mon since 1995 and for ventien slute 1932. <sup>13</sup> In addition, as shown in Figure 2, agreed used contacting denot stee by rate and sex have remained stable since 1937 for all population groups except black men, where the incidence of cancer has decreased by 13%. since 1997.

Analyses were conducted using SEER Stat version 6.4.4 (www.see cancer gov/seerstat) and SAS version 9.1 (SAS institute, Cary, MC). This study was approved by the Wilford Hall Medical Center institutional review board.

#### All Cancer Sites

From 1980 through 2000, the United States population grew by 23% (from 227 million to 279 million), whereas the total yearly cancer incidence increased by 66% (from 807,000 to 1.34 million). From 2010 to 2030, the US population is expected to grow by an additional 19% (from 305 million to 365 million), and the total expected cancer incidence is expected to increase by an additional 45% (from 1.6 million to 2.3 million; Fig 3). This increased incidence is driven dis proportionately by instances diagnosed in those patients age  $\geq 65$  years and in minorities. Specifically, between 2010 and 2030, a 67% increase in one or incidence is anticipated for patients age 65 years or

#### Cancer Incidence Projections for the United States From 2010 to 2030

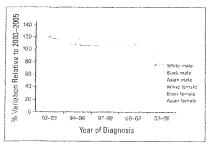


Fig 2. Variation in cancer incidence, 1992 to 2005. All rates are age-adjusted using the year 2000 standard population. All sites of invasive cancer (excluding non-melanoma stin cencer) were included in this analysis.

older (1.9 million to 1.6 million instances), compared with only an 11% increase in cancer incidence anticipated for patients younger than the age of 65 years (0.63 million to 0.67 million instances; Figs 4A, 4B). From 2010 to 2030, the percent of all cancers diagnosed in older adults in expected to increase from 0.18 to 70%.

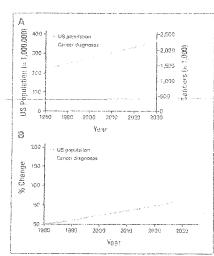


Fig. 3. Nistoric and projected growth in the United States population and all invasiva cancers by year, 1980 to 2030. Data from 1980 and 1980 are estimated using data from the Shurrellance, Epideminiogry, 2nd End Results distales s<sup>5</sup> Data from 2000 to 2030 at a satisfied as described in Mathods All sides of invasiva cancer (auchiding nonmatanome stin cancer) were included in this analysis.

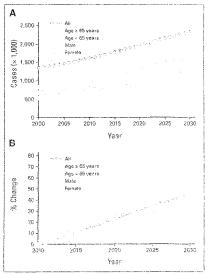


Fig 6, Projected cases of all invasive cancers in the United States by age and sex (\*) Monmelanome skin cancers were excluded from projections

With respect to rare and origin, a 99% increase in cancer incidence is anticipated for minorities (0.33 million to 0.66 million instances), compared with only 2-31% increase anticipated for non-Hispanic whites (1-3 million to 1.7 million instances; Fig 5A). The increase in cancer furidence for minorities may be attributed to an increased incidence of 64% for blacks (non-Hispanic), 132% for Asian/Pacific Islanders (non-Hispanic, 78% for American Indian). Alaska Nativas (non-Hispanic), 101% for multiracial (non-Hispanic), and 142% for Hispanics of any race (Fig 5B). From 2010 to 2030, the percentage of all cancers diagnosed in minorities is expected to increase from 21% to 28% to 28%.

#### Site-Specific Data

Based on absolute case numbers for concer incidence, the leading cancer sites in the year 2030 are still expected to be prostate (38),000), long (189,000), and colorectum (136,000) in menuand breast (294,000 in swinger), and colorectum (122,000) in women. Cancer sites with the highest percentage of increase between 2010 through 2030 are expected to be stomach (67%), liver (59%), myeloma (57%), prostate (55%), practices (55%), bladder (54%), lung (52%), and colorectum (52%). For patients age 20.5. more than 50% increase in incidence by 2030 was projected for every single cancer site examined. In addition, for Asian/Pacific Islanders and Hispanics, a more than 100% increase in incidence by 2030 was projected for the majority of fudividual exacer site examined (Table 1

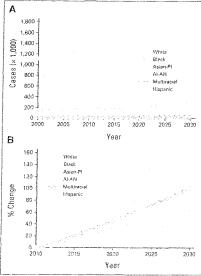


Fig. 5. Projected cases of all investive cancers in the United States by race and origin. (\*) Nonmelanoma skin cancers were excluded from projections. The Happinic origin group contains individuals of any race. This race groups white, black, Assay/Recific Islands. (P), American Indian (All/Aleska Hative (AN) and multirecial contain only non-Hispanic individuals.

and Appendix Table A1, online only). Projections by individual cancer site are prescuted in Appendix Figure AI (online only).

The burden of cancer on our population is expected to rise sharply over the next 20 years. Overall cancer incidence is expected to increase by 45% between 2010 and 2030, with the greatest increase borne by older adults and minorities. By 2030, approximately 70% of all cancers will be diagnosed in older adults, and 28% of all cancers will be diagnosed in minorities. Alarmingly, certain cancer sites with particularly high mortality rates, such as liver, stomach, pancreas, and lung. will be among those with the greatest relative increase in incidence Therefore, unless substantial improvements in cancer therapy and/or prevention strategies emerge, the number of cancer deaths may also grow dramatically over the next 20 years.

Efforts to date to address the rising number of older adults and minorities diagnosed with cancer have met with only modest success. For example, in 1999 the Institute of Medicine released a report envitted The Unequal Burden of Cancer: An Assessment of NH Research and Programs for Ethnic Minorities and the Medically Underserved<sup>13</sup> which included 22 specific recommendations for

policy initiatives to improve cancer treatment for minorities and the medically underserved through promotion of National Insti tutes of Health research efforts, communication of research findings, and enhancement of clinical trial recruitment and retention Despite these efforts, disparities in cancer treatment and outcomes have persisted. For example, a recent study suggested that cancer treatment disparities did not improve between 1992 and 2002, with minorities still more likely to receive substandard care for breast lung, prostate, and colorectal cancers. Further, blacks have continued to experience a disproportionate burden of both cancer incidence and mortality.5 and clinical trials have failed to accrue sufficient numbers of minorities and older adults. 6,14

Looking to the future, several novel programs are seeking to address shortcomings of the past. For example, the Institute of Medicine recently completed a seminal report entitled Retooling for an Aging America: Building the Health Care Workforce18 that provided 13 concrete policy suggestions to prepare the medical system for the coming surge in older adults. With respect to cancer specifically, the American Society of Clinical Oncology, in conjunction with the John A. Hartford Foundation, recently initiated support for 10 fellowship programs in geriatrics and oncology, which has already resulted in the successful training of 28 geriatric oucologists and the formation of the Cancer and Aging Research Group To address disparities in cancer care experienced by minorities. Congress recently approved the Patient Outreach Navigator and Chronic Disease Prevention Act of 2005, which is being used by the National Cancer Institute's Center to Reduce Cancer Health Disparities to support development of patient navigator programs to narrow race-based disparities by promoting culturally sensitive cancer care. 16

Such preparation for the future is critically important, as the striking increase in cancer incidence, and correspondingly an anticipated increase in cancer prevalence, could exceed the capacity of the current health care system. For example, studies from the American Society of Clinical Oncology (ASCO) and the Institute of Medicine project substantial shortages of medical oncologists and geriatricians over the next 20 years. <sup>17-18</sup> frontially, the aging of the American population may also contribute to a reduction in the number of physicians, as more physicians enter retirement themselves. In addition to a shortage of physicians, the anticipated increase in cancer incidence will require a major investment in the infrastructure needed to delive cancer care. Finally, the increasing incidence of cancer, coupled with the rising cost to treat an individual cancer patient.<sup>19</sup> could exert a synergistic effect on growth of cancer costs.

To address the expected impact of increasing cancer incidence on the health care system, several additional interventions should be considered. For example, professional societies such as the America-Association of Medical Colleges and ASCO are already actively explos ing strategies to increase the total number of physicians trained and recruitment to encology-oriented specialties. 420 Given the marked increase in cancer diagnoses in older adults, coupled with current and projected shortfalls in the number of geriatricisms, it may also be worthwhile to routinely integrate genatrics training into oncolegy fellowship programs. In addition, in an effort to counter the expected rise in cancer cases, prevention strategies of proven efficacy need to be promoted, such as vaccination for hepatitis B and human papillomavirus21; chemoprevention with tamoxifen and ralaxifene; social interventious such as tobacco and alcohol cessation; and removal of

220

Cancer Incidence Projections for the United States From 2010 to 2030

	All		Aga 65	+	Wome	1	Men	
Cancer Site and Year	No.	%	No	%	No.	%	No.	9
All					······································			
2010	1,599,000		967,000	-	761,000		838,000	
2020	1,957,000	22	1,302,000	35	900,000	18	1,057,000	2
2030						38	1,269,000	5
	2,318,000	45	1,618,000	67	1,049,000	36	1,209,000	,
Bladder								
2010	75,000		53,000		19,000		57,000	
2020	94,000	25	70,000	33	22,000	20	72.000	2
2030	116,000	54	89,000	68	27,000	45	89,000	
Sreasi								
Invasive								
2010	228,000	-	1 i 4,000		226,000		2,000	
2020	264,000	16	150.000	32	262,000	16	2,000	
2030	297,000	30	179,000	57	294.000	3G	3,000	
In situ	207,500	30	173,500	37	234.000	50	0,000	
2010	70.000		25.020		62.000	****	200	
	53,000		25.000		53,000			
2020	61.000	:4	33,000	33	61,000	14	200	
2630	67.000	26	39.000	56	67,000	26	300	
Cervix								
2010	13,000		6000.0	www	13,000		*****	
2020	15,000	15	5,000	40	15.000	15		
2030	17,000	31	6,000	76	17,600	31	~	
CNS								
2010	22.000	_	10,000		10,000		12,000	
2020	26,000	16	13,000	33	12,000	15	14,000	
2030				63		30	16,000	
	29,060	31	16,000	0.3	13,000	30	10,000	•
Coloractum								
2010	168,000		106,000	-	81.000	****	87.000	
2020	206,000	24	142,000	34	98,000	21	110,000	2
2030	255,000	52	182,900	72	120,000	48	135,000	
sophages								
2010	15.000		11,000		4,000		12 000	
2020	20,000	25	15,000	35	5,000	23	15 008	- 1
2030	24,000	49	18,000	68	5,000	49	19,000	
odgkin's lymphoma	24,000	-0	10,000	Ç	2,000		12,000	
2010	9,000		2.020		4,000	_	5,000	
			2.000	_				
2020	10.000	10	3.000	35	5.000	8	6,000	
2030	11,000	21	4,900	70	5,000	19	6,000	
dney								
2010	48,000	_	29 060		18,000		30.000	
7020	59,000	23	39,000	35	22,000	21	37,000	
2030	69,000	44	40.000	67	25,000	42	44,000	
Pry: N.								
2010	13,000	was.	8,000		3,000		10.000	
2020	16.000	25	11.000	37	3,000	23	13,000	
2030	18,000	45	13,000	56 66	3.000	36	15,000	
zeso nukamia	10,000	45	13,000	33	3.000		10,000	
	14 000		21.000		10:000		26.000	
2010	44,000		24,000		19,000		26,000	
2020	53,000	21	31,000	33	22,000	18	31,000	3
2030	84,000	45	40,000	38	26,000	41	38,000	4
rex								
2010	21,000	-	12.000		6,000		15,000	
2020	27,000	28	17.000	42	8,006	28	19.000	
2030	34,000	5.0	22,000	88	10,000	54	24,000	
ng								
2010	222,000		163 000		102,000		120,000	
2020		200		3.6				
	280,000	28	215,000	34	126,000	23	155,000	
2030	338,000	52	271,000	67	149,000	46	189,000	

18 2008 by American Seciety of Circuit Oncology S

Smith et al

	All		Age 65	÷	Wome	n	Men		
Cancer Site and Year	No.	%	No.	%	No	₩	No.	9(	
Melanoma		COLUMN TO SERVICE COMPANY COMP							
2010	70,000		34,000		29,000		41,000		
2020	79,000	13	44,000	30	31,000	.8	48,000	3	
2030	87,000	25	52,000	54	34,000	17	53,000	3	
Myelonia					01,000		00,000		
2010	20,000		13,000	1807	9.000		11,000	_	
2020	26,000	26	18,000	. 36	11,000	24	14,000	2	
2030	32,000	57	24,000	77	14,000	53	18,000	5	
Von-Hodgkin's lymphoma		-	4.1000		7.1,000				
2010	67,000	***	39,000	_	31,000		36,000	_	
2020	81,000	21	52,000	33	37.000	20	44,000	2	
2030	97,000	4.4	55,000	67	44,000	43	53,000	4	
Drat cavity and pharynx			50,000	٠.			00,000		
2010	37.000		19.000	_	11,000		25,000		
2020	44,000	19	25,000	34	13,000	18	30,000	3	
2030	49,000	35	31,000	61	15,000	36	34,000	3	
Overv	40,000	33	31,000	01	13,000	30	344,000		
2010	24.000	-	13.000	****	24.000				
2020	28,000	17	17,000	31	28,000	17	_		
2030	33.000	34	20,099	59	33,000	34	_	_	
Paricisas	33.000	,se	20,000	20	33,000	ÇI4E	. –	-	
2010	40,000		07.000		00.000		20.000		
2020	50,000	25	27.000		20,000		20,000		
2030			36,000	34	25,000	23	25.000	2	
rostate	62,000	53	46,000	73	31,000	50	31,000		
2010	242.000								
2020	246,000		182,000	****			246,000	-	
	322,000	30	252,000	39			322,000	3	
2030	382.000	55	310,000	71	_		382,000	5	
tonach									
2010	25,000		15,000		10,000	-	16,000	-	
2020	33,000	29	22.000	39	12,000	26	20.000	3	
2030	42,000	57	30,000	88	16.000	55	26.000	6	
95(18									
2010	9,000		300		gride(i)		9,000	-	
2020	9,000	3	409	34	***	***	9,000		
2030	9,000	7	500	53			9,000		
tyroid									
2010	31.000				23.000			***	
2020	35,000	11	12,000	35	26,000	10	9 000	1	
2030	38,000	50	14,000	59	28,000	18	10,000	2	
euro.									
2010	44,000		24,000	****	44,000		-	-	
2020	52,000	19	32,000	32	52,000	19		-	
2030	58.000	32	38,000	56	58,000	32	-	-	

NOTE: Projected patients numbers are rounded to the nearest 1,000, except projections < 1,000 which are rounded to the nearest 1,00. Percent change from 2010 (calculated using unrounderfincidence projections)

premulignant lesions such as colonic polyps. <sup>12</sup> Finally, to counter the rising costs of cancer care, oncology-oriented residency and fellowship programs should emphasize training in the cost-effective use of medical resources, and phase III cancer clinical trials should begin to include cost-effectiveness analysis as an important end point.

To address the anticipated surge in cancer incidence specifically in older adults, significant research investments are needed. Growing evidence from diverse cancers such as glioblastoma, <sup>23</sup> prostate cancer, <sup>24</sup> endometrial cancer, <sup>25</sup> breast cancer, <sup>26</sup> and acute myelogenous leukemia <sup>27</sup> suggests that age at disgnosic is a critical factor modifying

both cancer biology and response to therapy. Therefore, randomized clinical trials and nonrandomized clinical studies are urgently needed to identify clinically beneficial, cost-effective treatment strategies tailored to older adults. Since chronological age is a poor descriptor of functional age, future studies in geriatric populations should explore factors other than chronological age, such as comorbidity, functional and nutritional status, cognitive functioning, and social support. In Such studies could ultimately lead to evidence-based clinical guidelines that will help cancer physicians as they adapt their therapies to the unique functional and physiologic limitations of their older patients.

#### Caucer Incidence Projections for the United States From 2010 to 2030

The anticipated marked increase in cancer among minorities is also particularly important for several reasons. In addition to racebased disparities in care patterns and outcomes as discussed earlier, the marked increase in cancer among Asian/Pacific Islanders and Hispanics creates the unique challenge of treating difficult malignancies, such as stomach and liver cancer, that are relatively more common in these racial/ethnic groups, in addition to the complexity of providing culturally competent communication to individuals from different backgrounds. Looking to the future, a high priority should be placed not only on addressing disparities in cancer care, but also on increasing recruitment of minorities to cancer clinical trials, 13 in order to improve understanding of race-based differences in cancer biology,29 effectiveness of cancer therapy,30 and normal tissue response to cancer therapy.31

The projections in this study are based on the assumption that age-, sex-, race-, and origin-specific cancer incidence rates will remain relatively constant over time. Although this assumption appears reasonable based on historical data as presented in Figure 1, it is likely that continued efforts to promote cancer prevention and risk factor modification, such smoking cessation<sup>32</sup> or decreased use of hormone replacement therapy,33 will exert a downward pressure on cancer incidence in the future, though precise quantification of these effects is elusive. Therefore, it is important to underscore that these projections are subject to change as both society and medicine evolve, and will need to be periodically reevaluated. Nevertheless, because physician training and clinical trials often require 10 or more years to complete, the 20-year projections presented in this article are needed, as they will serve to inform current health policy and research priorities.

The number of cancer cases, particularly in older and minority individuals, is expected to vastly increase over the next two decades. Consequently, resources needed for cancer prevention, screening, detection, and treatment will need to increase concomitantly. Optimal cancer treatments for older and minority patients remain to be defined, and design of future clinical trials should consider these impending changes. Within a broader perspective, renewed governmental interest in health care reform should include a substantial focus on the elderly, minorities, and the medically underserved in order to address structural causes of unequal cancer care and to promote development of the national health care infrastructure needed to provide skilled and timely cancer care to even the most vulnerable segments of our population.

The author(s) indicated no potential conflicts of interest.

Conception and design: Benjamin D. Smith, Grace L. Smith, Arti Hurria, Gabriel N. Hortobagyi, Thomas A. Buchholz Administrative support: Benjamin D. Smith Provision of study materials or patients: Benjamin D. Smith Collection and assembly of data: Benjamin D. Smith Data analysis and interpretation: Benjamin D. Smith, Grace L. Smith,

Thomas A. Buithholz

Manuscript writing: Benjamin D. Smith, Grace L. Smith, Arti Hurcia, Gabriel N. Hortobagyi, Thomas A. Buchholz Final approval of manuscripti Benjamin D. Smith, Grace L. Smith, Arts Hurvis, Gabriel N. Hortobugyi, Thomas A. Buchholz

- 1. Census of Population, 1980 Census, http:// www.cerisus.gov/prod/www./abs/dacennal/1990 ceropoyt him
- United States Census Bureau 2008 Ha-tronal Population Projections: http://www.census. gov/population/www/projections/
- 3. US Census Bureau: 1990 Census http:// factfunder census gov/servlet/DatesetMainPage Sander Lang=en8\_ts=7260636581258\_ds\_name= DEC\_1890\_STF1\_8\_program= 4, Erikson C, Salsberg E, Forta G, et al. Future
- supply and demand for oncologists. Challangas in assuming access to oncology services. J Oncol Prac sce 3 79-85, 2007
- tree 3 79-93, 2007 5. Russ LAG, Welbert D, Krapcho M, et al. SEER Cancer Stressors Review, 1975-2005 Bathasota, MD Haironei Cancer Institute, 2008 http://seer.cancer.gov/ csr/1975 2005/
- cs/1975\_2005/ 6. Hutchins LF, Unger JM, Crowley JJ, st at Underepxessmation of patients 55 years of ege or older in cancer-treatment trials. N Engl J Wed 341: 2661-2657, 1989.
- Bouchardy C. Rapiti E. Biagojavic S, et al. Older female cancer pagents, Importance, causes, and consequences of underfreatment. J. Can Oncol 25:18:8-1869, 2007.

  8. Gross CP, Smith BD, Wolf E, et al. Racial
- disparties in cancer therapy. Did the Gap narrow between 1992 and 2002? Cancer 112,900-908.

- Surveillance, Epidemiology, and End Results (SEER) Program. (www.seer.cancer.gov) SEER"Stat Detabase. Incidence SEER 17 Regs Emitted-Use + Detables, Incidence - Steht 17 Mags turnisc-Use 4 Humonin Kahma Empacies Coursian Cases, Mor 2007 Sub (2000-2005) «Katmar/Rua Population Ad-justment» - Liniked To County Authorities - Total US, 1969-2005 Counties, National Cases Institute, DCCPS, Sufficilitätes Trässarch Program, Carical
- Statistics Branch 19. Cencer Query Systems: Delay-Adjusted SEER Incidence Raiss, hitp://siab.cancer.gov/delay/canques
- 11. Clagg LX, Feuel EJ, Midthons DN oi al impact of reporting delay and reporting error on cancer incidence rates and trends J Natl Cancer insi
- cancer incidence rates and trends. J. Netl Cancer Inst. 84:1537-1545, 2002.
  12. Jemet A., Siegel R., Ward E., et al. Cancer statistics. 2008. CA Cancer J. Clin. 59:71-98, 2006.
  13. Haynes MA, Smedtys RD. Underserved CoCReMartM. The Unequal Surden of Concer. An Assessment of Netl Research end Programs for Ethnic Efficiences and the Marchall, funds served Washington, DC. The National Academies Press, 1999.
- M. Murthy VH. Krumholz HM. Gross CP. Partici pation in cancer climical trials: Race, ser., and age-based disparities. JAMA 291 2720-2726, 2004 15. Floria A, Balducci L, Nasim A, et al. Mentor-
- ing junior faculty in genatric oncology. Report from the Canner and Aging Research Group. J. Chn Oncol.
- 26.3125-3127, 2008 16. Freund KM. Barregha TA, Celhoun E, et al National Cancer Institute Patient Navigation Pro-

- m. Methods, protocols, and measures. Cancer 113:3391-3399, 2008 17. Hortobagyi GNF A sho-tage of phoologists?
- The American Society of Clinical Outology work-force study J Clin Oncol 25 1458-1468, 2007 18. Services ColFHCWf0ABcHC Retooling for
- an aging America. Building the Health Care Worth force, in Haynes MA, Smedley BD lods! Washing-ion, DC, National Academies Press, 2008. 19. Warran JL, Yabroff KR, Meekins A, et al.
- Evaluation of trends in the cost of initial cencer treatment. J Natl Cancer (nst 100:888-897, 2008 20. American Association of Medical Colleges Workforce statement, http://www.aamic.org/workforce/
- 21. Dunna EF, Datta SD, E Markowitz L: A review of prophylactic human papillomavirus vaccines. Rec-ommendations and monitoring in the US. Cancel 113:2995-3003, 2008
- 22. Greenwald P: Cancer prevention clinical mats J Clin Oncol 29 illisS-22S, 2002 23. Godia T, van den Bant MJ, Hegi ME, et al
- Nomborams for pradicting survival of patients with newly diagnosed globilations. Prognostic factor analysis of ECRTC and NCIC (vial 26981-22981/CE 3. Lancet Oncol 9:29-38, 2008.
- 24. Bill-Axelian A, Holmbarg L, Route M, et al. Radical prostatectomy versus watchful weiting in early prostate cancer. N Engl J Med 352 1977-1984.
- 25. Creutzberg CL, van Purion WL, Koper PC, et all Surgery and postoperative rachotherapy versus surgery alone for patients with stage-1 endometries

#### Smith et al

- carcinoma Multicentre randomised trul PORTEC Study Group, Lancet 355 1404-1411, 2000 26. Berlehik H, Honot JC, Pootmans P, et al Recursione fixes alter treatment of breast cancer with standard radiotherapy with or without addi-tional radiation. N. Earg J. Med 454, 1378-1387, 2000 27. Dombset H, Raffoux E, Gardin C, Acute my-aiolic faukaman in the elderly. Senin Oncol 35:430– 438, 2008
- 438, 2008
  28. Yancik R, Wesley MN, Ries LA, et al. Effect of age end comorbidity in postmenopausal breast cen-

- cer patients aged 55 years and older JAMA 285-885-892, 2001
  28. Carev LA, Perou CNi, Livasy CA, et al. Raco, brasst cancer subtypes, and survival in the Caro-line Breast Cancer Study. JAMA 295-2492-2502, 2006
  38. Polite BN, Cirrincions C, Flaming GF, et al. Racoil differences in clinical ocicomes from meta-state breast cancer. A pooled enalysis of CALG8 3242 and 5840-Cancer and Leykemia Group B J Clin Oncol 26/2059-2665, 2008
- 31. Tuamokumo NL. Haftiy BG. Clascal outcome and cosmessis in African-American patients (reated with conservative surgery and radiation therapy Cancer J. 9.13-320, 2003.

  32. Jennal A, Thun MJ, Ries LA, et al. Annual report to the nation on the status of cencer, 1975-3005 reating health is flag cancer, tobacco use, and to bacco control. I Natl Cancer Inst 100 1872-1899, 2008.

  33. Ravidin PM, Cromin KA, Howadder R, et al. The decrease in breast cancer incidence in 2003 in the United States. N Engl J Med 356:1870-1874, 2007.

#### Appendix

	White		Blac	k	Asian Pacific Is		Americar and Al Nati	aska	Multira	ıcia!	Hispanio	
Cancer Site and Year	No.	%†	No.	%1	No. %t		No %t		No	% t	No # %	
All		**********										
2010	1,268,000	new .	165,000	***	41,000		6 000		12,600	_	107,000	
2020	1,480,000	17	217 (200									
2020				31	64,000	58	9,000	38	18,000	45	171,000	5
	1,638,000	31	272 000	154	94,600	135	10,000	76	24,000	101	260,000	13
Bladder												
2010	67,000		4,000	****	1.000	-	100		500	-	3.000	194
2020	81,000	21	5,000	36	2.000	67	200	48	800	52	5,000	6
2030	97.000	45	7,000	83	3.000	165	300	96	1.000	120	8,000	13
Breast												
!nvasive												
2010	179,000	-	23,000	1919	7.000		600		2,000		16.000	-
2020	197,000	10	29.000	23	11,000	49	1,000	27	3,000	38	24,000	5
2030	210,000	17	34,000	46	14,000	105	3,000	52	3,000	89	33,000	11
la situ												
2010	42.000	were.	5,000	_	2.000		100		400	,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,	3,000	
2020	45.000	8	7,000	25	3,000	49	200	28	600	36	5,000	5
2020	47,000	11	8,000	48	4,000	103	200	59	800	92	7 000	11
Carver	47,000		0.000	40	** 3,000,0	100	1003	33	500	-02	7 000	
2010	0.000		2.002		200		:00				0.000	
2020	8,000		2,000		600	-	100	_	100		3,000	
	8,000	3	2,000	18	900	\$3	100	25	200	37	4.000	4
2030	8,000	4	3,000	35	1,000	93	100	47	200	87	5,000	ē
CNS												
2010	18,000	-	i.000		500	***	100	***	200	-	2,000	
2020	20.000	3.1	2,000	21	700	42	100	28	300	38	3.000	4
2030	21,000	23	2,000	dd	1000	93	100	45	400	85	4,000	ΕO
Coloracium												
2010	131,000		19,000		5,000		700		1,000	*****	11,000	
3020	154,000	17	25,000	32	0.000	61	1,000	23	2.000	47	18,000	6
2030	179,000	37	33.000	70	12,000	143	1.000	88	2.000	310	28,000	15
Esophagus												
2010	13,000		2,000		300	NAME.	100	186110	100	Miller	1.000	
2020	15,000	20	2.000	34	500	69	100	43	200	47	1 000	ő
2030	(5.000	36	2,000	67		155	. 100	Se.	300	1.03	. 2,000	10
dodgkin's tymphoma				26.1	: : : :	. 135	00	>		/300/	. 2,000	1.0
2010	7,000		1,000	Finance	200		0		100		1,000	
2020	7,000	4	1,000	12	200	30	0	16			1,000	
2030	7,000	8	1,000	23	300	30 69	100	33	200	₫0 90	2,000	4
Eusu Sáney	7.000	8	1,000	43	300	98	100	<b>ತ</b> ತ	200	90	2,900	9
2010	22.000	_	2.000		000		200		,			
2020	37,000		5 000	0.0	900		300		400	_	4 000	
	43,000	16	7,000	39	1,000	58	400	34	500	43	7.000	6
2030	47,000	28	B.000	60	2.000	133,	500	66	700	96	10,000	14
Eiyiix												
2010	10.000		2,000	*****	200	-	Q		100		700	-
2020	12,000	19	3,000	33	300	G4	0	42	100	45	1,000	5
2030	13.600	30	3,000	63	400	148	100	77	200	97	2.000	16
echemia												
2010	35,000		4,000	-	1,000	-	100		400		4,000	-
2020	41,000	16	5.000	27	2,000	48	200	32	500	27	6,000	ŝ
2030	42,000	34	6,000	30	2,000	173	200	65	800	9:3	8,000	3.3
rvex												
2010	13,000		3,900		2.000	_	200	_	200	_	3,000	
2020	15,000	(5	4,000	27	3,000	60	300	32	200	41	5,000	6
2030	17.000	28	4,000	53	€,000	134	300	61	300	\$5	5 000	14
	,550				on followin			01	300	20	0 000	1.6

© 2009 by American Scheduler Charles and April 101, 1000 Concernation and All All Albert Concernations (All Albert Concernations)

Smith et al

	White	e	Blac	k .	Asian Pacific Is		Amencar and Al Nati	aska	Multiracial		Hispa	nic.	
Cancer Site and Year	rlo	96, ÷	No.	461	No	% t	No.	961	No	%1	No. ‡	961	
Lung													
2010	187,000		24,000	_	5,000		800	***	2.000		9,000	~	
2020	221,000	22	33,000	35	0,000	66	1,000	50	2,000	51	15,000	68	
5020	255,000	40	42,000	. 74	12,000	156	2,000	99	3,000	112	24,000	171	
Melanoma													
2010	67,000	Material	300	-	200	-	100	errore.	690	-	2,000		
2020	75,000	11	400	28	300	49	100	32	900	41	2,000	5	
2030	82,000	21	500	67	400	112	100	70	1,000	95	3,000	115	
Mysloma													
2010	14.000	-	4.000	-	400		100	-	100	_	2,000		
2020	17,000	18	5,000	33	700	53	100	43	200	47	3.000	6.3	
2030	19.000	37	7,000	73	FG00	149	200	76	300	109	4,000	159	
Non-frodgitin's lymphoma													
2010	54,000		5,000	4000	2,000	-	200	name in	500		5,000		
2020	63,000	16	7,000	24	3,000	56	300	40	063	45	8,000	56	
2030	71,000	32	8,000	51	4,000	132	400	75	1.000	103	12,000	135	
Oral cavity and pherynx													
2010	29,000		4,000	and the same	1.000	-	200	to the same	300		2,000		
2020	33,000	1.4	5,000	26	2,000	50	200	31	400	41	3,000	59	
2030	35,000	23	6,000	51	2.000	109	200	35	1,000	92	5,000	136	
Overy													
2010	19 000	***	2,000	****	009		100		200		2.000	~	
2020	21,000	11	3.000	25	1,000	<i>6</i> 9	100	32	300	40	3,000	50	
2030	23,000	20	3,000	52	2.000	107	200	52	400	91	4,000	122	
Pencreas													
2010	31,000	_	5 000		1,000		200	-	300		3.000	rowr	
2020	37,000	18	6.000	34	2,000	54	300	48	400	48	5,000	66	
2030	43,000	38	8,000	75	3,000	157	300	97	600	132	7.000	163	
Prostate			-,		41-1-				4.5-2				
2010	190 000		34.000		5,000	ww	500	-	2,000	Torre	16,000	****	
2020	235.000	2.0	47,000	39	8,000	70	900	50	3 000	50	28,000	75	
2030	261 000	37	59.000	75	13,000	160	1.000	96	4,000	104	45,000	183	
Stomach			00,000		10.500	100	1.000		1,000	10	-5,000	100	
2010	16,000	_	4.000		2,000	arman .	200		200	-	3,000	_	
2020	19,000	18	5,000	33	3,000	63	200	01	360	68	5,000	. 62	
-2030	23,000	39	6.000	77	4,000	152	306	84	400	113	8,000	152	
estis	******	1.4	4.500		.,020		0.0				0,000	1.54	
2010	7 000	-	200		100		100		100		. 1,000		
2020	7,000	2	300	10	200	21	100	10	200	42	1,000	26	
2030	7,000	- 4	300	18	200	43	100	8	200	96	2,000	55	
hycoid			500	150	200		100	J	****	20	2,000	31	
2010	24.000		2.000		1.000		100		300	7070	3,000		
2020	25,000	4	3,000	19	2,000	39	100	19	200 200	37	5,000	a	
2030	25,000	5	3,000	34	3 000	B1	200	32	500	86	6,000	9	
terus	22,000	7	2,070	Ju	3,000	91	200	3.0	550	00	0,000	25	
2010	35,000		4.000	-	1,000		200		300	-	3,000	-	
2020	39,000	12	5,000	33	2,000	48	200	34	500	40	5,000	5	
2030	41,000	12	6,000	61	3,000	103	200	57	600	88	7,000	120	

NOTE. Projected patient numbers are rounded to the nearest 1,000, accept projections < 1,000 which are rounded to the nearest 100 Only individuals of non-Hispanic outgin are reported in these columns.

File cent change from 2010 fediculated using involvated incidence projections. 
Rendered the projection of the proje

### 226

#### House Appropriations Committee Defense Subcommittee

## Witness Disclosure Form

Clause 2(g) of rule XI of the Rules of the House of Representatives requires nongovernmental witnesses to disclose to the Committee the following information. A non-governmental witness is any witness appearing on behalf of himself/herself or on behalf of an organization other than a federal agency, or a state, local or tribal government.

Your Name, Business Address, and Telephone Number:

Laurie Fenton Ambrose President & CEO Lung Cancer Alliance 888 16 <sup>th</sup> St. NW Washington, DC 20006 202-463-2080	
Are you appearing on behalf of yourself or a non-governmental organization? Please list organization(s) you are representing.	
Representing Lung Cancer Alliance	
<ol> <li>Have you or any organization you are representing received any Federal grants or contracts (including any subgrants or subcontracts) since October 1, 2007?</li> <li>Yes No XXX</li> </ol>	
3. If your response to question #2 is "Yes", please list the amount and source (by agency and program) of each grant or contract, and indicate whether the recipient of such grant or contract was you or the organization(s) you are representing.	
Signature: Date: 4/29/10	Parasa.

Mr. Dicks. Any questions?

Mr. Frelinghuysen. Good to have you back.

Mr. DICKS. Thank you very much for your testimony. We appreciate it. Thank you very much.

Thursday, May 20, 2010.

#### **NEUROFIBROMATOSIS**

#### WITNESS

#### KAREN GUNSUL, VICE PRESIDENT, WASHINGTON STATE NEUROFI-BROMATOSIS FAMILIES—WSNF

Mr. Dicks. Karen Gunsul.

Ms. Gunsul. Good morning.

Mr. DICKS. Good morning, Karen, welcome.

Ms. Gunsul. Thank you. Mr. Dicks. We will put your statement in the record. You have 5 minutes to summarize.

Ms. Gunsul. I understand.

I am a business owner from Seattle, Washington.

Mr. Dicks. Well, welcome.

Ms. Gunsul. Thank you. Your whole State said hello.

I am representing the Washington State Neurofibromatosis Families and a national coalition of States under NF, Inc. We are asking for \$20 million to continue the Army's highly successful peerreviewed Neurofibromatosis Research Program. I am also the mother of a 17-year-old son Sam who has NF.

Neurofibromatosis, if you don't know, is a genetic disorder involving uncontrolled tumor growth along the nervous system, which can result in a variety of symptoms; disfigurement, deformity, deafness, blindness, brain tumors, cancer and/or death. NF is not rare.

Mr. DICKS. Is it a lung disease, too?

Ms. Gunsul. No, not yet, but it does cause tumors to grow anywhere along nerve pathways, so it can be. You just don't know when and where it is going to strike. It is more common than muscular dystrophy and cystic fibrosis times three. It is not as widely known because for years it has been poorly diagnosed, and approximately 100,000 Americans currently have NF, and it occurs in 1 in 2,500 births.

It strikes worldwide without regard to gender or race, and approximately 55 percent of those cases are spontaneous mutations of genes, such as my son's. We have no history of NF in our family, and 50 percent of the cases are inherited.

There are two types of NF, NF1, which is more common, that my son has, and NF2, which primarily causes deafness, tumors that affect the ears and balance problems.

When my son was diagnosed in 1996, I learned as much as I possibly could about neurofibromatosis, and the one thing that stood out to me is that there are no known treatments and no known cure. And 14 years ago that was tough news to take.

While there are broad implications for the general public, the Army can see direct military application. Research on NF stands to benefit the military because this disorder is closely linked to cancers, brain tumors, learning disabilities, brain tissue degeneration,

nervous system degeneration, deafness, memory loss and balance. And because NF manifests in the nervous system, findings generated by the Army-supported research on NF address peripheral nerve regeneration. This is very important to understand for

wound healing and war-related illnesses.

In recognizing NF's importance to both the military and to the general population, Congress has given the Army's NF program strong bipartisan support for years. After the initial 3-year grants were successfully completed, Congress appropriated continued funding for the Army NF research program on an annual basis. From fiscal year 1996 through now, this funding has amounted to \$214 million in addition to the original \$8 million, 3-year grant. These grants, through the Army program, reach across all 50 States, and they are highly regarded in the medical community.

There are currently five clinical trial sites located across the country, and they are all coordinated and monitored through the Huntsville, Alabama, central site. The Army program funds innovative, groundbreaking research which would not otherwise have

been pursued.

At our last meeting with Army officials administering the program, they indicated that they could easily fund more applications if funding were available because of the high quality of the applications received. They stated they felt they were turning away good science.

In order to ensure maximum efficiency, the Army collaborates closely with other Federal agencies that are involved in NF research, National Institutes of Health. They have several members of the National Institute of Neurological Disorders and Stroke. The NINDS group sits on the Army's NF Integration Panel—

Mr. DICKS. You have 1 minute.

Ms. Gunsul. Thanks—which sets the oversight and long-term vision strategies for the program.

The results from this program have been fast, and we are right

on the brink of some very exciting findings.

The difference was brought home to me personally last month. After my son had three very large tumors removed from his left leg, I sat down with Sam's surgeon, and we discussed potential therapies that are now right on the horizon for restricting tumor growth and stopping the formation of tumors.

The science is real, and we are very excited by the potential. We are asking for \$20 million to continue the Army's important NF re-

search. It is money well spent. Thank you.

Mr. DICKS. Thank you very much. We appreciate your testimony. [The statement of Ms. Gunsul follows:]

#### House Appropriations Subcommittee on Defense Karen Gunsul, Vice President, Washington State Neurofibromatosis Families - WSNF

#### May 20, 2010

Thank you, Mr. Chairman, for the opportunity to present testimony to the Subcommittee on the importance of continued funding for Neurofibromatosis (NF), a terrible genetic disorder closely linked to many common diseases widespread among the American population.

On behalf of Washington State Neurofibromatosis Families (WSNF) a participant in a national coalition of NF advocacy groups, I speak on behalf of the 100,000 Americans who suffer from NF as well as approximately 175 million Americans who suffer from diseases linked to NF such as cancer, brain tumors, heart disease, memory loss and learning disabilities. I also speak from the heart as the mother of a 17 year old son, Sam, who deals with NF every day. Sam, at his young age, has undergone 12 separate surgeries; most of them caused directly by NF, and continues to deal with the consequences and pain of this disorder. To find treatments and, ultimately, a cure, for this disorder would benefit him and countless others.

Mr. Chairman, I am requesting increased support, in the amount of \$20 million, to continue the Army's highly successful Neurofibromatosis Research Program (NFRP). The Peer-Reviewed Neurofibromatosis (NF) Research Program, one of the Department of Defense's Congressionally Directed Medical Research Programs (CDMRP), is now conducting clinical trials at nation-wide clinical trials centers created by NFRP funding. These clinical trials involve drugs that have already succeeded in eliminating tumors in humans and rescuing learning deficits in mice. Administrators of the Army program have stated that the number of high-quality scientific applications justify a much larger program.

#### What is Neurofibromatosis (NF)?

NF is a genetic disorder involving the uncontrolled growth of tumors along the nervous system which can result in terrible disfigurement, deformity, deafness, blindness, brain tumors, cancer, and/or death. NF can also cause other abnormalities such as unsightly benign tumors across the entire body and bone deformities. In addition, approximately one-half of children with NF suffer from learning disabilities. While not all NF patients suffer from the most severe symptoms, all NF patients and their families live with the uncertainty of not knowing whether they will be seriously affected because NF is a highly variable and progressive disease.

NF is not rare. It is three times more common than Muscular Dystrophy and Cystic Fibrosis combined, but is not widely known because it has been poorly diagnosed for many years. Approximately 100,000 Americans have NF, and it appears in approximately one in every 2,500 births. It strikes worldwide, without regard to gender, race or ethnicity. Approximately 50 percent of new NF cases result from a spontaneous mutation in an individual's genes – as is my son's – and 50 percent are inherited. There are two types of NF: NF1, which is more common, and NF2, which primarily involves tumors causing deafness and balance problems. In addition, advances in NF research stand to benefit over 175 million Americans in this generation alone because NF, the most common neurological disorder caused by a single gene, is directly linked to many of the most common diseases affecting the general population.

#### NF's Connection to the Military

Research on NF stands to benefit the military because this disorder is closely linked to cancer, brain tumors, learning disabilities, brain tissue degeneration, nervous system degeneration, deafness, memory loss, and balance. Because NF manifests itself in the nervous system, findings generated by the Army-supported research on NF address peripheral nerve regeneration after injury from such things as missile wounds and chemical toxins, and is important to gaining a better understanding of wound healing and war-related illnesses. In addition, NF research now includes important investigations into genetic mechanisms which involve not just the nervous system but also other cancers.

#### Link to Other Illnesses

Researchers have determined that NF is closely linked to cancer, heart disease, learning disabilities, memory loss, brain tumors, and other disorders including deafness, blindness and orthopedic disorders, primarily because NF regulates important pathways common to these other disorders such as the RAS, cAMP and PAK pathways. Research on NF therefore stands to benefit millions of Americans:

<u>Cancer</u> – NF is closely linked to many of the most common forms of human cancer, affecting approximately 65 million Americans, because of its tumor suppresser function. Research has demonstrated that NF's tumor suppressor protein, neurofibromin, inhibits RAS, one of the major malignancy causing growth proteins involved in 30 percent of all cancer. Accordingly, advances in NF research may well lead to treatments and cures not only for NF patients but for all those who suffer from cancer and tumor-related disorders. Similar studies have also linked epidermal growth factor receptor (EGF-R) to malignant peripheral nerve sheath tumors (MPNSTs), a form of cancer which disproportionately strikes NF patients.

<u>Heart disease</u> - Researchers have demonstrated that mice completely lacking in NF1 have congenital heart disease that involves the endocardial cushions which form in the valves of the heart. This is because the same ras involved in cancer also causes heart valves to close. Neurofibromin, the protein produced by a normal NF1 gene, suppresses ras, thus opening up the heart valve. Promising new research has also connected NF1 to cells lining the blood vessels of the heart, with implications for other vascular disorders including hypertension, which affects approximately 50 million Americans. Researchers believe that further understanding of how an NF1 deficiency leads to heart disease may help to unravel molecular pathways involved in genetic and environmental causes of heart disease. Learning disabilities - Learning disabilities are the most common neurological complication in children with NF1. Research aimed at rescuing learning deficits in children with NF could open the door to treatments affecting 35 million Americans and 5 percent of the world's population who also suffer from learning disabilities. Leading researchers have already rescued learning deficits in both mice and fruit flies with NF1 with a number of drugs, and clinical trials have now been approved by the FDA. This NF research could potentially save federal, state, and local governments, as well as school districts billions of dollars annually in special education costs resulting from a treatment for learning disabilities. It also holds enormous implications for understanding and treating associated social and behavioral problems in children who suffer from learning disabilities.

<u>Memory loss</u> – Researchers have also determined that NF is closely linked to memory loss and are now investigating conducting clinical trials with drugs that may not only cure NF's cognitive disorders but also result in treating memory loss as well with enormous implications for patients who suffer from Alzheimer's disease and other dementias. Indeed, one leading Army funded researcher is pursuing parallel research into both NF and Alzheimer's simultaneously.

<u>Deafness</u> – NF2 accounts for approximately 5 percent of genetic forms of deafness. It is also related to other types of tumors, including schwannomas and meningiomas, as well as being a major cause of balance problems.

#### The Army's Contribution to NF Research

Recognizing NF's importance to both the military and to the general population, Congress has given the Army's NF Research Program strong bipartisan support. After the initial three-year grants were successfully completed, Congress appropriated continued funding for the Army NF Research Program on an annual basis. From FY96 through FY10, this funding has amounted to \$214.05 million, in addition to the original \$8 million appropriation in FY92. In addition, between FY96 and FY09, 243 awards have been granted to researchers across the country.

The Army program funds innovative, groundbreaking research which would not otherwise have been pursued, and has produced major advances in NF research, including conducting clinical trials in a nation-wide clinical trials infrastructure created by NFRP funding, development of advanced animal models, and preclinical therapeutic experimentation. In addition, the program has brought new researchers into the field of NF. Unfortunately, despite this progress the number of awards has decreased over the last several years due to a decrease in funding levels, resulting in many highly qualified applications going unfunded. Army officials administering this program have indicated that they could easily fund more applications if funding were available because of the high quality of the research applications received.

In order to ensure maximum efficiency, the Army collaborates closely with other federal agencies that are involved in NF research, such as the National Institutes of Health (NIH). Senior program staff from the National Institute of Neurological Disorders and Stroke (NINDS), for example, sits on the Army's NF Research Program Integration Panel which sets the long-term vision and funding strategies for the program. This assures the highest scientific standard for research funding, efficiency and coordination while avoiding duplication or overlapping of research efforts.

Because of the enormous advances that have been made as a result of the Army's NF Research Program, research in NF has truly become one of the great success stories in the current revolution in molecular genetics. Accordingly, many medical researchers believe that NF should serve as a model to study all diseases. Indeed, since the discovery of the NF1 gene in 1990, researchers are now on the threshold of developing a treatment and cure for this terrible disease.

Thanks in large measure to this Subcommittee's support; scientists have made enormous progress since the discovery of the NF1 gene. Major advances in just the past few years have ushered in an exciting era of clinical and translational research in NF with broad implications for the general population. These recent advances have included:

- Phase II and Phase III clinical trials involving new drug therapies for both cancer and cognitive disorders:
- Creation of a National Clinical and Pre-Clinical Trials Infrastructure and NF Centers;
- Successfully eliminating tumors in NF1 and NF2 mice with the same drug;
- · Developing advanced mouse models showing human symptoms;
- · Rescuing learning deficits and eliminating tumors in mice with the same drug;
- · Determining the biochemical, molecular function of the NF genes and gene products;

· Connecting NF to more and more diseases because of NF's impact on many body functions.

#### **Future Directions**

NF research has now advanced to the translational and clinical stages which hold incredible promise for NF patients, as well as for patients who suffer from many of the diseases linked to NF. This research is costly and will require an increased commitment on the federal level. Specifically, future investment in the following areas would continue to advance research on NF:

- · Clinical trials;
- Funding of clinical trials network to connect patients with experimental therapies;
- DNA Analysis of NF tissues;
- · Development of NF Centers, tissue banks, and patient registries;
- · Development of new drug and genetic therapies;
- Further development of advanced animal models;
- Expansion of biochemical research on the functions of the NF gene and discovery of new targets for drug therapy; and
- Natural history studies and identification of modifier genes studies are already underway to
  provide a baseline for testing potential therapies and differentiate among different phenotypes of
  NF.

#### Fiscal Year 2011 Request

Mr. Chairman, the Army's highly successful NF Research Program has shown tangible results and direct military application with broad implications for the general population. The program has now advanced to the translational and clinical research stages, which are the most promising, yet the most expensive direction that NF research has taken. The program has succeeded in its mission to bring new researchers and new approaches to research into the field. Therefore, increased funding is now needed to take advantage of promising avenues of investigation, to continue to build on the successes of this program, and to fund this promising research thereby continuing the enormous return on the taxpayers' investment.

## I respectfully request an appropriation of \$20 million in your FY11 Department of Defense Appropriations bill for the Army's Neurofibromatosis Research Program.

Mr. Chairman, in addition to providing a clear military benefit, the DOD's Neurofibromatosis Research Program also provides hope for the 100,000 Americans who suffer from NF, as well as the 175 million of Americans who suffer from NF's related diseases such as cancer, learning disabilities, memory loss, heart disease, and brain tumors. Leading researchers now believe that we are on the threshold of a treatment and a cure for this terrible disease. With this Subcommittee's continued support, we will prevail.

Thank you for your support of this program and I appreciate the opportunity to present this testimony to the Subcommittee.

#### House Appropriations Committee Defense Subcommittee

### Witness Disclosure Form

Clause 2(g) of rule XI of the Rules of the House of Representatives requires nongovernmental witnesses to disclose to the Committee the following information. A non-governmental witness is any witness appearing on behalf of himself/herself or on behalf of an organization other than a federal agency, or a state, local or tribal government.

Your Name, Business Address, and Telephone Number:
Karen Gunsul Gunsul Clark Iverson 1402 3 <sup>rd</sup> Avenue, Suite 808 Seattle, WA 98101 206-749-4161
Are you appearing on behalf of yourself or a non-governmental organization? Please list organization(s) you are representing.
WSNF - Washington State Neurofibromatosis Families
NF, Inc
Have you or any organization you are representing received any Federal grants or contracts (including any subgrants or subcontracts) since October 1, 2007?  Yes X No
3. If your response to question #2 is "Yes", please list the amount and source (by agency and program) of each grant or contract, and indicate whether the recipient of such grant or contract was you or the organization(s) you are representing.
N/A
Signature: MYCM SUL Date: 5/3/2010

Please bring this original form on the day of your testimony.

Date: 5/3/2010

Signature:

Mr. DICKS. Any questions? Thank you. Thank you very much.

THURSDAY, MAY 20, 2010.

#### MELANOMA RESEARCH FOUNDATION (MRF)

#### WITNESS

MARTIN A. WEINSTOCK, M.D., PH.D., PROFESSOR OF DERMATOLOGY AND COMMUNITY HEALTH, BROWN UNIVERSITY ALPERT MEDICAL

Mr. DICKS. Martin A. Weinstock, M.D., Ph.D., professor of dermatology and community health, Brown University. Welcome.

Dr. Weinstock. Thank you very much, Mr. Chairman, for the opportunity to testify before you. I am here representing melanoma research and the Melanoma Research Foundation, which is the largest independent national organization devoted to melanoma in the United States.

Mr. Chairman, I am requesting \$10 million for melanoma research in fiscal year 2011 defense appropriations bill through the Peer-Reviewed Cancer Research Program within the Defense Health Account.

Melanoma, as you may know, is a type of cancer which nearly always arises in the skin. Invasive melanoma affects nearly 70,000 Americans every year, and about 9,000 of those die every year. I met the sister of one of those people who succumbed to melanoma just last year about an hour ago, just coming to Washington, D.C. It is actually quite common. That is actually about one an hour dying from this disease.

It has been increasing over time. At a time when most cancers are decreasing in incidence and mortality, melanoma is increasing. It is the most rapidly increasing of any of the common types of cancer. And, indeed, since about the 1930s, when we started collecting these data, melanoma had an incident rate that has increased twentyfold. That's not 20 percent, that is 2,000 percent, twentyfold since that time.

Melanoma also, compared to other cancers, tends to affect younger adults. So people in the 25- to 29-year age group, it is the most common cancer in the United States in that age group.

We have learned in recent years through the various research that has gone that, in fact, melanoma is more than just one disease, it is multiple diseases. The most common types of melanoma are related to intense ultraviolet radiation exposure from the sun or from artificial sources either in childhood or in the early adult

years. This is the type of exposure that our military has.

Also, many people who are afflicted by melanoma are, indeed have the type of melanoma that is related to cumulative ultraviolet exposure either from the sun or artificial sources over the course of their lives. So recent exposure is important. For many people, the most common type of melanoma, it is early adult life and childhood exposure.

So the connection to the military, obviously, is obviously very important, because we put our military men and women in areas of intense sun exposure, and that has been linked to increased risk of melanoma. There are some recent publications to that effect, and

we know the etiology of melanoma, so that that is an important risk factor.

In order to appropriately treat those people, we need to detect those melanomas early, and for those that aren't detected early

enough, we need to find a cure.

So right now we have about 150,000 Army National Guard, Coast Guard, Air Force and Marines in Iraq where the intensity of sun exposure is quite great, and that is common, such as in Vietnam in years past, and it generates melanomas in these people years after their service.

Mr. DICKS. You have 1 minute to summarize.

Dr. WEINSTOCK. Okay. So basically the peer-review cancer research—

Mr. DICKS. Can I ask a question?

Dr. Weinstock. Sure.

Mr. DICKS. Why hasn't the National Cancer Institute funded this? I just don't understand why melanoma, which is a very serious cancer, would not get more attention from the National Cancer Institute. Is there an answer to that?

Dr. Weinstock. Well, I can say that there is some funding from the National Cancer Institute, but more is needed. I can't answer why in their wisdom they have decided not to increase levels. I can just say that the Peer-Reviewed Cancer Research Program established in fiscal year 2009 is specifically geared towards this purpose, which uniquely affects members who have served in the military, and so we respectfully request \$10 million for melanoma research.

Mr. DICKS. Thank you very much. We appreciate your testimony. [The statement of Dr. Weinstock follows:]

#### House Appropriations Subcommittee on Defense May 20, 2010

Testimony of Martin A. Weinstock, M.D., Ph.D. Professor of Dermatology and Community Health Brown University Alpert Medical School

#### Melanoma Research Foundation (MRF)

Thank you, Mr. Chairman, for the opportunity to present testimony to the Subcommittee on the importance of continued funding for Melanoma Research.

I am a Professor of Dermatology and Community Health at Brown University, Chief of Dermatology at the VA Medical Center in Providence, Rhode Island, and Chairman of the American Cancer Society Skin Cancer Advisory Committee. I am a practicing dermatologist and researcher on skin cancer and its precursors and have authored over 300 medical and scientific publications and given over 200 invited lectures in the US and internationally on 5 continents.

I am here representing the Melanoma Research Foundation (MRF), the largest independent, national organization devoted to melanoma in the United States. The MRF is committed to the support of medical research in finding effective treatments and eventually a cure for melanoma. The MRF also educates patients and physicians about prevention, diagnosis and the treatment of melanoma and is an active advocate for the melanoma community, helping to raise awareness of this disease and the need for a cure.

Mr. Chairman, I am requesting \$10 million for melanoma research in the Fiscal 2011 Defense Appropriations bill through the Peer-Reviewed Cancer Research Program within the Defense Health account.

#### What is Melanoma?

Melanoma is a type of cancer that nearly always arises in the skin. Invasive melanoma afflicts nearly 70,000 Americans every year, and we expect nearly 9,000 of them – about one every hour – to die from this disease. Today, when most types of cancer are becoming less frequent and killing fewer people, melanoma is continuing to increase, as it has done for many years. Indeed, since the 1930s, invasive melanoma has increased in frequency to a rate that is now about 20 times higher than it was at that time. That is not 20% higher, but 2000% higher.

Melanoma tends to afflict younger people than most other types of cancer, and indeed is the most common cancer in Americans age 25 to 29. It is increasing faster than any of the other common forms of cancer.

We have learned in recent years that melanoma is not a single disease, but rather multiple different diseases with different genetic and other characteristics. This may be one reason why melanoma is so hard to treat once it has spread beyond the region of the body in which it arose. Although most people with localized melanoma can be cured by surgical removal, once the

melanoma has spread to distant sites in the body, it typically kills within about a year.

#### Melanoma's Connection to the Military

It has long been known that ultraviolet radiation from the sun is a cause of melanoma, as well as other common skin cancers. Melanoma, however, is responsible for more deaths each year than all other skin cancers combined, and our estimates of deaths from melanoma have been increasing each year. We frequently put our men and women serving in the military in areas where the sun is intense, such as Iraq or Vietnam, and hence increase their risk of developing melanoma years later.

The link between sun exposure in the military and risk of melanoma has been reported in the medical literature, such as the report in the Annals of Epidemiology in the year 2000 about World War II veterans who developed melanomas many years later. However, it must be appreciated that the association is complex. There are many types of melanoma, and even though the most common types have been linked to sun exposure and exposure to ultraviolet radiation generally, there are some less common types that appear unrelated to the sun and ultraviolet. And while most melanomas are related to exposure to the sun in childhood or younger adult years, a large number are related to cumulative exposure throughout life, and for those, both exposure as a younger adult and exposure much later may result in the melanoma occurrence.

With more than 150,000 U.S. Army, National Guard, Coast Guard, Air Force and Marine personnel currently stationed in Iraq, where the intensity of sun exposure is similar to that of the Pacific, there is a potential for a long-term risk of melanoma. We currently estimate that approximately two-thirds of melanomas are attributed to ultraviolet exposure, generally from the sun. In addition, as many serious cases arise many years after the worst exposure, it is likely that we will see increased rates among other veterans who have served in sunny climates.

#### Fiscal Year 2011 Request

Fewer scientists are conducting research into melanoma; in part due to the fact melanoma research is woefully underfunded. The last time a drug was approved for advanced melanoma was over twelve years ago, and 85% of people who take that drug get no benefit from it at all. Fortunately, this is changing. Advances in understanding of melanoma have opened the door to many new avenues for treating this cancer. It is likely that a new drug will be approved within the year, and possibly two drugs will come on the market in the next 18 months.

More research is needed to understand the unique and complex nature of the many different types of melanoma and to develop effective early detection and treatment. An investment in research now will make a significant impact on the ability to reduce deaths from melanoma. Accelerating moving treatments into the clinical setting is critical--every hour of every day another person dies of melanoma in the United States. Increased funding, especially at the federal levels, is critical to finding a cure and improving current detection and treatment strategies.

The Peer Reviewed Cancer Research Program (PRCRP) was established in fiscal year 2009 to support research into specifically designated cancers with relevance to military service members

and their families. The PRCRP directly impacts military welfare by providing research into cancers that may develop due to deployments or exposure to various military environments, such as intense sun exposure.

Recognizing the impact that melanoma has on both the military and the general population, Congress has provided funding for melanoma research through the Peer-Reviewed Cancer Research Program. We respectfully request \$10 million for melanoma research in the Fiscal 2011 Defense Appropriations bill through the Peer-Reviewed Cancer Research Program within the Defense Health account.

Thank you for your support of this program and I appreciate the opportunity to deliver testimony before the Subcommittee.

House Appropriations Committee Defense Subcommittee

## Witness Disclosure Form

Clause 2(g) of rule XI of the Rules of the House of Representatives requires nongovernmental witnesses to disclose to the Committee the following information. A non-governmental witness is any witness appearing on behalf of himself/herself or on behalf of an organization other than a federal agency, or a state, local or tribal government.

Your Name, Business Address, and Telephone Number:		
MARTIN A. WEINSTOCK MO PHD		
VAMEDICAL CENTER PROVIDENCE		
530 Cupinstalle Rivering		
401-457-3333		
Are you appearing on behalf of yourself or a non-governmental organization? Please list organization(s) you are representing.		
MELANOMA RESEARCH FOUNDATION		
the state of the s		
<ol> <li>Have you or any organization you are representing received any Federal grants or contracts (including any subgrants or subcontracts) since October 1, 2007?</li> </ol>		
(Yes) No		
(1es) 140		
3. If your response to question #2 is "Yes", please list the amount and source (by agency and program) of each grant or contract, and indicate whether the recipient of such		
grant or contract was you or the organization(s) you are representing.		
As a part-time employee of the Department of Veterans		
Affairs, I am lend investigator of a large medical research project conducted with VA Funds. I am also an investigator at Bhode Island Hospital For grants funded by the National		
project conducted with VA Finds In also an in it t		
at Bhody Island Harn tal Bar and F 111 4 All		
Title City III		
Institutes of Menlth.		
Signature: Man 19 2010		

Please bring this original form on the day of your testimony.

Thursday, May 20, 2010.

## THE NATIONAL ASSOCIATION TO PROTECT CHILDREN

## WITNESS

#### DAVID KEITH, SPOKESPERSON

Mr. DICKS. David Keith, National Association to PROTECT Children.

Mr. KEITH. Thank you, Mr. Chairman and distinguished members, for giving me this opportunity to speak to you.

Mr. Chairman, in 1980, when you and I were 26, I enjoyed filming An Officer and a Gentleman in your district.

Mr. DICKS. Great movie, one of the best. Port Townsend. I was there last weekend.

Mr. Keith. It is a beautiful place. I understand that—

Mr. DICKS. Rhododendron Festival.

Mr. KEITH. I understand that hotel, that motel room, tourists

come to see where I hung myself in that thing. Pretty weird.

I want to come and tell you about what I have decided to do with the final chapter of my life. The members of this committee remember how shocked and appalled Americans were to see the graphic photographs of cruelty and abuse in the Iraqi prison Abu Ghraib.

I ask for your full attention now as I describe something much, much worse. Those Abu Ghraib photos are eclipsed in volume and savagery by the millions of images of little children being raped, tortured, sodomized and bleeding that flood the Internet to fill the bottomless appetite of a global pedophile marketplace.

Child exploitation is the great blind spot to a homeland security focused on protecting our ports, financial assets and intellectual property, but is bafflingly oblivious to international criminal networks soliciting the filmed abuse of American children. Children in the U.S. military families are no exception.

A 2008 investigation by the London Times delivered a stunning indictment to our cybersecurity response when it reported British officials had found secret coded messages between terrorists embedded in child pornographic images and pedophilic Web sites because this is "a secure way of passing information between terrorists."

Internet-facilitated child exploitation is investigated by four military criminal investigative organizations in each military branch, or MCIOs. These MCIOs do their best, but their capacity is a national disgrace. Only half a dozen of their investigators are trained and ready to conduct on-line investigations, about the size of the police force of Forks, Washington, Mr. Chairman, to protect the entire U.S. military. This small ghost patrol knows the locations of hundreds of child exploitation suspects and their victims in the U.S. right now, but they cannot take action due to sheer lack of resources.

Last month PROTECT coordinated a meeting of the best and the brightest. At a table here in Washington were Federal and State law enforcement agents, computer scientists from Oak Ridge National Laboratory and Cray Computer, makers of the world's most powerful supercomputers. Since that meeting those partners began a research and development project that could dramatically change

the game for law enforcement.

The one indispensable partner not participating is the United States Government. In addition to underfunded MCIOs, the ICE Cyber Crimes Center, C3, took crippling budget cuts this year. DOJ lags far behind, leaving the National Internet Crimes Against Children Data System, NIDS, and the PROTECT Our Children Act, which reshaped our national child exploitation response, unfunded. Shame on us.

Modest emergency funding from this Congress is a simple—

Mr. DICKS. This is in the Justice Department budget; is that what you are saying?

Mr. KEITH. I realize that part of these things are outside of this committee.

Mr. DICKS. No, no. We are not being critical of your pointing this out. We just want to get your ideas.

Mr. Keith. Yes, sir. I understand that. Thank you.

A modest emergency funding from this Congress and a simple three-pronged attack will significantly advance the war against child predators in the military and those attacking our homeland; provide at least \$2 million in defense funding to the four military criminal investigation organizations for investigation of child exploitation, the development and deployment of new technology; provide at least 10 million in Homeland Security funding to ICE Cyber Crimes Center for the specific purpose of research and development in high-speed computing and related technology; provide at least 2 million in Justice funding for the implementation of the NIDS computer platform as authorized by the PROTECT Our Children Act of 2008.

I understand that two of these proposals for funding are beyond the purview of this subcommittee; however, no piecemeal attack will be an effective or an efficient use of precious taxpayer dollars, and I ask each of you to champion this simple three-pronged solution with the full House Appropriations Committee.

Finally, let me share one other project that PROTECT is working on that is gathering congressional momentum. The Hero to Hero bill will provide financial assistance and training to returning and disabled veterans, allowing them to transition into jobs combating child exploitation and abuse, allowing them literally to go from hero to hero.

Since the dawn of history, men have gone off to war understanding that they were leaving behind what they held most dear. Protecting our children and our families are why we fight, and it is why we are all here today. Given our children face this clear and present danger, we cannot fund wars overseas without first funding this war at home. It will take your leadership right now to make that happen.

Thank vou.

Mr. Dicks. Thank you. You make a very compelling statement. [The statement of Mr. Keith follows:]

Testimony of
David Keith
Campaign Chairman
National Association to Protect Children (PROTECT)
Before the
U.S. House Subcommittee on Defense Appropriations
Public Witness Hearing

May 20, 2010

Chairman Dicks, Ranking Member Young, distinguished members, thank you for the opportunity to testify here today. Mr. Chairman, I spent many enjoyable days in your district during the filming of An Officer and a Gentleman, and it's a pleasure to speak to you as a Congressman all these years later.

I know that the members of this Committee have seen the graphic and brutal photographs from Abu Ghraib. Millions of Americans were shocked to see these depictions of cruelty and abuse in an Iraqi prison, as I'm sure you were.

I am here today to bear witness to the existence of other photographs and video, on an order of magnitude that dwarfs Abu Ghraib. These images will not be released to the news media, nor can they be shown here today. But they present a serious threat to the people of the United States and to the health and integrity of our armed services.

Child pornographers and other sexual predators have declared war on American children. I ask that you join the battle and help us destroy this enemy.

The Abu Ghraib photographs showed dogs attacking nude adults. In 2007, a state law enforcement official testified before the U.S. House Judiciary Committee about photographs showing a young girl tied to a tipped-over chair, being sexually assaulted by a dog, as tears ran down her face.<sup>1</sup>

The Abu Ghraib photographs showed adults tied up in prison cells. In 2006, a former United States Attorney General testified before the Senate Banking Committee that he had seen "a young toddler tied up with towels, desperately crying in pain, while she is being brutally raped and sodomized by an adult man."<sup>2</sup>

The Abu Ghraib photographs showed images of lurid sexual degradation. Those photos are eclipsed—in number and in the sheer depth of their evil—by millions of child sexual abuse recordings now being trafficked over the Internet to fill the bottomless appetite of a global pedophile marketplace.<sup>3</sup>

Around the globe, that market extends deeply into the U.S. military, putting children and military families in danger.

Child exploitation is *the great blind spot* to a homeland security establishment that is focused on protecting our ports, financial assets and intellectual property but oblivious to international criminal networks soliciting the rape, torture and abuse of American children from afar.

A 2008 investigation by the British newspaper *The Times* illustrates just how upside down our nation's cybersecurity response has become, as a result of ignoring what matters most. The article reports British officials have found "secret coded messages... embedded into child pornographic images, and paedophile websites," because this is "a secure way of passing information between terrorists."

Within the U.S. military, Internet-facilitated child exploitation is investigated primarily by four military criminal investigative organizations, or MCIOs. These include the Naval Criminal Investigative Service, the Air Force Office of Special Investigations, the Army Criminal Investigative Division and the Coast Guard Investigative Service.

These MCIO's struggle mightily to protect children and families from sexual abuse and exploitation, but the sum total of their capacity is a national disgrace. There are approximately half a dozen investigators from all four MCIOs who are trained and ready to conduct online investigations. Most of these are dedicated only part-time to proactive investigations.

To go back to my old stomping grounds and yours, Mr. Chairman, that's about the size of the police force of Forks, Washington to protect the entire U.S. military. This tiny ghost patrol of investigators knows the location of hundreds of child exploitation suspects in the U.S. military right now, but they cannot and will not take action on most, due to sheer lack of resources.

Here are a few examples of the kind of cases of sexual abuse and exploitation that MCIOs investigate:

- Marine Staff Sgt. Tyrone Hadnott caused an international incident leading to the lengthy lockdown of a U.S. military installation, after he was arrested in Okinawa for the rape of a 14-year old girl.
- Senior Airman Timothy Miller shattered the lives of a military family when he sexually
  assaulted their toddler he was "babysitting" at a U.S. military base.
- Army Staff Sgt. Christopher Barbieri was convicted of child pornography after a child
  came forward and disclosed that he had sexually abused her for years, beginning at the
  age of 11. The victim testified that Barbieri showed her a child pornography video to
  teach her, "that's what little girls do."

 Command Master Chief Edward E. Scott of Naval Base Kitsap in Seattle was arrested after online investigators caught him attempting to arrange for sex with two 12 year-old children.

Last month, PROTECT and our sister organization, Promise to Protect, coordinated an incredibly important gathering here in Washington. Around the table were federal and state law enforcement agents, computer scientists from Oak Ridge National Laboratory (where the Atomic Bomb was created), and Cray, makers of the world's most powerful supercomputers. We posed a simple question: "If America asked its leading scientists and technology experts to attack the problem of child exploitation, what might be possible?"

In the weeks following that meeting, Cray has begun work on a research and development project that could dramatically change the game for law enforcement. About a dozen computer scientists at Oak Ridge National Lab are also hard at work—without any funding—researching new ways of locating child pornographers and their victims. The information giant LexisNexis is engaged and offering solutions, and last week the most brilliant minds at Google offered their help. Microsoft has been working on solutions for several years.

The one indispensible partner not fully at the table is the United States government. That's not all the fault of the Department of Defense. The ICE Cyber Crimes Center (C3), one of the most innovative and important federal operations in this arena, took crippling budget cuts this year. The Department of Justice also lags far behind, leaving the Congressionally-mandated National Internet Crimes Against Children Data System (NIDS) and the PROTECT Our Children Act – which reshaped our national child exploitation response—unfunded.

What modest emergency funding from this Congress would have the greatest overall impact on our national effort, both in terms of the military and homeland security? A simple, three-pronged attack is well within reason as part of the appropriations legislation being considered here, an incredible return on investment that would advance the war against child predators in the military and those attacking our homeland:

- Provide at least \$2 million in Defense funding to the four Military Criminal Investigation
  Organizations mentioned earlier for investigation of child exploitation and for the
  development and deployment of new technology.
- Provide at least \$10 million in Homeland Security funding to the ICE Cyber Crimes
  Center to replace crippling budget losses and for the specific purpose of research and
  development in high speed computing and related technology.
- Provide at least \$2 million in Justice funding for the implementation of the NIDS computer platform, as authorized by the PROTECT Our Children Act of 2008.

I understand that two of these proposals for funding are beyond the purview of this subcommittee here today. However, no piecemeal attack will be an effective or efficient use of precious taxpayer dollars, and I ask each of you to champion this simple three-pronged solution with the full House Appropriations Committee.

Finally, let me share one other project that PROTECT is working on, one that has garnered tremendous support from the Members of Congress with whom we've discussed it. The "Hero to Hero" bill would provide financial assistance to returning and disabled veterans, allowing them to transition into jobs combating child exploitation and abuse. These men and women who once defended our nation overseas will now have the opportunity to defend our nation's children from enemies foreign and domestic.

Since the dawn of history, men have gone off to war understanding that they were leaving what they held most dear behind. Protecting our children and families are why we fight, it is why we are all here today. Given the clear and present danger that our nation faces from child exploitation, we cannot fund these overseas wars without first taking care of our children. It will take your leadership, right now, to make that happen.

<sup>&</sup>lt;sup>1</sup> Prepared Statement of Special Agent Flint Waters, Wyoming Division of Criminal Investigation, Before the House Judiciary Committee, September 2007.

<sup>&</sup>lt;sup>2</sup> Prepared Statement of Attorney General Alberto R. Gonzales Before the Senate Committee on Banking, Housing, and Urban Affairs Concerning Sexual Exploitation of Children on the Internet, Washington, D.C., September 19, 2006.

<sup>&</sup>lt;sup>3</sup> For a discussion of the full magnitude of child exploitation in the U.S., please refer to House Energy and Commerce hearings on "Sexual Exploitation of Children Over the Internet," May 4, 2006.

<sup>&</sup>lt;sup>4</sup> Times, "Link between child porn and Muslim terrorists discovered in police raids," October 17, 2008.

#### House Appropriations Committee Defense Subcommittee

## Witness Disclosure Form

Clause 2(g) of rule XI of the Rules of the House of Representatives requires nongovernmental witnesses to disclose to the Committee the following information. A non-governmental witness is any witness appearing on behalf of himself/herself or on behalf of an organization other than a federal agency, or a state, local or tribal government.

Your Name, Business Address, and Teleph	one Number:	
David Keith PO Box 27599, Knoxville, TN 37927 phone: (865) 525-0901		
Are you appearing on behalf of yourself list organization(s) you are representing The National Association to PROTECT Cl www.protect.org		
Have you or any organization you are recontracts (including any subgrants or survey)  Yes No No, we are prohibited from receiving any states.	bcontracts) since October 1, 2007?	
3. If your response to question #2 is "Yes", please list the amount and source (by agency and program) of each grant or contract, and indicate whether the recipient of such grant or contract was you or the organization(s) you are representing.		
Signature: David Keith	Date: 5/17/2010	

Please bring this original form on the day of your testimony.

Mr. DICKS. Mr. Frelinghuysen. Mr. Frelinghuysen. Thank you.

Mr. Dicks. Any of my colleagues have any questions?

Mr. Moran. I should be sitting down there. Nice to see you, David.

He really has been working hard, and he is trying to get an across-the-board approach to this issue. It is very convincing testimony.

Thank you.

Mr. DICKS. Thank you. We appreciate your good work. I hope you get back to Port Townsend or Forks.

THURSDAY, MAY 20, 2010.

# AMERICAN SOCIETY OF TROPICAL MEDICINE AND HYGIENE (ASTMH)

#### WITNESS

## DR. BERMAN, AMERICAN SOCIETY OF TROPICAL MEDICINE AND HYGIENE (ASTMH)

Mr. DICKS. Dr. Berman, American Society of Tropical Medicine and Hygiene.

Thank you, Dr. Berman, you have 5 minutes to present your

statement and summarize.

Colonel Berman. Thank you, Mr. Chairman. I am Dr. Berman, Colonel, United States Army Medical Corps, Retired, representing the American Society of Tropical Medicine and Hygiene, which is the principal professional medical organization in the United States and actually in the world for tropical medicine and global health. ASTMH represents physicians, researchers, epidemiologists and other health professionals dedicated to the control and prevention of tropical diseases.

Because the military operates in so many tropical regions, reducing the risk that tropical diseases present to service personnel is critical to mission success. Malaria and other insect-transmitted diseases, such as leishmaniasis and dengue, are particular examples of this. Antimalarial drugs have saved countless lives throughout the world, including troops serving in tropical regions during World War II, Korea and Vietnam. The U.S. military has taken a primary role in the development of antimalarial drugs, and nearly all antimalarial drugs and most promising vaccines to date were developed, at least in part, by U.S. military researchers.

Three hundred fifty million people are at risk of leishmaniasis in

Three hundred fifty million people are at risk of leishmaniasis in 88 countries; 12 million are currently infected. Leishmaniasis was a particular problem for Operation Iraqi Freedom as a result of

which 700 American service personnel became infected.

Because of leishmaniasis's prevalence in Iraq and Southwest Asia in general, the DOD has spent large resources on this disease, and DOD personnel are the leaders in development of new antileishmanial drugs. I might add both for malaria and leishmaniasis, I count or did count am still counting as one of those leadership personnel.

Dengue is the leading cause of illness and death in the—a leading cause in the tropics and subtropics. One hundred million people

are affected yearly. Although dengue rarely occurs in the continental United States, it is endemic in Puerto Rico, many tourist destinations, and periodic outbreaks occur in Samoa and Guam.

The intersection of militarily important diseases and tropical medicine is the reason that 15 percent of ASTMH members are also members of the military. For this reason we respectfully request that the subcommittee expand funding for the DOD's long-standing and successful efforts to develop new drugs, vaccines and diagnostics to protect servicemen and women from malaria and

tropical diseases.

Specifically we request that in fiscal year 2011 the subcommittee ensure 70 million to DOD to support its infectious disease research efforts through USAMRIID, WRAIR and NMRC. Presently DOD funding for this important research is about 47 million. To keep up with biomedical inflation, fiscal year 2011 funding needs to be 60 million, and to fill the gaps that have been created by underfunding, ASTMH urges Congress to fund DOD ID research at 70 million in fiscal year 2011.

We very much appreciate the subcommittee's consideration of our views. We stand ready to work with the committee and staff on

these and other tropical disease matters.

Thank you.

Mr. Dıčks. Thank you very much for your statement.

[The statement of Ms. Finney follows:]

Written Testimony Submitted to the
House Defense Appropriations Subcommittee
Regarding FY 2011 Funding for Malaria and Tropical Disease Related Programs
Sally Finney, M.Ed., CAE
Executive Director, American Society of Tropical Medicine and Hygiene

#### Introduction

The American Society of Tropical Medicine and Hygiene (ASTMH) – the principal professional membership organization representing, educating, and supporting scientists, physicians, clinicians, researchers, epidemiologists, and other health professionals dedicated to the prevention and control of tropical diseases – appreciates the opportunity to submit written testimony to House Defense Appropriations Subcommittee. Because the military operates in and deploys to so many tropical regions, reducing the risk that tropical diseases present to servicemen and women is often critical to mission success. Malaria and tropical diseases, including arboviruses such as dengue fever, are particularly important as the military has a long history of deploying to regions endemic to these diseases and they can often result in casualties.

For this reason, we respectfully request that the Subcommittee expand funding for the Department of Defense's longstanding and successful efforts to develop new drugs, vaccines, and diagnostics designed to protect servicemen and women from malaria and tropical diseases. Specifically, we request that in Fiscal Year (FY) 2011, the Subcommittee ensure \$70 million to the Department of Defense (DoD) to support its infectious disease research efforts through the Army Medical Research Institute for Infectious Diseases, the Walter Reed Army Institute of Research (WRAIR), and the U.S. Naval Medical Research Center. Presently, DoD funding for this important research is at about \$47 million. To keep up with biomedical inflation since 2000, FY 2011 funding must be about \$60 million. In order to fill the gaps created by underfunding, ASTMH urges Congress to fund DoD infectious disease research at \$70 million in FY 2011.

We very much appreciate the Subcommittee's consideration of our views, and we stand ready to work with Subcommittee members and staff on these and other important tropical disease matters.

#### **ASTMH**

The 3,700 members of the Society work in a myriad of public, private, and non-profit environments. The largest proportion of our membership (34%) work in academia at the nation's leading research universities. Fifteen percent of ASTMH members are employed by the U.S. military, and 11% are employed in public institutions and federal agencies. Nine percent of ASTMH members are in private practice, with another four percent working in industry (e.g. pharmaceutical companies). The balance of the ASTMH membership works in numerous other capacities and for various other entities seeking to reduce and prevent tropical disease.

The central public policy priority of ASTMH is reducing the burden of infectious disease in the developing world. To that end, we advocate implementation and funding of federal programs that address the prevention and control of infectious diseases that are leading causes of death and disability in the developing world, and which pose threat to U.S. citizens. Our current priorities include malaria and tropical diseases such as dengue fever and Leishmaniasis.

### **Tropical Medicine and Tropical Diseases**

The term "tropical medicine" refers to the wide-ranging clinical, research, and educational efforts of physicians, scientists, and public health officials with a focus on the diagnosis, mitigation, prevention, and treatment of vector borne diseases prevalent in the areas of the world with a tropical climate. Most tropical diseases are located in either sub-Saharan Africa, parts of Asia (including the Indian subcontinent), or Central and South America. Many of the world's developing nations are located in these areas; thus tropical medicine tends to focus on diseases that impact the world's most impoverished individuals.

ASTMH aims to advance policies and programs that prevent and control those tropical diseases which particularly impact the global poor. The United States has a long history of leading the fight against tropical diseases which cause human suffering and pose a great financial burden that can negatively impact a country's economic and political stability. The benefits of U.S. investment in tropical diseases are not only humanitarian, they are diplomatic as well. ASTMH members and others work to reduce the impact of tropical diseases and to directly and positively impact populations that are otherwise generally ignored, but on whom many countries' futures depend. Tropical diseases, many of them neglected for decades, impact U.S. citizens working or traveling overseas as well as our military personnel. Furthermore, some of the agents responsible for these diseases can be introduced and become established in the U.S. (as was the case with West Nile virus), or might even be weaponized.

# Malaria and Military Operations

Servicemen and women deployed by the U.S. military comprise a majority of the healthy adults traveling each year to malarial regions on behalf of the U.S. government. For this reason, the U.S. military has long taken a primary role in the development of anti-malarial drugs, and nearly all of the most effective and widely used anti-malarials were developed in part by U.S. military researchers. Drugs that have saved countless lives throughout the world were originally developed by the U.S. military to protect troops serving in tropical regions during WWII, the Korean War, and the Vietnam War.

Fortunately, in recent years the broader international community has stepped up its efforts to reduce the impact of malaria in the developing world, particularly by

reducing childhood malaria mortality, and the U.S. military is playing an important role in this broad partnership. But military malaria researchers are working practically alone in the area most directly related to U.S. national security: drugs and vaccines designed to protect or treat healthy adults with no developed resistance to malaria who travel to regions endemic to the disease. These drugs and vaccines would benefit everyone living or traveling in the tropics, but are particularly essential to the U.S. for the protection of forces from disease during deployments.

Increasingly, the prophylaxis and therapeutics currently given to U.S. servicemen and women are losing their effectiveness. From World War II through Vietnam, the quinine-based anti-malaria drug chloroquine was the chemoprophylaxis and therapy of choice for the U.S. military. Over time, however, the malaria parasite developed widespread resistance to chloroquine, making the drug less effective at protecting deployed troops from malaria. Fortunately, military researchers at the Walter Reed Army Institute of Research (WRAIR) achieved the scientific breakthroughs that led to the development of mefloquine, which quickly replaced chloroquine as the military's front-line drug against malaria.

Unfortunately, the malaria parasite has demonstrated a notorious and consistent ability to quickly develop resistance to new drugs. The latest generation of medicines is no exception. Malaria parasites in Southeast Asia have already shown resistance to mefloquine; resistant strains of the parasite have also been identified in West Africa and South America. There are early indications that parasite populations in southeast Asia may already be developing limited resistance to artemisinin, currently the most powerful anti-malarial available. Further, the most deadly variant of malaria – *Plasmodium falciparum* – is believed by the World Health Organization to have become resistant to "nearly all anti-malarials in current use." Resistance is not yet universal among the global *Plasmodium falciparum* population, with parasites in a given geographic area having developed resistance to some drugs and not others. However, the sheer speed with which the parasite is developing resistance to mefloquine and artemisinin – drugs developed in the 1970s – bodes of a crisis of such significance that military malaria researchers cannot afford to rest on their laurels.

Developing new antimalarials as quickly as the parasite becomes resistant to existing ones is an extraordinary challenge, and one that requires significant resources. The Global War on Terrorism may result in U.S. military operations in regions endemic to malaria, and without new anti-malarials to replace existing drugs as they become obsolete military operations could be halted in their tracks by malaria. The recent malaria outbreak affecting 80 of 220 Marines in Liberia in 2003 serves as an ominous reminder of the impact of malaria on military operations. Humanitarian missions also place Americans at risk of malaria as evidenced by several Americans contracting malaria while supporting Haitian earthquake relief efforts.

To ensure that as many American soldiers as possible are protected from tropical and other diseases, Congress provides funding each year to support Department of Defense programs focused on the development of vaccines and drugs for priority infectious diseases. To that end, the WRAIR and the Naval Medical Research Center coordinate one of the world's premier tropical disease research programs. These entities contributed to the development of the gold standard for experimental malaria immunization of humans, and the most advanced and successful drugs current being deployed around the world.

## **Neglected Tropical Diseases and Military Operations**

Currently, the WHO has a list of fifteen diseases denoted as "neglected tropical diseases." One of WRAIR's strategic assets is its Pilot Bioproduction Facility (PBF), where scientists develop new vaccines suitable for testing in humans and in complete compliance with FDA regulations. Like the broader WRAIR mission, the PBF is truly a national public health research asset, as the vast majority of investigational vaccines produced there have a broad global impact on a host of neglected tropical diseases. Few other U.S. government agencies devote as much time, funding, manpower, and direct research to tackling these devastating diseases. The work ultimately goes beyond protecting soldiers and benefits the people living in the countries where these diseases cause the most harm. The recent success of the RTS, S malaria vaccine and its advancement to Phase 3 trials is just one success story from this program.

Leishmaniasis and dengue fever are two other neglected tropical diseases that significantly impact our servicemen and women abroad. Leishmaniasis is a vector borne disease that is caused by the parasite Leishmania. It is transmitted through the bite of the female phlebotomine sandfly. Leishmaniasis comes in several forms, the most serious of which is visceral leishmaniasis, which affects internal organs and can be deadly if left untreated. According to the WHO, over 350 million people are at risk of leishmaniasis in 88 countries around the world. It is estimated that 12 million people are currently infected with leishmaniasis and 2 million new infections occur annually. Coinfection of leishmaniasis and HIV is becoming increasingly common, and WHO notes that because of a weakened immune system leishmaniasis can lead to an accelerated onset of AIDS in HIV-positive patients.

Because of leishmaniasis' prevalence in Iraq, the DoD has spent significant time and resources on development of drugs and new tools for the treatment of leishmaniasis. WRAIR discovered and developed Sitamaquine, a drug that once completed, will be an oral treatment for leishmaniasis. While essential for the safety of our servicemen and women abroad, these types of innovations will also be extremely beneficial to the at risk populations world wide that are living in leishmaniasis endemic countries.

Dengue fever, according to the WHO is the most common of all mosquito-borne viral infections. About 2.5 billion people live in places where dengue infection is possible. There are four different viruses that can cause dengue infections. While infection from one of the four viruses will leave a person immune to that strain of the virus, it does not prevent them from contracting the other three, and subsequent infections can often be more serious.

The DoD has seen about 28 cases of dengue in soldiers per year. While none of these cases resulted in the death of a soldier, hospitalization time is lengthy. Historically, dengue has been a problem for servicemen and women in Haiti in 1997, in Somalia in 1992 and 1993, and in several places during WWII from 1942 – 1945. Currently, there are several research and development efforts under way within the department of defense both for treatments and vaccines for dengue.

## FY 2011 DOD Appropriations

To protect U.S. military personnel, research must continue to develop new anti-malarial drugs and better diagnostics and vaccines for tropical diseases. Much of this important research currently is underway at the Department of Defense. Additional funds and a greater commitment from the federal government are necessary to make progress in malaria and tropical disease prevention, treatment, and control.

ASTMH agrees that malaria and NTDs remain a serious and ongoing threat to U.S. military deployments to countries and regions endemic to these diseases, and we believe that increased support for efforts to reduce this threat is warranted. A more substantial investment will help to protect American soldiers and potentially save the lives of millions of individuals around the world. Therefore, we request that the Subcommittee ensure \$70 million to the Department of Defense (DoD) to support its infectious disease research efforts through the Army Medical Research Institute for Infectious Diseases, the Walter Reed Army Institute of Research, and the U.S. Naval Medical Research Center.

The role of infectious disease in the success or failure of military operations is often overlooked, but even a cursory review of U.S. and world military history underscores the fact that keeping military personnel safe from infectious disease is critical to mission success. The drugs and prophylaxis used to keep our men and women safe from malaria and NTDs during previous conflicts in tropical regions are no longer reliable. Ensuring the safety of those men and women in future conflicts and deployments will require research on new anti-malaria tools. Thank you for your attention to this matter. We appreciate the opportunity to share our views, and please be assured that ASTMH stands ready to serve as a resource on this and any other tropical disease policy matters.



House Appropriations Committee Defense Subcommittee

# Witness Disclosure Form

Clause 2(g) of rule XI of the Rules of the House of Representatives requires nongovernmental witnesses to disclose to the Committee the following information. A non-governmental witness is any witness appearing on behalf of himself/herself or on behalf of an organization other than a federal agency, or a state, local or tribal government.

Your Name, Bus	siness Address, and Telephone Number:
Josh Berman, MD-PhD, FAAP American Society of Tropical Medicine and Hygiene 111 Deer Lake Road, Suite 100 Deerfield, IL 60015	
	earing on behalf of yourself or a non-governmental organization? Please ion(s) you are representing.
American Soci	ety of Tropical Medicine and Hygiene
	any organization you are representing received any Federal grants or cluding any subgrants or subcontracts) since October 1, 2007?
and program)	nse to question #2 is "Yes", please list the amount and source (by agency of each grant or contract, and indicate whether the recipient of such ract was you or the organization(s) you are representing.
	N 1 M m 2010
Signature:	Remall Date: 7 May 2010
P	lease bring this original form on the day of your testimony.

Mr. DICKS. Karen Mason, Ovarian Cancer National Alliance. Good morning, and you have 5 minutes to summarize. Your state-

ment will be put in the record.

Ms. MASON. Good morning, Mr. Chairman, ranking member and members of the subcommittee. I am honored to appear before you in support of the Ovarian Cancer National Alliance's request of \$30 million for the Department of Defense Ovarian Cancer Research Program.

My name is Karen Mason, and I am an intensive care nurse from Pitman, New Jersey. I also serve as an Integration Panel member of the Ovarian Cancer Research Program, which I will refer to as

the OCRP for the rest of my testimony.

As a 9-year survivor of late-stage ovarian cancer, I feel a strong sense of responsibility to my community and sit before you today as the voice of all women with this disease, past, present and future. It is my hope that today I can be seech you to share this responsibility to fund research conducted by the OCRP to find new treatments and an early detection for women with or at risk of ovarian cancer.

This year approximately 20,000 women will be diagnosed with ovarian cancer; 15,000 women will die of this disease. Ovarian cancer has no tests, like the mammogram for breast cancer or the Pap test for cervical cancer. Because there is no reliable early detection test, women must rely on their and their doctors's knowledge of ovarian cancer symptoms. However, most women and even their doctors do not know the symptoms of ovarian cancer, which are bloating, pelvic or abdominal pain, urinary urgency or frequency, difficulty eating or feeling full quickly. These symptoms are often confused with less threatening conditions.

Unfortunately, even with symptom awareness, by the time a woman has symptoms, she will already have late-stage cancer. Two out of three women with ovarian cancer are diagnosed when their

cancer is late stage, as mine was.

Care and treatments are brutal and consist of long debulking surgeries followed by months of chemotherapies. Even when the initial treatment response seems positive, around 70 to 95 percent

of women diagnosed at stages 3 or 4 will have a recurrence.

During my 9 years of survivorship, I have befriended many women who also had late-stage ovarian cancer. One by one I have watched most of these women die. Today, in the Delaware Valley, I know of no other woman diagnosed at a late stage who has survived as long as I have. I still speak to women newly diagnosed to offer them hope, but now I must hold a piece of my heart in re-

The OCRP has one bold aim, to eliminate ovarian cancer. Since 1997, the OCRP has funded out-of-the-box, innovative research focused on detection, diagnosis, prevention and control of ovarian cancer. Many of the funded proposals can be characterized as high risk and high reward. Although we take risks in the research we fund, we believe that investing in innovative research will result in great breakthroughs in the fight against ovarian cancer.

The OCRP is also special in that it involves patient advocates at all levels. I have volunteered my time for the past 3 years to serve as an Integration Panel member for the OCRP. I work alongside

physicians, scientists and other patient advocates, and together we select proposals we think merit funding. Patient advocates hold equal weight with the scientists and physicians when funding proposals and deciding the program's vision for the future.

Mr. DICKS. You have 1 minute.

Ms. Mason. The OCRP needs increased funding. This spring we have received approximately 350 preapplications. In the end we will only be able to fund approximately 32 full proposals. The ovarian cancer community worries that the cure could be heading into the trash can. Only with increased funding can the OCRP grow and continue to contribute to the fight against ovarian cancer.

The ovarian cancer community was very disappointed last year when our funding was cut from 20 million to 18.75 million for 2010. This cut is shocking when you consider our mortality has not decreased, and new treatments and an early detection test are so desperately needed. By increasing our funding to 30 million for 2011 so that more research can be carried out, we not only help women in battling the deadly beast, but the future generations of women at risk for having ovarian cancer.

Thank you again for this opportunity.

Mr. DICKS. Thank you for your statement. You make a very compelling case.

Ms. Kilpatrick.

Ms. KILPATRICK. Thank you, Mr. Chairman, and thank you for your testimony. I understand you are a registered nurse.

Ms. Mason. Yes.

Ms. KILPATRICK. You are 9 years—

Ms. Mason. Yes, of late stage.

Ms. KILPATRICK. And I am sure you have seen in your career

what procedures, medications allowed you to resist.

Ms. Mason. I think that my initial surgery that was done in a major cancer center was just long and tedious, and the doctors stayed there and removed every bit of cancer. Ovarian cancer has a way of spreading like Rice Krispies throughout your abdomen and pelvis. And once the big tumors are removed, the physician then has to spend hours picking out all these little tiny pieces.

Ms. KILPATRICK. So then the people who have this disease obvi-

ously are not getting the proper care?

Ms. Mason. Well, my long surgery was followed by months of chemotherapy. I think that my own particular body was very sensitive to the chemotherapy drugs. There aren't many women like me. I was extremely lucky, and I do feel a great sense of responsibility to help change, you know, the facts of this cancer.

And although cancer survival rates have improved since the war on cancer was declared for ovarian cancer, that is not true. We are

kind of basically where we were 40, 50 years ago.

Ms. KILPATRICK. I am with you on that. I look forward to following up.

Thank you, Mr. Chairman.

Mr. DICKS. Mr. Frelinghuysen.

Mr. Frelinghuysen. I just wanted to thank you, Ms. Mason. I work pretty closely with Kaleidoscope of Hope and Paint the Town Teal, and there is a critical mass up there which I think is spreading the message. Thank you for being here.

Ms. Mason. Thank you. [The statement of Ms. Mason follows:]



Statement of

Karen Mason, RN

of

Pitman, New Jersey

Testimony before the Appropriations Subcommittee on Defense

In support of the Department of Defense Ovarian Cancer Research Program (DoD OCRP)

U.S. House of Representatives

May 20, 2010

10:00 AM

**Summary of Testimony:** Karen Mason offers testimony regarding the appropriation request of a minimum of \$30 million in FY 2011 for the Department of Defense Ovarian Cancer Research Program (DoD OCRP) to fund research to eliminate ovarian cancer.

Good morning, Mr. Chairman, Ranking Member and Members of the Subcommittee. I am honored to appear before you in support of the Ovarian Cancer National Alliance's request of a minimum of \$30 million for the Department of Defense Ovarian Cancer Research Program. My name is Karen Mason and I am an intensive care nurse from Pitman, New Jersey. I also serve as an Integration Panel member for the Ovarian Cancer Research Program, which I will refer to as the OCRP for the remainder of my testimony.

As a nine year survivor of late stage ovarian cancer, I feel a strong sense of responsibility to my community and sit before you today as the voice of all women with this disease, past, present and future. It is my hope that today I can be seech you to share this responsibility to fund research conducted by the OCRP that works to find new treatments and an early detection test for ovarian cancer.

This year, approximately 20,000 women will be diagnosed with ovarian cancer and 15,000 women will die of this disease. Ovarian cancer has no test like the mammogram for breast cancer or pap test for cervical cancer. Because there is no reliable early detection test, women must rely on their – and their doctors' - knowledge of ovarian cancer symptoms.

However, most women, and even their doctors, do not know the symptoms of ovarian cancer, which are bloating, pelvic or abdominal pain, urinary urgency or frequency, and difficulty eating or feeling full quickly. These symptoms are often confused with less threatening conditions.

Unfortunately, even with symptom awareness, by the time a woman has symptoms, she will already have late stage cancer. Two out of three women with ovarian cancer are diagnosed when their cancer is late stage, as mine was.<sup>2</sup> Current treatments are brutal and consist of long "debulking" surgeries

<sup>&</sup>lt;sup>1</sup> "Ovarian Cancer." National Cancer Institute. May 4, 2010 <a href="http://www.cancer.gov/cancertopics/types/ovarian">http://www.cancer.gov/cancertopics/types/ovarian</a>.

<sup>&</sup>lt;sup>2</sup> M. J.Horner, L. A. G. Ries, M. Krapcho, N. Neyman, R. Aminou, N. Howlader, S. F. Altekruse, E. J. Feuer, L. Huang, A. Mariotto, B. A. Miller, D. R. Lewis, M. P. Eisner, D. G. Stinchcomb, E. K. Edwards, eds. *SEER Cancer Statistics Review 1975-2006*. National Cancer Institute, 2009. http://seer.cancer.gov/csr/1975\_2006.

followed by months of chemotherapies. Even when the initial treatment response seems positive, around 70 - 95 percent of women diagnosed at stages 3 or 4 will have a recurrence.<sup>3</sup>

During my nine years of survivorship, I have befriended many women who also had late-stage ovarian cancer. One by one, I have watched most of these women die. Today in the Delaware Valley, I know of no other woman diagnosed at a late stage who has survived as long as I have. I still speak to woman newly diagnosed to offer them hope, but now I must hold a piece of my heart in reserve.

The OCRP has one bold aim: to eliminate ovarian cancer. Since 1997, the OCRP has funded out of the box, innovative research focused on detection, diagnosis, prevention and control of ovarian cancer. Many of the funded proposals can be characterized as high risk and high reward. Although we take risks in the research we fund, we believe that investing in innovative research will result in great breakthroughs in the fight against ovarian cancer.

An example of a scientific breakthrough that came out of the OCRP was the creation of the OVA-1 test for risk stratification. This test was recently brought to the market and has received much media attention, most notably in the March 9th edition of the Wall Street Journal. In 2003, Dr. Zhen Zhang, an investigator at John Hopkins School of Medicine received an Idea Development Award from the OCRP in the amount of \$563,022.00. Dr. Zhang's research eventually led to the creation of OVA1, which is a blood test that can help physicians determine if a woman's pelvic mass is at risk for being malignant. While OVA1 is not an early detection test, it is a step in the right direction.

The OCRP is also special in that it involves patient advocates at all levels. I have volunteered my time for the past three years to serve as an Integration Panel Member for the OCRP. I work alongside physicians, scientists and other patient advocates and together, we select proposals that we believe merit funding. Patient advocates hold equal weight with scientists and physicians when funding proposals and deciding the program's vision for the future.

<sup>&</sup>lt;sup>3</sup> Armstrong, M.D., Deborah. "Treatment of Recurrent Disease Q&A." John Hopkins Pathology. May 9, 2010 <a href="http://ovariancancer.jhmi.edu/recurrentqa.cfm">http://ovariancancer.jhmi.edu/recurrentqa.cfm</a>>.

<sup>&</sup>lt;sup>4</sup> Johannes, Laura. "Test to Help Determine If Ovarian Masses Are Cancer." <u>The Wall Street Journal</u> March 9, 2010.

<sup>&</sup>lt;a href="http://online.wsj.com/article/SB10001424052748704869304575109703066893506.html">http://online.wsj.com/article/SB10001424052748704869304575109703066893506.html</a>.

Last fall during our vision setting day, I suggested that if the OCRP was truly seeking innovative out of the box researchers, perhaps the reviewers should be blinded as to who the researchers were and what institutions they represent. Imagine my delight when the panel agreed. Because researchers and institutions were blinded to us, a relatively unknown researcher from a lesser institution could conceivably be invited to submit a full proposal based solely on his or her idea.

However, one of my community's biggest fears is that the relatively low incidence of ovarian cancer (lifetime risk of developing invasive ovarian cancer is 1 in  $71^5$ ) versus other types of cancers (lifetime risk of developing breast cancer is 1 in  $8^6$ ) has resulted in a much smaller investment in ovarian cancer research, thus dissuading young scientists from studying ovarian cancer and instead choosing to head into other organ sites for their careers in order to secure research funding.

Additionally, Michael Seiden, M.D, Ph.D, President and CEO of Fox Chase Cancer Center and a fellow Integration Panel Member aptly stated that:

"Reducing the burden of ovarian cancer requires recruiting and, more importantly, mentoring a group of scientists and clinicians who are committed to building sustained and productive careers in ovarian cancer research. Few academic medical or research centers have the large ovarian cancer research teams and the number of junior faculty focused on developing careers that are supported through peer-reviewed, competitively funded ovarian cancer research. Often junior facult have few if any peers at their research center with common interests; thus, this group often lacks specific mentoring and networking opportunities that would maximize the pace of their career development."

The OCRP addressed this concern last year. We voted to award funding for the creation of an Ovarian Cancer Academy. The Academy puts the African proverb "it takes a village to raise a child" into action by training the next generation of ovarian cancer researchers. This award will develop a unique, interactive virtual academy that will provide intensive mentoring, national networking, and a peer group

<sup>&</sup>lt;sup>5</sup> "What Are the Key Statistics About Ovarian Cancer?" American Cancer Society. May 2, 2010 <a href="http://www.cancer.org/docroot/cri/content/cri\_2\_4\_1x\_what\_are\_the\_key\_statistics\_for\_ovarian\_cancer\_33.asp">http://www.cancer.org/docroot/cri/content/cri\_2\_4\_1x\_what\_are\_the\_key\_statistics\_for\_ovarian\_cancer\_33.asp</a>.

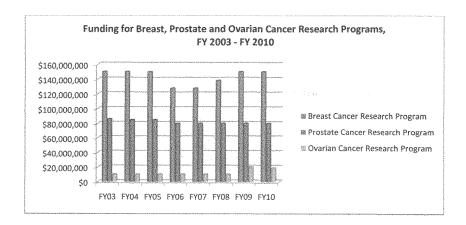
<sup>&</sup>lt;sup>6</sup> "Probability of Breast Cancer in American Women." American Cancer Society. May 3, 2010 <a href="http://www.cancer.gov/cancertopics/factsheet/Detection/probability-breast-cancer">http://www.cancer.gov/cancertopics/factsheet/Detection/probability-breast-cancer</a>.

for junior faculty. Under the guidance of mentors and a chosen Academy Dean, it is hoped that successful, highly productive ovarian cancer researchers will emerge.

But in order to continue supporting innovative research, the OCRP needs increased funding. This spring, we received approximately 350 pre-applications. In the end, we will only be able to fund 32 full proposals. The ovarian cancer community worries that the cure could be heading to the trash can. Only with increased funding can the OCRP grow and continue to contribute to the fight against ovarian cancer.

#### Ovarian Cancer Community Concerned by Funding Cuts to the OCRP

The ovarian cancer community was extremely disappointed when we found out that OCRP funding was reduced from \$20 million in 2009 to \$18.75 in 2010. This was the first cut that the OCRP has received since it was first created. It is shocking when you consider our mortality rate has not decreased and new treatments and an early detection test are still so desperately needed.



The OCRP remains a modest program compared to the other cancer programs in the Congressionally-Directed Medical Research Programs, and yet has made vast strides in the fight against ovarian cancer with relatively few resources. With an increase in funding, the program can support more research into screening, early diagnosis and treatment of ovarian cancer.

#### **Congressional Support for FY 2011 Appropriation Request**

This year, the ovarian cancer community has been proactive in securing support for our FY 2011 appropriation request. A letter addressed to you from Congresswoman Rosa DeLauro and Congressman Dan Burton in support of the \$30 million appropriation for the OCRP was also signed by 84 Representatives from both sides of the aisle: Representatives Andrews, Baldwin, Berkley, Berman, Blumenauer, Boswell, Boucher, Corrine Brown, Capuano, Carney, Carson, Castor, Cleaver, Cohen, Conyers, Crowley, Cummings, Susan Davis, DeGette, Delahunt, Doggett, Donna Edwards, Ellison, Farr, Frank, Gerlach, Gene Green, Grijalva, Gutierrez, John Hall, Halvorson, Hastings, Hirono, Hodes, Holt, Eddie Bernice Johnson, Kildee, Kilroy, Kind, Peter King, Kucinich, Lance, Levin, LoBiondo, Loebsack, Lynch, Maloney, Edward Markey, Marshall, McDermott, McGovern, Meeks, Michaud, George Miller, Brad Miller, Dennis Moore, Gwen Moore, Christopher Murphy, Patrick Murphy, Nadler, Norton, Oberstar, Pascrell, Peterson, Rahall, Richardson, Rush, Schakowsky, Bobby Scott, David Scott, Sestak, Shea-Porter, Snyder, Mike Thompson, Tierney, Tonko, Tsongas, Van Hollen, Velazquez, Walz, Wasserman Schultz, Waxman, Wu and Yarmuth.

A companion letter in the Senate was sent to the Chairman and Ranking Member of the Senate Defense Appropriations Subcommittee, Senators Inouye and Cochran. Lead signers on this letter were Senator Robert Menendez and Senator Olympia Snowe, who were joined by Senators Daniel Akaka, Barbara Boxer, Sherrod Brown, Roland Burris, Ben Cardin, Bob Casey, Susan Collins, Chris Dodd, Richard Durbin, Kirsten Gillibrand, John Kerry, Kay Hagan, Ted Kaufman, Herb Kohl, Frank Lautenberg, Joe Lieberman, Blanche Lincoln, Jack Reed, Bernard Sanders, Charles Schumer, Debbie Stabenow, Sheldon Whitehouse, and Ron Wyden.

# Appropriation Request for FY 2011

On behalf of the entire ovarian cancer community – patients, family members, clinicians and researchers – we greatly appreciate your leadership and support of federal programs that seek to reduce and prevent suffering from ovarian cancer. Thank you in advance for your support of a minimum \$30 million in FY 2011 funding for the Department of Defense Ovarian Cancer Research Program.

## House Appropriations Committee Defense Subcommittee

## Witness Disclosure Form

Clause 2(g) of rule XI of the Rules of the House of Representatives requires nongovernmental witnesses to disclose to the Committee the following information. A non-governmental witness is any witness appearing on behalf of himself/herself or on behalf of an organization other than a federal agency, or a state, local or tribal government.

Your Name, Business Address, and Telephone Number:

Karen Mason Underwood Memorial Hospital 509 North Broad St. Woodbury, NJ 08096 (856) 845-0100

1. Are you appearing on behalf of yourself or a non-governmental organization? Please list organization(s) you are representing.

The Ovarian Cancer National Alliance

2. Have you or any organization you are representing received any Federal grants or contracts (including any subgrants or subcontracts) since October 1, 2007?



No

3. If your response to question #2 is "Yes", please list the amount and source (by agency and program) of each grant or contract, and indicate whether the recipient of such grant or contract was you or the organization(s) you are representing.

Amount: \$30,000.00 grant

Source: Centers for Disease Control and Prevention Recipient: Ovarian Cancer National Alliance

Signature:

Please bring this original form on the day of your testimony.

Date: May 20, 2010

Thursday, May 20, 2010.

## SOCIETY OF GYNECOLOGIC ONCOLOGISTS

#### WITNESS

DANIEL L. CLARKE-PEARSON, M.D., PRESIDENT, SOCIETY OF GYNECO-LOGIC ONCOLOGISTS, PROFESSOR AND CHAIR, OBSTETRICS AND GYNECOLOGY, UNIVERSITY OF NORTH CAROLINA MEDICAL SCHOOL, CHAPEL HILL, NORTH CAROLINA

Mr. Dicks. Our next witness is Daniel L. Clarke-Pearson, M.D., president, Society of Gynecologic Oncologists. Thank you, sir, welcome.

Dr. CLARKE-PEARSON. Thank you. Good morning, Mr. Chairman and members of the subcommittee. Thank you for inviting me to

testify at today's hearing.

My name is Daniel Clarke-Pearson. I am a physician and president of the Society of Gynecologic Oncologists. The Society of Gynecologic Oncologists is a national medical specialty organization of physicians who are trained in the comprehensive management of women with malignancies of the reproductive tracts, such as ovarian cancer. Our purpose is to improve the care of women with gynecologic cancers by encouraging research, raising the standards of practice, disseminating knowledge, and the prevention and treatment of gynecologic malignancies.

I also practice medicine at the University of North Carolina in Chapel Hill, where I am a professor in the School of Medicine, and I am the chairman of the department of obstetrics and gynecology. A large part of my clinical practice is committed to the care of

women with ovarian cancer.

I am honored to be here and pleased that this subcommittee is focusing its attention on the Department of Defense Congressionally Directed Medical Research Program in Ovarian Cancer, OCRP.

As this subcommittee may know, ovarian cancer causes more deaths than any other cancers of the female reproductive tract. One of our biggest challenges lies in the fact that only 19 percent of all ovarian cancers are detected in a localized stage when the 5-

year survival rate is about 90 percent.

Unfortunately, as Ms. Mason just said, most ovarian cancer is diagnosed at a late stage when the cancer is spread throughout the abdomen and pelvis. In these cases the 5-year survival is only about 30 percent. We, the members of SGO, along with out patients who are battling ovarian cancer, depend on the DOD OCRP research funding. It is through this research funding that a screening and early detection method for ovarian cancer can be identified. Therefore, the SGO respectfully recommends that the subcommittee provide DOD OCRP with a minimum of \$30 million for Federal funding in fiscal year 2011.

Since its inception, the DOD OCRP has funded 209 research grants totaling more than \$140 million in funding. The common goal of these research grants has been to promote innovative, integrated and multidisciplinary research that will lead to prevention and early detection and ultimate control of ovarian cancer.

Much has been accomplished in the last decade to move us forward. In my home State of North Carolina, DOD OCRP has funded research on important questions such as the designing of personalized cancer treatments that may prolong survival based on individual cancer gene expression. We are also looking to adapt a radiology imaging technique used successfully in prostate cancer to po-

tentially detect early ovarian cancers.

Mr. Chairman, in your home State of Washington, the DOD OCRP has funded five grants in the last 5 years either at the University of Washington or at the Hutchinson Cancer Center, looking at questions such as the development of tests to detect new small molecules in blood that are present in high levels in early ovarian cancers that might be used for early ovarian cancer detection.

Another research project is examining the entire human genome in women, searching for genes or other groups of genes that may cause ovarian cancer in a familial inheritance rather than just focusing just on BRCA genes, and also developing an infrastructure for the collection and storage and testing of new biomarker blood

In Ranking Member Young and Mr. Boyd's State of Florida, nine grants have been funded since the inception of OCRP. These have contributed much to ovarian cancer research enterprise, specifically through the creation of a model of ovarian cancer in mice that allows the evaluation of the interaction of gene mutations in female hormones, and through studies to determine whether a gene, Bcl-2, which is expressed in ovarian cancer, can be used as a novel marker for early detection.

Mr. DICKS. You have 1 minute to wrap it up.

Dr. Clarke-Pearson. Yes, sir.

 $Mr.\ Dicks.\ But\ you\ are\ doing\ very\ well.$  Dr. Clarke-Pearson. These examples of achievement are obscured to a great degree by opportunities that have been missed because of underfunding.

The program's success has been documented in numerous ways, including 469 publications in professional journals, 576 abstracts

and presentations, and 24 patents and applications.

The Society of Gynecologic Oncologists joins with the Ovarian Cancer National Alliance and the American Congress of Obstetricians and Gynecologists to urge this subcommittee to increase Federal funding at a minimum to \$30 million in fiscal year 2011. I thank you for your leadership and the leadership of the subcommittee on this issue.

Mr. Dicks. Thank you for your statement. We appreciate it very much.

Ms. Kilpatrick.

Ms. KILPATRICK. Thank you very much.

How are you funded? How is the society funded?

Dr. Clarke-Pearson. Mostly membership dues and fees for our annual meeting.

Ms. KILPATRICK. And the OCRP is funded-

Dr. Clarke-Pearson. Yes, in terms of developing projects. Of course, the National Cancer Institute as well funds some research by our members.

Ms. KILPATRICK. Thank you.

Thank you, Mr. Chairman.

Mr. DICKS. Thank you.

[The statement of Dr. Clarke-Pearson follows:]



## Statement of

Daniel L. Clarke-Pearson, M.D.
President - Society of Gynecologic Oncologists
Professor and Chair, Obstetrics and Gynecology
University of North Carolina Medical School
Chapel Hill, North Carolina

On Behalf of

The Society of Gynecologic Oncologists

Before

The House Defense Appropriations Subcommittee

Thursday, May 20, 2010 at 10:00 am

Mr. Chairman, Ranking Member and members of the subcommittee, thank you for inviting me to testify at today's hearing. My name is Dr. Daniel Clarke-Pearson, and I am the President of the Society of Gynecologic Oncologists (SGO). I practice medicine at the University of North Carolina in Chapel Hill, North Carolina, where I am a professor in the medical school and chairman of the department of obstetrics and gynecology.

I am honored to be here and pleased that this subcommittee is focusing attention on the Department of Defense (DoD) Congressionally Directed Medical Research Program in Ovarian Cancer (OCRP). Since its inception now 13 years ago, this DoD program has delivered benefits to ovarian cancer research that far exceed the annual level of Federal funding.

This morning, I will try to outline some of the important contributions this DoD program has made to ovarian cancer research and the well –being of our patients. In fact, it is quite easy to demonstrate that the value to science and the benefits to medicine and patient care far exceed the annual financial commitment of the Federal government.

As this subcommittee may know, ovarian cancer usually arises from the cells on the surface of the ovary and can be extremely difficult to detect. According to the American Cancer Society, in 2009, more than 21,500 women were diagnosed with ovarian cancer and approximately 15,000 lost their lives to this terrible disease. Ovarian cancer causes more deaths than all the other cancers of the female reproductive tract combined, and is the fourth highest cause of cancer deaths among women. Overall, women with ovarian cancer have a 5-year survival rate of about 46 percent. However, only 19% of all ovarian cancers are detected at the localized stage, when the 5-year relative survival rate approaches 93%. Most ovarian cancer is diagnosed at late or advanced stage, when the 5-year survival rate is only 31%.

Nationally, biomedical research funding has grown over the last decade through increased funding to the National Institutes of Health, in no small part to the amazing efforts of members of this Subcommittee. Yet funding for gynecologic cancer research, especially for the deadliest cancer that we treat, ovarian cancer, has been relatively flat. Since FY 2003, the funding levels for gynecologic cancer research and training programs at the NIH, NCI, and CDC

have not kept pace with inflation, with the funding for ovarian cancer programs and research training for gynecologic oncologists actually suffering specific cuts in funding due to the lose of an ovarian cancer Specialized Project of Research Excellence (SPORE) in 2007 that had been awarded to a partnership of DUKE and the University of Alabama-Birmingham. Were it not for the DoD OCRP, many researchers might have abandoned their hopes of a career in basic and translation research in ovarian cancer and our patients and the women of America would be waiting even longer for reliable screening tests and more effective therapeutic approaches.

As President of the Society of Gynecologic Oncologists (SGO), I believe that I bring a comprehensive perspective to our request for increased support. The SGO is a national medical specialty organization of physicians who are trained in the comprehensive management of women with malignancies of the reproductive tract. Its purpose is to improve the care of women with gynecologic cancer by encouraging research, disseminating knowledge which will raise the standards of practice in the prevention and treatment of gynecologic malignancies and cooperating with other organizations interested in women's health care, oncology and related fields. The Society's membership, totaling more than 1,300, is comprised of gynecologic oncologists, as well as other related women's cancer healthcare specialists including medical oncologists, radiation oncologists, nurses, social workers and pathologists. SGO members provide multidisciplinary cancer treatment including chemotherapy, radiation therapy, surgery and supportive care. More information on the SGO can be found at <a href="https://www.sgo.org">www.sgo.org</a>.

We, the members of the SGO, along with our patients who are battling ovarian cancer every day, depend on the DoD OCRP research funding. It is through this type of research funding that a screening and early detection method for ovarian cancer can be identified which will allow us to save many of the 15,000 lives that are lost to this disease each year. Therefore, the SGO respectfully recommends that this Subcommittee provide the DoD OCRP with a minimum of \$30 million in Federal funding for FY 2011.

Department of Defense Ovarian Cancer Research Program: Building an Army of Ovarian Cancer Researchers

#### New Investigators Join the Fight

Since its inception in FY 1997, the DoD OCRP has funded 209 grants totaling more than \$140 million in funding. The common goal of these research grants has been to promote innovative, integrated, and multidisciplinary research that will lead to prevention, early detection, and ultimately control of ovarian cancer. Much has been accomplished in the last decade to move us forward in achieving this goal.

In my home state of North Carolina, the DOD OCRP has funded research on important questions such as:

- Determining quality of life issues for women with ovarian cancer differ according to treatment stage and then proposing interventions targeted to treatment stage that can be tested in future research; while obtaining pilot data on problems and quality of life issues for women who experience a recurrence;
- Gene expression and regulation to understand the contribution of an alternative form
  of gene regulation, "Epigenetic regulation" to ovarian cancer with the intent of
  increasing our understanding of the underlying biology of ovarian cancer, and then
  possibly enabling the strategic design of customized therapeutic measures that could
  help prolong survival; and
- Finally, no diagnostic tests are available for the early detection of ovarian cancer; however; positron emission tomography (PET), a radiological examination of the patient has helped diagnose a large variety of tumors in a painless and non-invasive way. DoD funded research at Wake Forest looked at the applicability of a new PET isotope that was discovered for use in detection of prostate cancer to it also being used in ovarian cancer early detection.

Mr. Chairman, in your home state of Washington, the DoD OCRP has funded five grants in the last five years to either the University of Washington or to the Fred Hutchinson Cancer Center to study research questions regarding:

- The usefulness of two candidate blood-based microRNA markers for ovarian cancer detection, and the identification of microRNAs produced by ovarian cancer at the earliest stages, which may also be the basis for future blood tests for ovarian cancer detection;
- The first application of complete human genome sequencing to the identification of genes for inherited ovarian cancer. The identification of new ovarian cancer genes will

allow prevention strategies to be extended to hundreds of families for which causal ovarian cancer genes are currently unknown; and

Proposed novel technology, stored serum samples, and ongoing clinical studies, with
the intend of developing a pipeline that can identify biomarkers that have the greatest
utility for women; biomarkers that identify cancer early and work well for the women
in most need of early detection, that can immediately be evaluated in clinical research.

Also Mr. Chairman, one of the first, and very successful, grant recipients from the DoD OCRP hails from the Fred Hutchinson Cancer Research Center in Seattle, WA, Dr. Nicole Urban. Dr. Urban has worked extensively in the field of ovarian cancer early detection biomarker discovery and validation. Her current program in translational ovarian cancer research was built on work funded in FY 1997 by the OCRP, "Use of Novel Technologies to Identify and Investigate Molecular Markers for Ovarian Cancer Screening and Prevention." Working with Beth Karlan, M.D. at Cedars-Sinai and Leroy Hood, Ph.D., M.D. at the University of Washington, she identified novel ovarian cancer biomarkers including HE4, Mesothelin (MSLN), and SLPI using comparative hybridization methods leading to funding in 1999 from the National Cancer Institute (NCI) for the Pacific Ovarian Cancer Research Consortium (POCRC) Specialized Program of Research Excellence (SPORE) in ovarian cancer.

The DOD and NCI funding allowed her to develop resources for translational ovarian cancer research including collection, management, and allocation of tissue and blood samples from women with ovarian cancer, women with benign ovarian conditions, and women with healthy ovaries. The DOD grant provided the foundation for what is now a mature specimen repository that has accelerated the progress of scientists at many academic institutions and industry.

The original plate-based HE4 and MSLN assays have been licensed to Fujirebio Diagnostics Inc. (FDI), a diagnostics company that has recently received U.S. Food and Drug Administration approval for HE4 as a recurrence monitoring marker for ovarian cancer.

Using specimen-efficient bead-based assays, Dr. Urban has evaluated top markers in preclinical samples to learn which markers give early signal. She is leading an inter-institutional effort to introduce the best of the novel markers into a screening protocol. She is conducting the Novel Markers Trial, a prospective randomized Phase I screening trial in high-risk women, in

collaboration with Beth Karlan, M.D. (Cedars-Sinai), Jonathan Berek, M.D. (Stanford), Melanie Palomares, M.D. (City of Hope), and Pam Paley, M.D. (Swedish Medical Center).

In Ranking Member Young and Mr. Boyd's state of Florida, nine grants have been funded since the inception of the OCRP in FY 1997. These nine grants have contributed much to the ovarian cancer research enterprise, specifically:

- Work toward the establishment of a mouse ovarian tumor model that reflects the same causative factors (both genetic mutations and postmenopausal hormonal changes) as in the human malignancy as a useful resource for testing agents and strategies for the prevention of ovarian cancer. The investigation of the mouse model may also lead to increased understanding of the process and progression of ovarian neoplasm and provide clues for strategies in early detection of ovarian cancer in humans, which is critical in reducing the mortality of this disease;
- Utilizing cutting-edge biological and molecular strategies to dissect and characterize
  those molecular mechanisms already identified as potentially relevant in ovarian
  surface cell growth, survival, and apoptosis. This project is investigating the role of
  these various molecular mechanisms leading to a better comprehension of ovarian
  surface epithial carcinogenesis paving the way for targeted therapeutic intervention in
  the most lethal gynecologic malignancy today.
- Studies have shown high levels of a protein called Bcl-2 in ovarian cancer tissue. A
  DoD grant to the University of South Florida is working to determine whether Bcl-2
  can be used as a novel marker for ovarian cancer. Specifically, using a simple,
  quantitative, commercially available ELISA assay, this research project hopes to
  determine whether Bcl-2 is expressly elevated in the urine of patients with ovarian
  cancer so that urinary levels of Bcl-2 might be used as a new, specific, and sensitive
  biomarker for detection of ovarian cancer.

As you can see from these few examples, the 209 grants have served as a catalyst for attracting outstanding scientists to the field of ovarian cancer research. In the four year period of FY1998 – FY 2001 the OCRP enabled the recruitment of 29 new investigators into the area of ovarian cancer research.

Federally Funding is Leveraged Through Partnerships and Collaborations
 In addition to an increase in the number of investigators, the dollars appropriated over the

 last 13 years have been leveraged through partnerships and collaborations to yield even greater

returns, both here and abroad. Fellow North Carolinian and Past-President of the SGO, Dr. Andrew Berchuck of Duke University Medical Center leveraged his OCRP DoD grants to form an international Ovarian Cancer Association Consortium (OCAC) that is now comprised of over 20 groups from all across the globe. The consortium meets biannually and is working together to identify and validate single nucleotide polymorphisms (SNPs) that affect disease risk through both candidate gene approaches and genome-wide association studies (GWAS). OCAC reported last year in Nature Genetics the results of the first ovarian cancer GWAS, which identified a SNP in the region of the BNC2 gene on chromosome 9 (*Nature Genetics* 2009, 41:996-1000.)

Dr. Berchuck and his colleagues in the association envision a future in which reduction of ovarian cancer incidence and mortality will be accomplished by implementation of screening and prevention interventions in women at moderately increased risk. Such a focused approach may be more feasible than population-based approaches, given the relative rarity of ovarian cancer.

Dr. Peter Bowtell, from the Peter MacCallum Cancer Centre in Melbourne, Australia, was awarded a Fiscal Year 2000 Ovarian Cancer Research Program (OCRP) Program Project Award to study the molecular epidemiology of ovarian cancer. With funds from this award, he and his colleagues formed the Australian Ovarian Cancer Study (AOCS), a population-based cohort of over 2000 women with ovarian cancer, including over 1800 with invasive or borderline cancer. With a bank of over 1100 fresh-frozen tumors, hundreds of formalin-fixed, paraffinembedded (FFPE) blocks, and very detailed clinical follow-up, AOCS has enabled over 60 projects since its inception, including international collaborative studies in the United States, United Kingdom, and Canada. AOCS has facilitated approximately 40 publications, most of which have been released in the past two years.

Since the initial OCRP award, AOCS has also been supported by Australian National Health and Medical Research Council (NHMRC), state-based Cancer Council, and Cancer Australia. AOCS was recently chosen by the NHMRC to contribute to the International Cancer Genome Consortium effort. In 2007, Dr. Peter Bowtell and Dr. Gillian Mitchell were awarded an OCRP Translational Research Partnership Award to examine the frequency of BRCA1 and BRCA2 mutations in the AOCS. Without the award of the OCRP Program Project grant, this

powerful enabling resource for ovarian cancer research, world-wide, would not have been created.

One last important example of the value of the DoD OCRP's contribution to science is the program's focus on inviting proposals from the Historically Black Colleges and Universities and Minority-Serving Institutions. This important effort to reach beyond established clinical partnerships expands the core research infrastructure for these institutions which helps them in attracting new investigators, leveraging complementary initiatives, and supporting collaborative ventures.

Over the decade that the OCRP has been in existence, the 209 grantees have used their DoD funding to establish an ovarian cancer research enterprise that is much greater in value than the annually appropriated Federal funding.

## • Opportunities are Lost Because of Current Level of Federal Funding

These examples of achievement are obscured to a great degree by opportunities that have been missed. At this current level of funding, this is only a very small portion of what the DoD OCRP program could do as we envision a day where through prevention, early detection, and better treatments, ovarian cancer is a manageable and frequently curable disease. Consistently. the OCRP receives over 500 letters of intent for the annual funding cycle. Of this group, about 50 percent are invited to submit full proposals. Prior to FY 2009, the OCRP was only able to fund approximately 16 grants per year, a pay line of less than 7 percent. With an increase in funding to \$20 million in FY 2009, the OCRP was able to fund 22 awards. However, for FY 2010 the program was cut by \$1.25 million and so the possibility of the OCRP being able to fund even 20 grantees is in jeopardy. To provide sufficient and effective funding to enable us to do our jobs and create an environment where our scientific research can succeed, we need a minimum investment of \$30 million in FY 2011.

Department of Defense Ovarian Cancer Research Program: Exemplary Execution with Real World Results

Integration Panel Leads to Continuous Evaluation and Greater Focus

By using the mechanism of an Integration Panel to provide the two-tier review process, the OCRP is able to reset the areas of research focus on an annual basis, thereby actively managing and evaluating the OCRP current grant portfolio. Gaps in ongoing research can be filled to complement initiatives sponsored by other agencies, and most importantly to fund high risk/high reward studies that take advantage of the newest scientific breakthroughs that can then be attributed to prevention, early detection and better treatments for ovarian cancer. An example of this is the development of the OVA1 test, a blood test that can help physicians determine if a woman's pelvic mass is at risk for being malignant. The investigator, Zhen Zhang, Ph.D. at Johns Hopkins School of Medicine, received funding from an Idea Development Award in FY2003. Dr. Zhang discovered and validated five serum biomarkers for the early detection of ovarian cancer. This bench research was then translated and moved through clinical trials. The OVA test was approved by the FDA and is now available to clinicians for use in patient care.

#### More Than a Decade of Scientific Success

The program's successes have been documented in numerous ways, including 469 publications in professional medical journals and books; 576 abstracts and presentations given at professional meetings; and 24 patents, applications and licenses granted to awardees of the program. Investigators funded by the OCRP have succeeded with several crucial breakthroughs in bringing us closer to an algorithm for use in prevention and early detection of ovarian cancer.

The Society of Gynecologic Oncologists joins with the Ovarian Cancer National Alliance and the American Congress of Obstetricians and Gynecologists to urge this Subcommittee to increase Federal funding at a minimum to \$30 million in FY 2011 for the OCRP. This will allow for the discoveries and research breakthroughs in the first decade of this program to be further developed and expanded upon, hopefully bringing us by the end of the second decade of this program to our ultimate goal of prevention, early detection and finally elimination of ovarian cancer. I thank you for your leadership and the leadership of the Subcommittee on this issue.

OBGYN

#### House Appropriations Committee Defense Subcommittee

### Witness Disclosure Form

Clause 2(g) of rule XI of the Rules of the House of Representatives requires nongovernmental witnesses to disclose to the Committee the following information. A non-governmental witness is any witness appearing on behalf of himself/herself or on behalf of an organization other than a federal agency, or a state, local or tribal government.

Your Name, Business Address, and Telephone Number: Daniel L. Clarke-Pearson, MD University of North Carolina School of Medicine Professor and Chair, OB/GYN Department of Obstetrics and Gynecology CB# 7570 Room 5003 Old Clinic Building Chapel Hill, NC 27599 919-966-5280 1. Are you appearing on behalf of yourself or a non-governmental organization? Please list organization(s) you are representing. Society of Gynecologic Oncologists 2. Have you or any organization you are representing received any Federal grants or contracts (including any subgrants or subcontracts) since October 1, 2007? Yes 3. If your response to question #2 is "Yes", please list the amount and source (by agency and program) of each grant or contract, and indicate whether the recipient of such grant or contract was you or the organization(s) you are representing.

Agency: NIH/NICHD
Title: Women's Reproductive Health Research (WRHR) Career Development Center at UNC
HDD050113-02
Project Period: 9/27/05-3/10/10
Project Amount: \$370,367 Annual Direct Costs

Principle Investigator

This grant supports a center for training junior faculty for academic research in women's health

85/87/2818 81:55 9199666849 DBGYN PAGE 82/82

Signature: DAM mo Date: 5/6/10

Please bring this original form on the day of your testimony.

# AMERICAN COLLEGE OF OBSTETRICIANS AND **GYNECOLOGISTS**

#### WITNESS

#### MARY F. MITCHELL, SENIOR DIRECTOR OF PROFESSIONALISM AND GYNECOLOGIC PRACTICE, AMERICAN COLLEGE OF OBSTETRICIANS AND GYNECOLOGISTS

Mr. Dicks. Mary F. Mitchell, American College of Obstetricians and Gynecologists. We will put your entire statement in the record,

Mary, and you have 5 minutes to summarize.

Ms. MITCHELL. Mr. Chairman, ranking member and members of the subcommittee, thank you for inviting me to testify at today's hearing. My name is Mary Mitchell, and I am the Senior Director of Professionalism and Gynecologic Practice at the American College of Obstetricians and Gynecologists. I am here today on behalf of the college's companion organization, the American Congress of Obstetricians and Gynecologists, or ACOG, representing more than 54,000 physicians and partners in women's health. The gynecologist is often the first health care provider a woman sees, and ACOG and its fellows are committed partners in the fight against gynecologic cancer.

This morning I will outline the great need for research into all aspects of ovarian cancer and some of the important contributions made by the Department of Defense Congressionally Directed Med-

ical Research Program in ovarian cancer, the OCRP.

These needs and the contributions of the OCRP lead ACOG to respectfully request a minimum of \$30 million in Federal funding for the OCRP in fiscal year 2011. We believe that the unique structure of the program and its success in funding innovation combine to

yield a high return on the Federal financial investment.

In the more than 30 years since passage of the National Cancer Act, ovarian cancer mortality rates have not significantly improved. In large part this is because we do not have a reliable screening test for ovarian cancer. Without this critical tool, ovarian cancer, as you have heard, is too often diagnosed in a late stage when the 5-year survival rate is only 29 percent. And, as you have heard from Ms. Mason, 13,000 women die each year from ovarian cancer.

In contrast, since the 1950s, we have had an effective screen for cervical cancer, the Pap test, which has reduced mortality from cervical cancer by over half in the past 30 years. We need a test like the Pap test for ovarian cancer, and the research supported by

DOD's OCRP can help us get there.

Unfortunately, inadequate funding is a barrier to scientific progress. At the National Institutes of Health and the Centers for Disease Control and Prevention, funding for ovarian cancer research has not kept pace with inflation. Even in the DOD medical research program, ovarian cancer research is significantly underfunded relative to other cancers, and, as you have heard, funding was cut to \$18.75 million in fiscal year 2010.

We recognize the challenges of funding research, given so many competing demands, but we believe that the OCRP's flexible and collaborative approach ensures that the maximum value is gained

for the dollars spent through Federal appropriations. Through the Integration Panel structure mentioned by Ms. Mason, the OCRP is able to actively manage and evaluate its current grant portfolio and fill gaps in ongoing research at other agencies. With seed money from the OCRP, possible research strategies are efficiently reviewed, and then the most promising can be funded by other agencies. Collaboration is one reason the OCRP is so effective.

Mr. DICKS. You have 1 minute, ma'am.

Ms. MITCHELL. The new Ovarian Cancer Academy for junior faculty will allow early career researchers to optimize the pace of their career development, and the Consortium Award will bring together researchers from multiple institutions to study the early signs of ovarian cancer.

The OCRP has been an unqualified success, but as you have heard from other speakers, the current level of funding allows only a fraction of the approved proposals to actually receive a grant. ACOG joins with the American Society of Gynecologic Oncologists and Ovarian Cancer National Alliance to urge this subcommittee to increase Federal funding for the OCRP to at least \$30 million in fiscal year 2011 and allow for the further development of discoveries and research breakthroughs achieved in the first 13 years of this program.

We thank you very much for your leadership.

Mr. DICKS. Thank you. Thank you for your testimony.

[The statement of Ms. Mitchell follows:]



## Statement of

Mary Mitchell
Senior Director, Professionalism and Gynecologic Practice
Division of Practice Activities
American College of Obstetricians and Gynecologists

On Behalf of

The American Congress of Obstetricians and Gynecologists

Before

The House Defense Appropriations Subcommittee

Thursday, May 20th, 2010

Mr. Chairman, Ranking Member, and members of the subcommittee, thank you for inviting me to testify at today's hearing. My name is Mary Mitchell, and I am the Senior Director of Professionalism and Gynecologic Practice at the American College of Obstetricians and Gynecologists. I am here today on behalf of the College's companion organization, the American Congress of Obstetricians and Gynecologists (or ACOG), representing more than 54,000 physicians and partners in women's health. The gynecologist is often the first health care provider a woman sees, and ACOG and its Fellows are committed partners in the fight against gynecologic cancers.

ACOG has worked in various ways to ensure our Fellows have access to the most up-to-date research that they can then translate into better treatment for their patients. For example, the practice guidelines developed by ACOG educate Fellows on the prevention, screening, diagnosis, and management of many women's health conditions, including gynecologic cancers such as ovarian cancer. Specific documents relevant to this testimony include Committee Opinion #280 "The Role of the Generalist Obstetrician-Gynecologist in the Early Detection of Ovarian Cancer" and Practice Bulletin #83 "Management of Adnexal Masses." We also maintain a robust collaboration with others with an interest in gynecologic cancer. Committee Opinion #280 was developed and issued jointly with the Society for Gynecologic Oncologists (SGO), and we maintain an active liaison relationship with SGO, both at the committee level and leadership level. However, the resources we offer our Fellows can only go so far without more robust research. There is much we don't know about ovarian cancer – including how to screen for it in its early stages – and the consequences are deadly to far too many of the women who get this disease.

This morning, I will outline the great need for research into all aspects of ovarian cancer and some of the important contributions that the Department of Defense Congressionally Directed Medical Research Program in ovarian cancer (the OCRP) has made to ovarian cancer research. What I hope to show is that the unique structure of the program funds innovation in the field of ovarian cancer research, complements

(without duplicating) other Federal initiatives, and yields a high return on the financial investment of the program.

In the more than 30 years since the passage of the National Cancer Act, landmark legislation that prioritized national action and funding for cancer prevention and control, ovarian cancer mortality rates have not significantly improved. In large part, this is because we do not have a reliable screening test for ovarian cancer. Without this critical tool, ovarian cancer is too often diagnosed in a late stage, when the 5-year survival rates are only 29%, and 15,000 women will die each year as a result. In contrast, since the 1950s, we have had an effective screen for cervical cancer - the Pap test - which has reduced mortality from cervical cancer by half over the past 30 years. Today, 60% of the cervical cancer cases in the United States occur among women who have never been screened or do not get screened regularly. We need a test like the Pap test for ovarian cancer, and the research supported by the DoD's OCRP can help us get there.

# More Research Leads to More Rewards: the Case for More Funding

The research made possible by the OCRP helps to fill key gaps in other Federal funding. Since FY 2003, funding for gynecologic cancer research and training programs at the National Cancer Institute and the Centers for Disease Control and Prevention have not kept pace with inflation. If not for the DoD OCRP, many researchers may not have had the opportunity to begin or sustain a career in basic and translational research in ovarian cancer. It is particularly important to support early-career researchers, which the OCRP does through its New Investigator Award. As a result, dozens of new investigators have entered the field as OCRP grant recipients, and are leading the way towards new possibilities for screening, early diagnosis, and better treatment of ovarian cancer.

One example of a New Investigator Award went to fund a study at the University of Cincinnati. The goal of this grant was to understand how cancer develops and what contributes to both the onset and progression of the disease, in order to design better strategies for preventing, diagnosing, and treating

ovarian cancer. Other New Investigator Award grants have taken different routes to achieve similar goals, by exploring the molecular basis of ovarian cancer, designing treatments in specific stages of ovarian cancer to improve the overall quality of life of women with the disease, and identifying cellular pathways that contribute to the development of the disease, just to name a few. Breakthroughs in these research areas can lead to more effective screening and early diagnosis tools, and better treatment at all stages of the disease, saving patients from more invasive interventions and saving the healthcare system money.

However, even within the DoD medical research program, ovarian cancer research is grossly underfunded relative to other cancers, and was cut to \$18.75 million in FY 2010. We recognize the challenges of funding research, given so many competing demands, and we believe that the OCRP's collaborative approach ensures that the maximum value is gained for the dollars spent through Federal appropriations. The new Ovarian Cancer Academy for junior faculty will enable these early-career researchers to optimize the pace of their career development, and the Consortium Award will bring together researchers from multiple institutions to study the early signs of ovarian cancer. With the seed money provided by the OCRP, possible research strategies are efficiently reviewed and the most promising can then be funded by other agencies. To ensure maximum efficiency in carrying out these initiatives, ACOG respectfully recommends that this Subcommittee provide the OCRP with a minimum of \$30 million in Federal funding.

### From Bench to Bedside: a Truly Unique Research Program

Part of what makes the OCRP program so valuable to the field of ovarian cancer research is its flexibility in funding and managing grants. The OCRP is able to actively manage and evaluate its current grant portfolio, and fill gaps in ongoing research at other agencies. Most importantly, it is able to fund innovative high risk studies that take advantage of the newest scientific breakthroughs and yield high rewards.

The OCRP uses a two-tier grant review process that provides a broad range of perspectives, while ensuring that the program goals are met. First, it brings in scientists and experts in the field to examine the technical merits of the proposal, as well as consumers to examine the impact the proposed research will have on the disease and how it will ultimately translate to better treatment and outcomes for patients. Second, it uses an Integration Panel to conduct a programmatic review that compares proposals to other proposals and then bases funding decisions on a combination of scientific merit, balance within the program, and relevance to the goals of the program.

Physicians are using the fruit of this research in their offices **today.** The following examples serve as a testament to OCRP-funded research that physicians are using to better serve their patients:

- Based on a discovery that ovarian cancer tumors with a higher fraction of cells in cell cycle 5-phase are more difficult to treat, a new class of ovarian cancer-specific drugs was developed that helps kill aggressive tumors.
- Research targeting certain tumor cells in order to suppress tumor growth found that a particular
  combination of drugs has an advantage over tumors with low levels of VEGP, in addition to various
  other findings which have enabled physicians to better design combination therapy to treat ovarian
  cancer.
- Quality of life research has shown that interventions to improve the quality of life of women with ovarian cancer are most effective immediately after diagnosis, enabling physicians to offer interventions and support services at optimum times during treatments.

### A Success Story, but Still a Long Way to Go

The OCRP has been an unqualified success, but at the current level of funding, only a fraction of the proposals with fundable scores actually receive a grant. To provide sufficient and effective funding to create an environment where scientific research can succeed, we need a minimum investment of \$30 million in FY

- 2011. A \$30 million funding level would allow future researchers to build on the successes of current research, including in the following areas:
  - Research at the University of Southern California found that snake venom can be successful at fighting tumors, and researchers have created a synthetic version with the same tumor fighting ability. On-going research must now test whether this treatment should be used alone or in combination with chemotherapy, in addition to testing its ability as an imaging agent for certain types of ovarian cancer.
  - Translational research at the University of Michigan is working to identify novel therapeutic
    targets for ovarian cancer, and on-going research can potentially identify ways to personalize
    treatment for patients based on the gene expression of their tumors.
  - Research at the Cedars-Sinai Medical Center is working to understand the molecular and
    genetic processes that lead to ovarian cancer, with the goal of developing better strategies for
    early detection. Understanding the molecular pathways contributing to ovarian cancer can
    open the door to future research to design more targeted treatments.

ACOG joins with the Society of Gynecologic Oncologists and the Ovarian Cancer National Alliance to urge this Subcommittee to increase Federal funding for the OCRP to at least \$30 million in FY 2011. This funding will allow for the discoveries and research breakthroughs in the first thirteen years of this program to be further developed and expanded upon, ultimately leading to OCRP's sole goal of eliminating ovarian cancer. We thank you for your leadership on this issue.

# House Appropriations Committee Defense Subcommittee

# Witness Disclosure Form

Clause 2(g) of rule XI of the Rules of the House of Representatives requires nongovernmental witnesses to disclose to the Committee the following information. A non-governmental witness is any witness appearing on behalf of himself/herself or on behalf of an organization other than a federal agency, or a state, local or tribal government.

Your Name, Business Address, and Telephone Number:

Mary F. Mitchell American College of Obstetricians and Gynecologists PO Box 96920 Washington, DC 20090-6920 202-863-2502

1. Are you appearing on behalf of yourself or a non-governmental organization? Please list organization(s) you are representing.

American Congress of Obstetricians and Gynecologists, a companion organization to the American College of Obstetricians and Gynecologists

2. Have you or any organization you are representing received any Federal grants or contracts (including any subgrants or subcontracts) since October 1, 2007?

Yes. Grants received by the American College of Obstetricians and Gynecologists

3. If your response to question #2 is "Yes", please list the amount and source (by agency and program) of each grant or contract, and indicate whether the recipient of such grant or contract was you or the organization(s) you are representing.

Grants listed on the attached sheet were all received by the American College of Obstetricians and Gynecologists; I have received no grants myself

Signature: Nay F. Nutrlill Date: 5/17/10

Please bring this original form on the day of your testimony.

ŀ	H:\GRANT\Grant Awards Since 10-01-2007		American Colle			CPT 04-29-10
		Obstetricians & Gynecologists				:
		Feder	al Grants & Cor	itracts		<u> </u>
i .	<u>_</u>			1		ļ
		_1		: 		
		09-30-2007-	09-30-2007-	09-30-2008-	09-30-2009-	
A	Agency	09-29-2009	09-29-2008	09-29-2009	09-29-2010	Total
C	Centers for Disease Control & Prevention	120,000.00				120,000.00
ī	National Center on Birth Defects					
а	and Developmental Disabilities	_i				
C	Centers for Disease Control & Prevention		140,000.00	140,000.00	l	280,000.00
1	National Center for Immunization and					i
F	Respiratory Diseases				i	
		1				
(1) F	Health Resources & Services Administration		250,000.00	245,633.00	250,000.00	745,633.00
P	Maternal and Child Health Bureau					
(2) F	Health Resources & Services Administration		360,000.00	297,000.00	300,000.00	957,000.00
N	Maternal and Child Health Bureau					
1						i
C	Centers for Disease Control & Prevention		382,656.00	375,971.00	277,495.00	1,036,122.00
N	National Center for HIV, Viral Hepatitis,					1
S	STDs and TB Prevention			į		
						1
);	ndian Health Service	3	222,380.00	125,000.00		347,380.00
	The second secon		i i i i i i i i i i i i i i i i i i i	5	t	1
(3) R	RTI International Sub Agreement		259,470.00		÷	259,470.00
					i	i camar intra
(4) R	RTI International Sub Contract	· · · · · · · · · · · · · · · · · · ·	60,000.00			60,000.00
	A CONTRACTOR OF THE PARTY OF TH				1	) 
٨	Vational Institutes of Health		10,000.00			10,000.00
	Office of the Director				·	1 <b>,</b> <u>-</u>
		<u></u>				<del></del>
(5) C	Centers for Disease Control & Prevention	· · · · · · · · · · · · · · · · · · ·	15,000.00	15,000.00	i	30.000.00
	Vational Center for Zoonotic, Vector-			77, 77, 77, 7	L	<u> </u>
	Borne, and Enteric Diseases				i	i
(6) C	Centers for Disease Control & Prevention		50,000.00			50,000.00
	National Center for Chronic Disease					
	Prevention and Health Promotion				· · · · · · · · · · · · · · · · · · ·	
					!	ļ
(7) C	Centers for Disease Control & Prevention	+		50,000.00		50,000.00
	Vational Center on Birth Defects	7			1	
	and Developmental Disabilities					1
					<del> </del>	
	Centers for Disease Control & Prevention				60,000.00	60,000.00
	lational Center for HIV, Viral Hepatitis,				. Treezas	) T <b>%</b> 1
	TDs and TB Prevention					
				-	<del></del>	
	otal	120,000.00	1 749 505 00	1,248,604.00	887 495 00	4 005 605 00
			-,3,500.00	-,=-0,00-1.00	237,733.00	.,555,555.00
/1) P	hudget poriod starts Contambou 1 and and a	muct 21			l	· · · · · · · · · · · · · · · · · · ·
	Sudget period starts September 1 and ends Au	Rnyr 31				
	Sudget period starts July 1 and ends June 30	2000				
	Sudget period, September 30, 2007 to June 16,					
	Sudget period, October 1, 2007 to July 31, 2010	<i>J</i> .				
	warded 02-19-2008					
	warded 08-29-2008				<u> </u>	: }
(/) A	warded 04-14-2009					:

Mr. DICKS. Michelle Galvanek, The Leukemia & Lymphoma Society. Thank you, Michelle. We will put your statement in the record. You have 5 minutes to summarize.

Thursday, May 20, 2010.

# THE LEUKEMIA & LYMPHOMA SOCIETY

#### WITNESS

# MICHELLE GALVANEK

Ms. GALVANEK. Thank you. Good morning, Mr. Chairman and members of the subcommittee. My name is Michelle Galvanek, and I am a volunteer with the Leukemia & Lymphoma Society. And I would like to thank you for allowing me to testify today on behalf of the LLS and the thousands of blood cancer patients we serve. Since 1949, the Society has been dedicated to finding a cure for blood cancers. To that end, in fiscal year 2009, the Society provided approximately \$69 million in research grants. A number of our grant recipients also received funds from the National Institute of Health, private foundations and the Department of Defense. The funding from the Department of Defense is through the congressionally directed medical research program.

For fiscal year 2011, the Leukemia & Lymphoma Society, along with other cancer groups, the C3 Colorectal Cancer Coalition, the Kidney Cancer Association, the International Myeloma Foundation, the Lymphoma Research Foundation, and the Vietnam Veterans of America support the peer reviewed cancer research program and request it to be funded at \$50 million in fiscal year 2011.

Additionally, we request that the program fund research into the same cancers it did in 2010, namely blood, kidney, colorectal, pediatric brain and melanoma. I know firsthand about the benefits of research as my husband is an 11-year leukemia survivor. The LOS supports the inclusion of all 5 cancers in the PRCR, and particularly blood cancer. The reasons for having a blood cancer research program at the DOD are the benefits such a program would have for military service members and the fact that blood cancer research has led to break throughs in the treatment of other cancers. Civil agencies in the Federal Government have recognized the importance of blood cancers to those who serve in our military.

For example, the Department of Veterans Affairs has determined

that service members who have been exposed to ionizing radiation and contract multiple myeloma, non-Hodgkin lymphoma or leukemia other than chronic lymphocytic leukemia are presumed to have contracted those diseases as a result of their military service. Secondly, in-country Vietnam veterans who contract Hodgkin's disease, chronic lymphocytic leukemia, multiple myeloma or non-Hodgkin's lymphoma are presumed to have contracted these diseases as a result of their military service. Because these diseases are presumed to have been service connected in certain instances, VA benefits are available to affected veterans.

Furthermore, the Institute of Medicine has found that Gulf War veterans are at risk for contracting a number of blood cancers due to exposure to Benzene, solvents and insecticides. One example is

IOM has found sufficient evidence of a causal relationship between exposure to Benzene and acute leukemias. In addition, the C.W. Bill Young Department of Defense Marrow Donor Program works to develop and apply bone marrow transplants to military casualties with marrow damage resulting from radiation or exposure to chemical warfare agents containing mustard. Bone marrow transplants are also a commonly used second-line therapy for blood can-

cers more so than other cancers.

Finally, research into blood cancers have produced results that can help patients with other cancers too. The idea of combination chemotherapy was first developed to treat blood cancers in children and is now common among cancer treatments. Bone marrow transplants were first used as curative treatments for blood cancer patients, and these successes led the way to stem cell transplants and immune cell therapies for patients with other diseases. In general, blood cancer cells are easier to access themselves from solid tumors, making it easier to study cancer causing molecules in blood cancers and to measure the effects of new therapies that target these molecules that are frequently also found in other cancers.

Mr. DICKS. You have 1 minute.

Ms. GALVANEK. Thank you, sir. Several agents designed only to kill cancer cells and leave healthy cells undamaged were first developed for blood cancer patients and are already helping or being developed to help other cancer patients as well. In conclusion, because blood cancer research is relevant to our Nation's military and because blood cancer research often leads to treatment in other cancers, I would urge the subcommittee to include \$50 million for the Peer Reviewed Cancer Research Program for funding into blood, colon, skin and kidney cancer, as well as pediatric brain tu-

mors. Thank you very much. I would just point out that Mr. DICKS. Thank you very much. I would just point out that Mr. Young, the ranking member and former chairman of the subcommittee, has been a leader on this particular form of cancer and has been a great advocate in this committee for more research in

this area. Ms. Kaptur.

Ms. Kaptur. Mr. Chairman, just very quickly, I just wanted to ask whether your data provides you with any statistics that show for veterans from any of our conflicts—you mentioned Benzene. Do veterans contract these particular type of cancers, blood-related cancers at a higher rate than others? Can you provide that—you sort of mentioned some of it.

Ms. GALVANEK. I don't have that answer off the top of my head, but I can follow up with you and get that to you.

Mr. Dicks. Her statement has a few examples. Thank you for being a volunteer.

Ms. Galvanek. Thank you. It is the best way I spend my time. Thank you.

The statement of Ms. Galvanek follows:

# 290

# TESTIMONY OF MICHELLE GALVANEK THE LEUKEMIA & LYMPHOMA SOCIETY

Regarding FY 2011 Appropriations

#### Submitted to the House Appropriations Subcommittee for Defense

May 20, 2010

# Introduction

Mr. Chairman and members of the committee, my name is Michelle Galvanek, . I am pleased to appear today and testify on behalf of the Society and the approximately 900,000 Americans currently living with blood cancers and the approximately 140,000 who will be diagnosed with one this year. Furthermore, every 10 minutes, someone dies from one of these cancers -- leukemia, lymphoma, Hodgkin's disease and myeloma.

I have been involved as a volunteer with the Leukemia & Lymphoma Society (LLS) for over 12 years, since losing one of my best friends to leukemia at age 29. I serve on the Board of Trustees for the National Capital Area chapter of the LLS, as Immediate Past President, and as Vice Chair of the National Board of Representatives. I have participated in many fundraisers on behalf of LLS, personally raising hundreds of thousands of dollars in support of LLS' mission. I know first-hand about the benefits of research, as my husband is an 11-year CML survivor.

During its 61-year history, the Society has been dedicated to finding a cure for the blood cancers, and improving the quality of life of patients and their families. The Society has the distinction of being both the nation's second largest private cancer organization and the largest private organization dedicated to biomedical research, education, patient services and advocacy as they pertain to blood-related cancers.

Our central contribution to the search for cures for the blood cancers is providing a significant amount of the funding for basic, translational and clinical research. In 2009, we provided approximately \$69 million in research grants. In addition to our research funding role, we help educate health care and school professionals as needed and provide a wide range of services to individuals with a blood cancer, their caregivers, families, and friends through our chapters across the country. Finally, we advocate responsible public policies that will advance our mission of finding cures for the blood cancers and improving the quality of life of patients and their families.

We are pleased to report that impressive progress is being made in the effective treatment of many blood cancers, with 5-year survival rates doubling and even tripling over the last two

decades. More than 90 percent of children with Hodgkin's disease now survive, and survival for children under 5 years old with acute lymphocytic leukemia has risen to more than 90 percent.

Just nine years ago, in fact, a new therapy was approved for chronic myelogenous leukemia (CML), a form of leukemia for which there were previously limited treatment options, all with serious side-effects – five year survival rates were just over 50%. Let me say that more clearly, if ten years ago your doctor told you that you had CML, you would have been informed that there were limited treatment options and that you should get your affairs in order. Today, those same patients have access to this new therapy, called Gleevec, which is a so-called targeted therapy that corrects the molecular defect that causes the disease, and does so with few side effects. Now, five year survival rates are as high as 96% for patients newly diagnosed with chronic phase CML.

The Society funded the early research that led to Gleevec's approval, as it has contributed to research on a number of new therapies. We are pleased that we played a role in the development of this life-saving therapy, but we realize that our mission is far from realized. Many forms of leukemia, lymphoma and myeloma still present daunting treatment challenges. There is much work still to be done, and we believe that the research partnership between the public and private sectors – as represented in the Department of Defense's Congressionally Directed Medical Research Program – is an integral part of that important effort and should be further strengthened.

# The Grant Programs of The Leukemia & Lymphoma Society

LLS administers two integrated research funding programs - the Research Grant Program and the Therapy Acceleration Program - to support our mission: Cure leukemia, lymphoma, Hodgkin's disease and myeloma, and improve the quality of life of patients and their families.

With advisory input from world-renowned biomedical research experts, LLS supports the entire research continuum relevant to improved outcomes for blood cancer patients, from basic laboratory science to clinical trials of new agents, and from investigator-initiated research to multi-disciplinary academic collaborations and private-sector drug development alliances. Research funding is aimed at effective discovery and development of new therapies for all blood cancer patients who need them.

The Research Grant Program provides grant funding to support scientific studies at academic centers around the world, through three grant mechanisms:

- The Career Development Program provides stipends to investigators of exceptional promise in the early stages of their careers, helping them to devote their careers to leukemia, lymphoma and/or myeloma research.
- The Translational Research Program supports outstanding investigations deemed by our expert advisors most likely to translate basic biomedical discoveries into new, safe and effective treatments, ultimately prolonging and enhancing patients' lives.
- The Specialized Center of Research Program encourages multidisciplinary research by teams of leading-edge academic investigators that hastens the discovery and development of better treatments for leukemia, lymphoma and myeloma patients. A

Center is composed of at least three independent research programs that are integrated and supported by scientific core laboratories.

The **Therapy Acceleration Program (TAP)** is a strategic LLS initiative launched in 2007 with \$4 million in seed funding. This program promises to accelerate new and better treatments and clinical tests into preclinical development and clinical trials. Working in concert with academic investigators, medical centers, and companies, TAP is further bridging the gap between discovery and human applications to increase the likelihood that novel, possibly breakthrough, treatments will be made available to patients as soon as possible.

TAP encompasses three innovative efforts:

- The Academic Concierge Division identifies current LLS-funded research with the greatest clinical promise and provides the funding and support needed to advance selected projects to the product stage.
- The Clinical Trial Division partners LLS with certain of the country's leading clinical trial centers to accelerate the testing of new blood cancer therapies in clinical trials.
- The Biotechnology Accelerator Division allies LLS with companies to combine scientific and financial resources and accelerate the development of potential therapies which wouldn't otherwise be prioritized by the company.

# **Impact of Hematological Cancers**

Despite enhancements in treating blood cancers, there are still significant research challenges and opportunities. Hematological, or blood-related, cancers pose a serious health risk to all Americans. These cancers are actually a large number of diseases of varied causes and molecular make-up, and with different treatments, that strike men and women of all ages. In 2010, almost 140,000 Americans will be diagnosed with a form of blood-related cancer and almost more than 50,000 will die from these cancers. For some, treatment may lead to long-term remission and cure; for others these are chronic diseases that will require treatments across a lifetime; and for others treatment options are still extremely limited. For many, recurring disease will be a continual threat to a productive and secure life.

A few focused points to put this in perspective:

- Taken together, the hematological cancers are fifth among cancers in incidence and <u>fourth in</u> mortality.
- Approximately, 900,000 Americans are living with a hematological malignancy in 2010.
- More than 50,000 people will die from hematological cancers in 2010, compared to 160,000 from lung cancer, 41,000 from breast cancer, and 27,000 from prostate.
- Blood-related cancers still represent serious treatment challenges. The improved survival for those diagnosed with all types of hematological cancers has been uneven. The five-year survival rates are:

Hodgkin's disease	87%
Non-Hodgkin's lymphoma	69%
Leukemias (total)	54%
Multiple Myeloma	37%
Acute Myelogenous Leukemia	23%

- Individuals who have been treated for leukemia, lymphoma, and myeloma may suffer serious
  adverse consequences of treatment, including second malignancies, organ dysfunction
  (cardiac, pulmonary, and endocrine), neuropsychological and psychosocial aspects, and poor
  quality of life.
- For the period from 1975 to 2003, the incidence rate for non-Hodgkin's lymphoma increased by 76%.
- Non-Hodgkin's lymphoma and multiple myeloma rank second and fifth, respectively, in terms of increased cancer mortality since 1973.
- Lymphoma is the third most common childhood cancer and the fifth most common cancer among Hispanics of all races. Recent statistics indicate both increasing incidence and earlier age of onset for multiple myeloma.
- Multiple myeloma is one of the top ten leading causes of cancer death among African Americans
- Hispanic children of all races under the age of 20 have the highest rates of childhood laukeming.
- Despite the significant decline in the leukemia and lymphoma death rates for children in the
  United States, leukemia is still the leading cause of death in the United States among children
  less than 20 years of age, in females between the ages of 20 and 39 and males between the
  ages of 60-79.
- Lymphoma is the fourth leading cause of death among males between the ages of 20 and 39
  and the fifth leading cause of death for females older than 80. Overall, cancer is now the
  leading cause of death for U. S. citizens younger than 85 years of age, overtaking heart
  disease as the primary killer.

# Possible Environmental Causes of Hematological Cancers

The causes of hematological cancers are varied, and our understanding of the etiology of leukemia, lymphoma, and myeloma is limited. Extreme radiation exposures are clearly associated with an increased incidence of leukemias. Benzene exposures are associated with increased incidence of a particular form of leukemia. Chemicals in pesticides and herbicides, as well as viruses such as HIV, EBV and hepatitis C, apparently play a role in some hematological cancers, but for most cases, no environmental cause is identified. Researchers have recently

published a study reporting that the viral footprint for simian virus 40 (SV40) was found in the tumors of 43 percent of NHL patients. These research findings may open avenues for investigation of the detection, prevention, and treatment of NHL. There is a pressing need for more investigation of the role of infectious agents or environmental toxins in the initiation or progression of these diseases.

#### **Importance To The Department of Defense**

The Leukemia & Lymphoma Society, along with its partners in the C3 Colorectal Cancer Coalition, Kidney Cancer Association, International Myeloma Foundation, Lymphoma Research Foundation and the Vietnam Veterans of America, believe biomedical research focused on the hematological and other cancers such as colon, kidney, skin and pediatric brain tumors is particularly important to the Department of Defense for a number of reasons. LLS feels inclusion of blood cancer as an eligible disease for any cancer research program is particularly important.

Research on blood-related cancers has significant relevance to the armed forces, as the incidence of these cancers is substantially higher among individuals with chemical and nuclear exposure. Firstly, blood cancers are linked to members of the military who were exposed to ionizing radiation, such as those who occupied Japan after World War II and those who participated in atmospheric nuclear tests between 1945-1962. Service members who contract multiple myeloma, non-Hodgkin's lymphoma, and leukemias other than chronic lymphocytic leukemia are presumed to have contracted these diseases as a result of their military service; hence, they are eligible to receive benefits from the Department of Veterans Affairs (VA).

Secondly, in-country Vietnam veterans who contract Hodgkin's disease, chronic lymphocytic leukemia, multiple myeloma, or non-Hodgkin's lymphoma are presumed to have contracted these diseases as a result of their military service and the veterans are eligible to receive benefits from the VA. Recently, VA Secretary Shinseki has started an effort to add more leukemia's to the service connected list for Vietnam veterans exposed to agent orange, therefore paying benefits to those veterans who contract the disease.

Thirdly, the Institute of Medicine (IOM) has found that Gulf War veterans are at risk for contracting a number of blood cancers. For instance, the IOM has found sufficient evidence of a causal relationship between exposure to benzene and acute leukemias. Additionally, the IOM has found there is sufficient evidence of an association between benzene and adult leukemias, and solvents and acute leukemias. Finally, the IOM has also found there is also limited or suggestive evidence of an association between exposure to organophosphorous insecticides to non-Hodgkin's lymphoma and adult leukemias; carbamates and Benzene to non-Hodgkin's lymphoma; and solvents to multiple myeloma, adult leukemias, and myelodysplastic syndromes – a precursor to leukemia.

In addition, research in the blood cancers has traditionally pioneered treatments in other malignancies. Cancer treatments that have been developed to treat a blood-related cancer are now used or being tested as treatments for other forms of cancer. Combination chemotherapy

and bone marrow transplants are two striking examples of treatments first developed for treating blood cancer patients. More recently, specific targeted therapies have proven useful for treating patients with solid tumors as well as blood-related cancers.

From a medical research perspective, it is a particularly promising time to build a DoD research effort focused on blood-related cancers. That relevance and opportunity were recognized for a six year period when Congress appropriated \$4.5 million annually - for a total of \$28 million - to begin initial research into CML through the Congressionally Directed Medical Research Program (CDMRP). As members of the Subcommittee know, a noteworthy and admirable distinction of the CDMRP is its cooperative and collaborative process that incorporates the experience and expertise of a broad range of patients, researchers and physicians in the field. Since the Chronic Myelogenous Leukemia Research Program (CMLRP) was announced, members of the Society, individual patient advocates and leading researchers have enthusiastically welcomed the opportunity to become a part of this program and contribute to the promise of a successful, collaborative quest for a cure.

Many extremely productive grants have been funded through this program. For example, from FY02-FY06 the CMLRP-funded research with accomplishments that fall into three rather broad areas:

#### 1) Basic science:

A better understanding of disease processes will facilitate the development of the next generation of therapeutic agents. The CMLRP has funded basic science research that has increased our knowledge of the patho-biology of CML, the molecular and cellular processes involved in the initiation of CML and the progression of disease. This may be exemplified by the work of Dr. Danilo Perrotti of The Ohio State University. Dr. Perrotti described the loss of activity of a protein phosphatase 2A (PP2A), a tumor suppressor, in CML cells. His research then determined that activity of the protein BCR/ABL, expressed in most CML cells and associated with disease development, inhibits PP2A activity which would allow CML cells to continue to proliferate. Dr. Perrotti took this basic understanding of this aspect of CML cell biology and took it one step further. He showed that treating cells with a compound that increases the activity level of PP2A in cells decreased tumor growth by virtually overpowering the negative effects of BCR/ABL, indicating that this compound has potential to be developed as a new CML treatment option.

# 2) Therapeutic development:

Genetic mutations that confer resistance to currently available CML treatment agents demonstrates the need for the development of new therapeutics that may be used in conjunction with these agents or as second line defense options when resistance develops. CMLRP-funded scientists have discovered and developed potential new therapeutic agents that may be used to combat or halt disease progression. For example, after screening a chemical library of small molecules, Dr. Joel Gottesfeld of The Scripps Research Institute identified a set of molecules that inhibits proliferation of CML cells in a BCR/ABL-independent manner. Secondly, Dr. Craig Jordan of University of Rochester used an antiproliferative compound, which specifically inhibits a molecule involved in the transcription of many genes, to inhibit the proliferation of CML cells while not affecting normal cells. Thirdly, Dr. E. Premkumar Reddy of Temple

University is developing an agent that will target CML cells that are Gleevec resistant. Finally, Dr. Kapil Bhalla of Medical College of Georgia Cancer Center has discovered a new agent that inhibits that activity of BCR/ABL.

#### 3) Model organism development:

Many model organisms are utilized by the scientific community for studying genetics, molecular mechanisms, cellular functions, or therapeutic efficacy including, but not limited to worms, flies, zebrafish, chickens, and mice. The model organism of choice may be dependent on a number of variables such as research strategy and feasibility, experimental design, statistical needs for data interpretation, and budget. In addition, using a variety of model organisms to study a disease may be advantageous.

Many CMLRP-funded researchers have been involved in developing and validating new mouse and zebrafish models of CML for understanding genetic, molecular and cellular changes that accompany the development and progression of CML; and for pre-clinical testing of potential new therapeutic agents. Mice are mammals, a potential advantage for relating research results to human disease. In addition, a large proportion of human genes have a mouse counterpart. However, zebrafish also share extensive genetic similarity with humans and have been shown to share many features of the innate immune system with those of humans. Also, zebrafish have a short generation interval (e.g. Lifespan) making them very amenable to and useful for genetic analysis.

In spite of the utility and application to individuals who serve in the military, the CML program was not included in January's 2007 Continuing Resolution funding other fiscal year 2007 CDMRP programs. This omission, and the program's continued absence seriously jeopardizes established and promising research projects that have clear and compelling application to our armed forces as well as pioneering research for all cancers.

In the past two appropriation cycles, this subcommittee has funded a Peer Reviewed Cancer Research Program (PRCRP) at \$16 and \$15 million annually. In FY2010, the Program listed several cancers as funding targets. Those were, blood, colorectal, kidney, pediatric brain and melanoma. We believe the PRCRP should continue to fund these cancers, particularly blood cancers. Secondly, we feel there is significant scientific opportunity to fund this program at \$50 million or more. We believe this would still lead to good science being funded. Frances Collins, Director of the National Institutes of Health (NIH) has indicated that a success rate for funded grants – or payline – could be more than 30 percent without funding bad science. In 2009, NIH's payline was approximately 21 percent. With those numbers, NIH could fund more than an additional \$100 million dollars in blood cancer research grants alone.

The Leukemia & Lymphoma Society strongly endorses and enthusiastically supports the effort to fund the PRCRP at \$50 million annually and respectfully urges the Subcommittee to include this funding in the FY 2011 Defense Appropriations bill.

We believe that building on the foundation Congress initiated over the last two years should not be abandoned and would both significantly strengthen the CDMRP and accelerate the development of all cancer treatments. As history has demonstrated, expanding its focus into areas that demonstrate great promise; namely the blood-related cancers of leukemia, lymphoma and myeloma, would substantially aid the overall cancer research effort and yield great dividends.

\*\*\*

House Appropriations Committee Defense Subcommittee

# Witness Disclosure Form

Clause 2(g) of rule XI of the Rules of the House of Representatives requires nongovernmental witnesses to disclose to the Committee the following information. A non-governmental witness is any witness appearing on behalf of himself/herself or on behalf of an organization other than a federal agency, or a state, local or tribal government.

Your Name, Business Address, and Telephone Number:
MICHELLE GALVANEK
5027 FULTON STINW
WASAMMOON, TOC 20076
1. Are you appearing on behalf of yourself or a non-governmental organization? Please list organization(s) you are representing.  THE LEUKEMIN + WMNHOMA SOLICY
Have you or any organization you are representing received any Federal grants or contracts (including any subgrants or subcontracts) since October 1, 2007?  Yes  No
3. If your response to question #2 is "Yes", please list the amount and source (by agency and program) of each grant or contract, and indicate whether the recipient of such grant or contract was you or the organization(s) you are representing.
THE LEVILEMIN & LYMPHOMA FOCITY HAS RECEIVED OFFINIS FROM CARC'S FERRATIO CANCETT EMICATION PROGRAM IN THE AMOUNT OF 15424,000 ANUAUY SINCE 2007:
Signature: Date: 19 mpy 2010

Please bring this original form on the day of your testimony.

Mr. DICKS. Thank you. We appreciate it. The National Breast Cancer Coalition, Fran Visco, J.D., president of the coalition. Hold on just a second. We are going to switch here. Mr. Moran has got a problem, and he wants to hear this witness. If you would just give us Carlea Bauman, President of the Colorectal Cancer Coalition. Welcome.

Thursday, May 20, 2010.

# **C3: COLORECTAL CANCER COALITION**

#### WITNESS

#### CARLEA BAUMAN, PRESIDENT, C3: COLORECTAL CANCER COALITION

Ms. Bauman. Good morning. Thank you. Mr. Chairman and members of the subcommittee, thank you for the opportunity to testify in support of the research that is being funded through the DOD's Peer Reviewed Cancer Research Program. My name is Carlea Bauman. I am the president of the C3: Colorectal Cancer Coalition. C3 is a nonprofit, nonpartisan advocacy organization seeking to eliminate suffering and death due to colorectal cancer in the DOD's Peer Reviewed Cancer Research Program. Thank you for listening to them. We were thrilled that in the fiscal year 2010 bill, for the first time, colorectal cancer research is being funded through the DOD's PRCRP. Because when you fund research for a disease, people diagnosed without disease live longer and enjoy a higher quality of life.

In 2010, there are \$15 million for 8 research areas that includes colorectal cancer. C3 is working with other advocacy groups to increase that funding for fiscal year 2011. We hope we can count or your support. We respectfully ask that you increase the funding for this important program in fiscal year 2011. Specifically we ask that you fund the DOD's PRCRP at \$50 million. Although the cancers included in this program are diverse, the research on these disease types is often synergistic. Efforts to develop a genetic profile for pediatric brain tumors will direct research efforts and permit greater targeting of treatment options and molecular profiling of melanoma will permit better predictions of therapeutic response and informed research efforts.

And researchers today working on colorectal cancer are producing biomarker tests that provide important information about which treatments will work and which will not. Today, treatment options for colorectal cancer have expanded to seven drugs, more precise surgery and radiation. Continuing to fund innovative research will result in more treatment option for colorectal cancer patients. 30 years ago, people diagnosed with metastatic colorectal cancer lived approximately 6 months after their diagnosis. Today they are living on average over 2 years past their diagnosis and some are even cured.

In the general population, colorectal cancer is the third most commonly diagnosed cancer and the second most common cause of cancer deaths for men and women in the United States. Nearly 147,000 people will be diagnosed with colorectal cancer and nearly 50,000 people will die this year. Funding for the DOD's PRCRP is an opportunity to advance the best research to eradicate diseases and support the warfighter for the benefit of the American public. A continued investment by the subcommittee in research focusing on these cancers may yield benefits beyond the specific cancers.

A study published in the Cancer Epidemiology Biomarkers and Prevention found differences in cancer incidence rates between military personnel and the general population. Rates were lower among military personnel than the general population for colorectal, lung and cervical cancers. However, for colorectal cancer, the difference in rates between the two populations was significant only among white males. Screening rates in the military for colorectal cancer like in the general population are much too low.

In 2008, only about 58 percent of those in the military who should be screened for colorectal cancer had been screened. And every day precancerous polyps that could be detected through screening are not being found. Today only 39 percent of colorectal cancer patients have their cancers detected at an early stage. For many patients, a diagnosis of colorectal cancer means a diagnosis of late stage colorectal cancer. Not nearly enough research is being done into late stage colorectal cancer treatments. The PRCRP represents an opportunity to conduct such research. Areas of focus for colorectal cancer research in the PRCRP could be an inexpensive, noninvasive accurate screening test, predicted markers to identify who will benefit from which treatments and accurate diagnostics that can evaluate the markers.

Mr. Dicks. You have 1 minute.

Ms. BAUMAN. Thank you, sir. Discoveries resulting from investment in PRCRP research have the potential to transform the investigation of cancer through the development of new prevention strategies and therapies and some day cures. I thank you for your commitment to cancer research at the Department of Defense and efforts to improve the lives of Americans facing and living with a cancer diagnosis. I respectfully request that this subcommittee continue to support the important work of the DOD's congressionally directed medical research programs by funding the PRCRP at \$50 million for fiscal year 2011. Once again, thank you for the opportunity to provide this testimony to this subcommittee.

Mr. DICKS. Thank you. Thank you very much.
Mr. MORAN. Mr. Chairman.
Mr. DICKS. Yes, Mr. Moran.

Mr. Moran. If I could, the next speaker will represent the Breast Cancer Survivors Coalition, which all of these groups really have to thank for initiating medical research. I am glad we have been as robust in funding that. When you look at what the Lung Cancer Coalition has submitted, lung is the largest, then colorectal cancer, then, of course, breast cancer and then pancreatic cancer and then prostate cancer, which we have specific funding for. Colorectal cancer is in a larger group, including pediatric cancer and the like. But we made so much progress.

Mr. Chairman, I want to thank you particularly for having this public hearing because otherwise we don't really hear from the other side. It is just a line item. These folks are putting a face to it. But in colorectal cancer, so much of this is a matter of screening. That is how you save lives. You have got to get it before it gets into the body and takes hold. And to think that only about half of our military are being adequately screened for colorectal cancer is just wrong when the incidence is over 50,000 deaths a year. Many of those are military folks. So I wanted to make that point and I appreciate, Ms. Bauman's testimony.

Ms. Bauman. Great. Thank you very much.

[The statement of Ms. Bauman follows:]



Testimony of Carlea Bauman
President
C3: Colorectal Cancer Coalition

to the
United States House of Representatives
Committee on Appropriations
Subcommittee on Defense
May 20, 2010, 10:00 am

United States House of Representatives Committee on Appropriations Subcommittee on Defense Testimony of Carlea Bauman President, C3: Colorectal Cancer Coalition May 20, 2010, 10:00 am

# Mr. Chairman and Members of the Subcommittee:

Thank you for the opportunity to testify in support of the research that is being funded through DoD through the Peer Reviewed Cancer Research Program. My name is Carlea Bauman. I am the President of the C3: Colorectal Cancer Coalition (C3).

C3 is a nonprofit, nonpartisan advocacy organization seeking to eliminate suffering and death due to colorectal cancer. Founded in 2005 in order to provide focus, infrastructure and support to the growing colorectal cancer advocacy movement, C3 supports the work of research and grassroots advocates throughout the United States. Our mission is to win the fight against colorectal cancer through research, empowerment and access.

Last year, our advocates – all of whom are colorectal cancer survivors, caregivers, or health care providers – asked Congress to include colorectal cancer in the Department of Defense (DoD)'s Peer Reviewed Cancer Research Program (PRCRP). Thank you for listening to them.

We were thrilled that in the fiscal year 2010 bill, for the first time, colorectal cancer research is being funded through the DoD's Peer Reviewed Cancer Research Program because when you fund research for a disease, people diagnosed with that disease live longer and enjoy a higher quality of life. In 2010, there are \$15 million dollars for eight research areas that include melanoma, pediatric brain cancer and blood cancers as well as colorectal cancer. C3 is working with other advocacy groups to increase that funding for fiscal year 2011. We hope we can count on your support.

Along with the Cutaneous Lymphoma Foundation, International Myeloma Foundation, Kidney Cancer Association, Lymphoma Foundation of America, Lymphoma Research Foundation, the Leukemia & Lymphoma Society, and the Vietnam Veterans of America we respectfully ask that you increase the funding for this important program in fiscal year 2011. Specifically, we ask that you fund the DoD's Peer Reviewed Cancer Research Program at \$50 million.

The PRCRP, funded through the DoD Congressionally Directed Medical Research Programs (CDMRP) supports high-quality cancer research, concentrating its resources on research mechanisms which complement rather than duplicate the research approaches of the major funders of medical research in the United States. Although the cancers included in this program are diverse, the research on these disease types is often synergistic.

Investigators increasingly look at the molecular profiles of cancer, often finding connections across cancers affecting different body sites. Advances or progress related to one cancer fuels

the research on the other cancers in this program, and treatments initially approved for one cancer are routinely found to be effective in others.

An enhanced investment in research focusing on these cancers may yield benefits beyond the specific cancers.

For example, one of the first targeted cancer therapies was Gleevec for treatment of chronic myelogenous leukemia (CML); in addition to providing tremendous life-saving benefit to those with CML, this drug has yielded specific knowledge about the development of targeted therapies as well as additional treatments for those who become resistant to this drug.

A class of oral targeted therapies are providing benefit for those with kidney cancer and also showing benefit for those diagnosed with other forms of cancer.

Efforts to develop a genetic profile for pediatric brain tumors will direct research efforts and permit greater targeting of treatment options, and molecular profiling of melanoma will permit better predictions of therapeutic response and inform research efforts.

Researchers today working on colorectal cancer are producing biomarker tests that provide important information about which treatments will work – and which will not. Today, treatment options for colorectal cancer have expanded to seven drugs, more precise surgery and radiation. Whereas thirty years ago treatment options were limited to surgery, one drug, perhaps radiation, and "best supportive care." Continuing to fund innovative research will result in more treatment options for colorectal cancer patients providing hope to those diagnosed with late stage cancer.

Thirty years ago people diagnosed with metastatic colorectal cancer lived approximately six months after their diagnosis. Today people diagnosed with metastatic colorectal cancer are living on average over two years past their diagnosis, and some are even cured.

In short, an increased investment in the PRCRP will provide significant help to those diagnosed with the cancers that are part of the program but will also yield benefits for other cancer patients and will advance overall progress in the fight against cancer.

The PRCRP also represents a unique partnership among the public, Congress, and the military. Congress has required the DoD to ensure that the research funded through the program has relevance to service members and their families. In a report to Congress the DoD notes that it considers this factor in awarding grants and that the research can help service members exposed to toxins and decrease the more than \$1 billion that the DoD spends on cancer care.

In a study published in the June 2009 edition of Cancer Epiemology Biomarkers & Prevention, researchers found that colorectal cancer was one of the most common forms of cancer among active-duty military personnel.<sup>1</sup>

<sup>&</sup>lt;sup>1</sup> Zhu, Kangmin, et al. Cancer Incidence in the U.S. Military Population: Comparison with Rates from the SEER Program, Cancer Epicmology Biomarkers & Prevention. June 2009. Available online at <a href="http://www.dtic.mii/egi-bin/GetTRDoc?Location=U2&doc=GetTRDoc.pdf&AD=ADA504845">http://www.dtic.mii/egi-bin/GetTRDoc?Location=U2&doc=GetTRDoc.pdf&AD=ADA504845</a>.

In the general population, colorectal cancer is third most commonly diagnosed cancer and the second most common cause of cancer deaths for men and women in the United States. Nearly 147,000 people will be diagnosed with colorectal cancer and nearly 50,000 people will die from colorectal cancer this year.<sup>2</sup>

Funding for the DoD's PRCRP is an opportunity to advance the best research to eradicate diseases and support the warfighter for the benefit of the American public. A continued investment by the Subcommittee in research focusing on these cancers may yield benefits beyond the specific cancers.

The study published in Cancer Epiemology Biomarkers & Prevention, found differences in cancer incidence rates between military personnel and the general population. Rates were lower among military personnel than the general population for colorectal, lung, and cervical cancers. However, for colorectal cancer, the difference in rates between the two populations was significant only among white males. It is unclear why white men in the military would have lower colorectal cancer incidence than other white men, although several factors may be related to the difference – specifically, the study authors speculated that the lower incidence rates in the military might be attributed to access to free screening, a healthier lifestyle, or other lifestyle factors.<sup>3</sup>

While the incidence rate of colorectal cancer for white males in the military may be lower than the general population, like the general population – many of those in the military who are diagnosed with colorectal cancer are diagnosed with late-stage disease. Screening rates in the military for colorectal cancer, like in the general population, are much too low. In 2008, only about 58% of those in the military who should be screened for colorectal cancer had been screened. And, every day pre-cancerous polyps that could be detected through screening are not being found. Today, only 39 percent of colorectal cancer patients have their cancers detected at an early stage. For many patients, a diagnosis of colorectal cancer means a diagnosis of late-stage cancer. Not nearly enough research is being done into late-stage colorectal cancer treatments. The PRCRP represents an opportunity to conduct such research.

The highly innovative research supported by the DoD also has far-reaching impact. In addition to the advantages for those cancers within the PRCRP, cancers that are not part of this initiative may also benefit. For example, treatments approved initially for kidney cancer have proven effective in other solid tumors outside the scope of this program. Monoclonal antibodies, designed to target specific molecules on the surface of cancer cells, were first used in the treatment of non-Hodgkin lymphoma. They are now the most widely used form of cancer immunotherapy, with clinical trials in progress for almost every type of cancer.

American Cancer Society. Cancer Facts & Figures 2010. Atlanta: American Cancer Society; 2010.

Zhu, Kangmin, et al. Cancer Incidence in the U.S. Military Population: Comparison with Rates from the SEER Program, Cancer Epiemology Biomarkers & Prevention. June 2009. Available online at <a href="http://www.dtic.mii/cgi-bin/GetTRDoc?Location=U2&doe=GetTRDoc.pdf&AD=ADA504845">http://www.dtic.mii/cgi-bin/GetTRDoc?Location=U2&doe=GetTRDoc.pdf&AD=ADA504845</a>.

http://www.humana-military.com/library/pdf/qm-report-card-2009.pdf.
 American Cancer Society. Cancer Prevention and Early Detection Facts & Figures 2008. Atlanta: American Cancer Society; 2008.

The PRCRP provides hope to cancer patients both in our armed forces and to the American public by promoting innovative and life-saving research.

Last year alone approximately 423,000 Americans were diagnosed with one of the cancers included in the PRCRP and nearly 128,000 Americans lost their lives to one of these diseases. To reduce their crippling human toll and improve the lives of those suffering from these cancers, it is essential that scientific investigators receive the resources they need to increase their understanding of these diseases and develop life-saving treatment options.

In a tight budget year, increased funding for the PRCRP makes fiscal sense because it goes not to one disease but to a pot of funding that will support research into treatments for at least eight different diseases.

Thirty years ago screening for colorectal cancer was not standard medical practice. Today we know that removal of polyps can prevent the vast majority of colorectal cancer, and that screening can find colorectal cancer early, when it's most curable.

Areas of focus for colorectal cancer research in the PRCRP could be:

- · An inexpensive, non-invasive, accurate screening test;
- · Predictive markers to identify who will benefit from which treatments; and
- Accurate diagnostics that can evaluate the markers.

Discoveries resulting from investment in PRCRP research have the potential to transform the investigation of cancer, through the development of new prevention strategies and therapies, and someday, cures.

The PRCRP stimulates new scientific knowledge by funding high-risk, high-gain research not sponsored by other agencies. Many of the award mechanisms offered support the exploration of revolutionary ideas and concepts, and focus on the potential of having a significant impact in the field of cancer research. A \$50 million investment will greatly enhance and accelerate such breakthroughs.

I thank you for your commitment to cancer research at the Department of Defense and efforts to improve the lives of Americans facing and living with a cancer diagnosis. I respectfully request that this Subcommittee continue to support the important work of the DoD's Congressionally Directed Medical Research Programs by funding the Peer Reviewed Cancer Research Program (PRCRP) at \$50 million for fiscal year 2011.

The funding will foster groundbreaking research and partnerships for development of better prevention, early detection and more effective treatments of cancer. It will improve quality of life by significantly decreasing the impact of cancer on service members, their families, and the American public. Once again, thank you for the opportunity to provide this testimony to the Subcommittee.

# House Appropriations Committee Defense Subcommittee

# Witness Disclosure Form

Clause 2(g) of rule XI of the Rules of the House of Representatives requires nongovernmental witnesses to disclose to the Committee the following information. A non-governmental witness is any witness appearing on behalf of himself/herself or on behalf of an organization other than a federal agency, or a state, local or tribal government.

Your Name, Business Address, and Telephone Number:

Carlea Bauman,
President
C3: Colorectal Cancer Coalition 1414 Prince Street, Suite 204
Alexandria, VA 22314
Anomalia, VII EEST
Tel: 703-548-1225 ext. 11
1. Are you appearing on behalf of yourself or a non-governmental organization? Please list organization(s) you are representing.
I am appearing on behalf of the C3: Colorectal Cancer Coalition.
2. Have you or any organization you are representing received any Federal grants or contracts (including any subgrants or subcontracts) since October 1, 2007? Yes No
3. If your response to question #2 is "Yes", please list the amount and source (by agency and program) of each grant or contract, and indicate whether the recipient of such grant or contract was you or the organization(s) you are representing.
Signature: (aviza Enman Date: 5/14/10
Please bring this original form on the day of your testimony.

Mr. DICKS. Thank you. Now we will go to Fran Visco, president of the National Breast Cancer Coalition. Thank you for being patient.

Thursday, May 20, 2010.

# NATIONAL BREAST CANCER COALITION

#### WITNESS

# FRAN VISCO, PRESIDENT, NATIONAL BREAST CANCER COALITION

Ms. VISCO. You are welcome. Thank you for inviting me. So I am Fran Visco. I am a 22-year breast cancer survivor and head of the National Breast Cancer Coalition, which is a coalition and umbrella for over 600 groups from across the country. I want to begin by thanking you for your leadership over the years in support of this program. I am not going to talk to you about the details of what we funded and what the specific successes of the program have been. I give you some examples in my testimony and all of the information is available on the program's Web site. What I do want to tell you is that this government program has been an incredible success on every level and it warrants level funding, this Competitive Peer Reviewed Biomedical Research Program.

This program is a unique structure. It is a collaboration among scientists, trained consumers and the United States Army. Its vision is to eradicate breast cancer by funding innovative research. This program funds gaps. It doesn't replicate or duplicate what other funding agencies and private funders do. This program can rapidly respond to what is happening in the world of breast cancer. Why? There is no bureaucracy. The United States Army has done an incredible job administering this program. It is streamlined, it is efficient. The administrative costs don't even rise to 10 percent. And importantly for the public, this is a transparent program. It is accountable to the taxpayers. The public can go to the Web site and see where the money is going, where their tax dollars are being spent. Every other year at a meeting called the Era of Hope, everyone who has been funded by this program has to present the results of their research to the public.

Mr. DICKS. When does that occur?

Ms. VISCO. Every other year. It is going to happen again in August of 2011 will be the next Era of Hope meeting.

Mr. DICKS. Can Members of Congress go?

Ms. VISCO. Oh, yes. Absolutely. We would love to have you. This program has been successful because it has been free of outside influence and it has the strongest conflict of interest policy of any research funding entity within or without government. What this program does is it pushes science to new levels. It challenges the status quo. It creates new models, some of which you have heard from other programs that you have funded. We create new models of research. We don't direct the research questions to be asked. We leave that to the scientific community. It has been replicated by other programs, by other countries, by breast cancer programs in other States from its mission to the mechanisms it creates to the structure of the program.

In fact, a number of years ago, the then general in charge of the program, General Martinez, told me that even the mechanisms and the way the integration panel works, he took that and used it elsewhere within the Department of the Army because he was so impressed with what we were able to do. So this works on every level. It doesn't just save lives. It changes how research is done. I want you to know that this program is where the hope lies, the hope of the women and men across the country and actually around the world who are dedicated to ending breast cancer. This is the program they look to because they know this is the program that is responding to the needs of patients. And that is really making a difference for all of us. Thank you.

Mr. DICKS. Thank you very much. Are there any questions? We have a little time here for anyone who has a question. Thank you. Let me ask you this. Do you think this is a better program than

National Cancer Institute?

Ms. VISCO. Yes, I do. Without question, I think this program for breast cancer is a better program than the National Cancer Institute.

Mr. DICKS. Why is that?

Ms. VISCO. For all the reasons I said. It is incredibly transparent, it is accountable, it is able to rapidly respond. There is no huge bureaucracy here that you have to try to overcome. It is looking at innovation. A couple of years ago, the then head of the National Institutes of Health testified to Congress. And he was talking about how proud he was of the four new innovations at NIH. And all four of them were copied from the DOD Breast Cancer Research Program. This is the program where the creativity and the innovation lie. This is the program that brings the public into it. The NCI, while it is doing very good work, does not rise to the level of the breast cancer research that the DOD program funds.

Ms. Kaptur. Mr. Chairman, since this witness is so articulate and though I won't only focus on breast cancers, I have listened to the various witnesses come before us this morning whether it is colorectal or lung or breast cancer, we thank you so much for the great work you are doing. What I fail to understand from a scientific standpoint is knowing everything we know about genetics, knowing everything we know about blood typing and analysis, why isn't it just a simple matter of genetic marking so that we can find better detection regimens. We spend so much money as a country.

Ms. VISCO. I could answer that. I am not sure by 11:00, but I could answer that. I will be as quick as I can. But I would love to have the conversation with you outside the hearing. The problem is that this isn't just an issue of early detection, nor is it an issue of genetic mutation. It isn't. It is much more complicated than that. Cancer is more complicated than that. We can find a pathway or a gene that is mutated. We can find people who are at high risk, but we don't know what to do with them. And when you find a mutated pathway or a mutated gene, there are some other pathways and genes and proteins that come into the story that it is not just one target that is going to make a difference, that is going to cure women or that is going to detect it early enough for everyone to make a difference.

We don't understand enough about the biology of this disease or really any cancer. The question was asked about ovarian cancer. Why am I here? I am a 22-year survivor. I had a pretty difficult breast cancer. I had lymph node involvement. I had state-of-the-art treatment. I don't think that is why I am here. We don't know why I am here. There is something about my DNA, the biology of my disease that responded to therapy, maybe didn't need therapy at all. We don't know enough about these diseases. They are incredibly complicated. We can't just focus on early detection because that is so far from the answer to these diseases.

The same thing with ovarian cancer, that woman thankfully is alive 9 years later. I don't know if it was her surgery or her treatment. It was probably something about the biology of her disease that we don't know yet. Those are the kinds of questions that we have to answer to really get rid of these diseases.

Mr. RYAN. Mr. Chairman, if I could just add something here. Of all of these diseases, I think there is an issue that I hope over time we can start focusing on and that is stress, especially in the military environment, military families, is how we can begin to reduce levels of stress, teach people how to cope with their levels of stress because it has been proven that over time stress will just accelerate cancer and other diseases. So I hope that we can continue that and make that a part of our focus.

Ms. VISCO. Actually I mention in my submitted testimony we actually are funding looking at stress levels in the military and accelerated breast cancer. That is one of the concepts that was funded

by the program.

Mr. RYAN. It was just in the earlier testimony too on the schools with the kids and the families and everything else here. I think we are going to see a theme running through a lot of this stuff. I think if we really want to kind of focus on something that is a cause of or something that increases these problems, we are going to find out time and time again it is stress. So we need to figure out how

to get to the root of the problem too at the same time.

Mr. MORAN. Mr. Chairman, I hate to belabor this. But the other thing that would be helpful is that in terms of prevention, we hear so many conflicting things. Breast feeding is good or aggressive exercise, any number of things, vitamins and so on. But one day we will see that this is the secret and then several months later we will say no, they were absolutely wrong. It would be helpful for a group such as yours to provide the kind of consistent device because women are desperate for credible information that they can use to apply to their own lives.

Ms. VISCO. Yes. And prevention research, of course, is one of the most underfunded areas of any disease but certainly in cancer. We really don't know enough about how to prevent these diseases. You

are absolutely right.

Mr. MORAN. Thank you.

Mr. Dicks. Thank you very much.

Ms. Visco. You are welcome.

[The statement of Ms. Visco follows:]



#### Testimony of Fran Visco, J.D. President National Breast Cancer Coalition

#### House Appropriations Subcommittee on Defense

May 20, 2010

#### Introduction

Thank you, Mr. Chairman and members of the Appropriations Subcommittee on Defense, for the opportunity to submit testimony today about a program that has made a significant difference in the lives of women and their families.

I am Fran Visco, a 21-year breast cancer survivor, a wife and mother, a lawyer, and President of the National Breast Cancer Coalition (NBCC). My testimony represents the hundreds of member organizations and thousands of individual members of the Coalition. NBCC is a grassroots organization dedicated to ending breast cancer through action and advocacy. The Coalition's main goals are to increase federal funding for breast cancer research and collaborate with the scientific community to implement new models of research; improve access to high quality health care and breast cancer clinical trials for all women; and expand the influence of breast cancer advocates wherever breast cancer decisions are made.

Chairman Dicks and Ranking Member Young, we appreciate your longstanding support for the Department of Defense Peer Reviewed Breast Cancer Research Program. As you know, this program was born from a powerful grassroots effort led by the National Breast Cancer Coalition, and has become a unique partnership among consumers, scientists, Members of Congress and the military. You and your Committee have shown great determination and leadership in funding the Department of Defense (DOD) peer-reviewed Breast Cancer Research Program (BCRP) at a level that has brought us closer to eradicating this disease. I am hopeful that you and your Committee will continue that determination and leadership.

I know you recognize the importance of this program to women and their families across the country, to the scientific and health care communities and to the Department of Defense. Much of the progress in the fight against breast cancer has been made possible by the Appropriations Committee's investment in breast cancer research through the DOD BCRP. To support this unprecedented progress moving forward, we ask that you support a separate \$150 million appropriation, level funding, for Fiscal Year (FY) 2011. In order to continue the success of the Program, you must ensure that it maintain its integrity and separate identity, in addition to level funding. This is important not just for breast cancer, but for all biomedical research that has benefited from this incredible government program.

#### Vision and Mission

The vision of the Department of Defense Breast Cancer Research Program is to "eradicate breast cancer by funding innovative, high-impact research through a partnership of scientists and consumers." The meaningful and unprecedented partnership of scientists and consumers has been the foundation of this model program from the very beginning. It is important to understand this collaboration: consumers and scientists working side by side, asking the difficult questions, bringing the vision of the program to life, challenging researchers and the public to do what is needed and then overseeing the process every step of the way to make certain it works. This unique collaboration is successful: every year researchers submit proposals that reach the highest level asked of them by the program and every year we make progress for women and men everywhere.

And it owes its success to the dedication of the U.S. Army and their belief and support of this mission. And of course, to you. It is these integrated efforts that make this program unique.

The Department of the Army must be applauded for overseeing the DOD BCRP which has established itself as a model medical research program, respected throughout the cancer and broader medical community for its innovative, transparent and accountable approach. This program is incredibly streamlined. The flexibility of the program has allowed the Army to administer it with unparalleled efficiency and effectiveness. Because there is little bureaucracy, the program is able to respond quickly to what is currently happening in the research community. Because of its specific focus on breast cancer, it is able to rapidly support innovative proposals that reflect the most recent discoveries in the field. It is responsive, not just to the scientific community, but also to the public. The pioneering research performed through the program and the unique vision it maintains has the potential to benefit not just breast cancer, but all cancers as well as other diseases. Biomedical research is literally being transformed by the DOD BCRP's success.

#### **Consumer Participation**

Advocates bring a necessary perspective to the table, ensuring that the science funded by this program is not only meritorious, but that it is also meaningful and will make a difference in people's lives. The consumer advocates bring accountability and transparency to the process. They are trained in science and advocacy and work with scientists willing to challenge the status quo to ensure that science funded by the program fill important gaps not already being addressed by other funding agencies. Since 1992, more than 600 breast cancer survivors have served on the BCRP review panels.

Last year, Carolina Hinestrosa, a breast cancer survivor and trained consumer advocate, chaired the Integration Panel and led the charge in challenging BCRP investigators to think outside the box for revelations about how to eradicate breast cancer. Despite the fact that her own disease was progressing, she remained steadfast in working alongside scientists and consumers to move breast cancer research in new directions. Unwilling to give up, she fought tirelessly until the end of her life for a future free of breast cancer.

Carolina died 11 mos ago (tomorrow) from soft tissue sarcoma, a late side effect of the radiation that was used to treat her breast cancer. She once eloquently described the unique structure of the DOD BCRP.

The Breast Cancer Research Program channels powerful synergy from the collaboration of the best and brightest in the scientific world with the primary stakeholder, the consumer, toward bold research efforts aimed at ending breast cancer.

No one was bolder than Carolina, who was fierce and determined in her work on the DOD BCRP and in all aspects of life she led as a dedicated breast cancer advocate, mother to a beautiful daughter, and dear friend to so many. Carolina's legacy reminds us that breast cancer is not just a struggle for scientists; it is a disease of the people. The consumers who sit alongside the scientists at the vision setting, peer review and programmatic review stages of the BCRP are there to ensure that no one forgets the women who have died from this disease, and the daughters they leave behind, and to keep the program focused on its vision.

For many consumers, participation in the program is "life changing" because of their ability to be involved in the process of finding answers to this disease. In the words of one advocate:

The BCRP gives hope to the breast cancer community, hope that cannot be simplified with a symbol or drawn in a pretty color. It is simply a plan of attack on a disease that kills so many and thus offers hope that we are working together to find the solution.--Joy Simha, IP member, Young Survival Coalition

Scientists who participate in the Program agree that working with the advocates has changed the way they do science. Let me quote Greg Hannon, the FY10 DOD BCRP Integration Panel Chair:

The most important aspect of being a part of the BCRP, for me, has been the interaction with consumer advocates. They have currently affected the way that I think about breast cancer, but they have also impacted the way that I do science more generally. They are a constant reminder that our goal should be to impact people's lives.--Greg Hannon, PhD, Cold Spring Harbor Laboratory

# Unique Structure

The DOD BCRP uses a two-tiered review process for proposal evaluation, with both steps including scientists as well as consumers. The first tier is scientific peer review in which proposals are weighed against established criteria for determining scientific merit. The second tier is programmatic review conducted by the Integration Panel (composed of scientists and consumers) that compares submissions across areas and recommends proposals for funding based on scientific merit, portfolio balance and relevance to program goals.

Scientific reviewers and other professionals participating in both the peer review and the programmatic review process are selected for their subject matter expertise. Consumer participants are recommended by an organization and chosen on the basis of their experience, training and recommendations.

The BCRP has the strictest conflict of interest policy of any research funding program or institute. This policy has served it well through the years. Its method for choosing peer and programmatic review panels has produced a model that has been replicated by funding entities around the world.

It is important to note that the Integration Panel that designs this Program has a strategic plan for how best to spend the funds appropriated. This plan is based on the state of the science – both what scientists and consumers know now and the gaps in our knowledge – as well as the needs of the public. While this plan is mission driven, and helps ensure that the science keeps to that mission of eradicating breast cancer in mind, it does not restrict scientific freedom, creativity or innovation. The Integration Panel carefully allocates these resources, but it does not predetermine the specific research areas to be addressed.

#### **Distinctive Funding Opportunities**

The DOD BCRP research portfolio includes many different types of projects, including support for innovative individuals and ideas, impact on translating research from the bench to the bedside, and training of breast cancer researchers.

#### Innovation

The Innovative Developmental and Exploratory Awards (IDEA) grants of the DOD program have been critical in the effort to respond to new discoveries and to encourage and support innovative, risk-taking research. Concept Awards support funding even earlier in the process of discovery. These grants have been instrumental in the development of promising breast cancer research by allowing scientists to explore beyond the realm of traditional research and unleash incredible new ideas. IDEA and Concept grants are uniquely designed to dramatically advance our knowledge in areas that offer the greatest potential. They are precisely the type of grants that rarely receive funding through more traditional programs such as the National Institutes of Health and private research programs. They therefore complement, and do not duplicate, other federal funding programs. This is true of other DOD award mechanisms also.

Innovator awards invest in world renowned, outstanding individuals rather than projects, by providing funding and freedom to pursue highly creative, potentially groundbreaking research that could ultimately accelerate the eradication of breast cancer. For example, in FY08, Dr. Mauro Ferrari of the University of Texas Health Science Center at Houston was granted an Innovator Award to develop novel vectors for the optimal delivery of individualized breast cancer treatments. This is promising based on the astounding variability in breast cancer tumors and the challenges presented in determining which treatments will be most effective and how to deliver those treatments to each individual patients. Also in FY08, Tomas Walsh of the University of Washington was awarded an IDEA grant to study genome wide discovery of inherited structural mutations in breast cancer families. And in FY2009, Philip Foulis from the James A. Haley Veterans Hospital and the Tampa VA Research and Education Foundation, Inc, was awarded a Concept Award to study combat related stress and accelerated breast cancer

The Era of Hope Scholar Award supports the formation of the next generation of leaders in breast cancer research, by identifying the best and brightest scientists early in their careers and giving them the necessary resources to pursue a highly innovative vision of ending breast cancer. Dr. Shiladitya Sengupta from Brigham and Women's Hospital, Harvard Medical School, received a FY06 Era of Hope Scholar Award to explore new strategies in the treatment of breast cancer that target both the tumor and the supporting network surrounding it.

One of the most promising outcomes of research funded by the DOD BCRP was the development of the first monoclonal antibody targeted therapy that prolongs the lives of women with a particularly aggressive type of advanced breast cancer. Researchers found that over-expression of HER-2/neu in breast cancer cells results in very aggressive biologic behavior. The same researchers demonstrated that an antibody directed against HER-2/neu could slow the growth of the cancer cells that over-expressed the gene. This research, which led to the development of the targeted therapy, was made possible in part by a DOD BCRP-funded infrastructure grant. Other researchers funded by the DOD BCRP are identifying similar targets that are involved in the initiation and progression of cancer.

These are just a few examples of innovative funding opportunities at the DOD BCRP that are filling gaps in breast cancer research.

#### Translational Research

The DOD BCRP also focuses on moving research from the bench to the bedside. DOD BCRP awards are designed to fill niches that are not addressed by other federal agencies. The BCRP considers translational research to be the process by which the application of well-founded laboratory or other pre-clinical insight result in a clinical trial. To enhance this critical area of research, several research opportunities have been offered. Clinical Translational Research Awards have been awarded for investigator-initiated projects that involve a clinical trial within the lifetime of the award. The BCRP has expanded its emphasis on translational research by also offering five different types of awards that support work at the critical juncture between laboratory research and bedside applications.

The Multi Team Award mechanism brings together the world's most highly qualified individuals and institutions to address a major overarching question in breast cancer research that could make a significant contribution towards the eradication of breast cancer. Many of these Teams are working on questions that will translate into direct clinical applications. These Teams include the expertise of basic, epidemiology and clinical researchers, as well as consumer advocates.

# Training

The DOD BCRP is also cognizant of the need to invest in tomorrow's breast cancer researchers. Dr. J. Chuck Harrell, Ph.D. at the University of Colorado, Denver and the University of North Carolina at Chapel Hill, for example, received a Predoctoral Traineeship Award to investigate hormonal regulation of lymph node metastasis, the majority of which retain estrogen receptors (ER) and/or progesterone receptors. Through his research, Dr. Harrell determined that lymph node microenvironment alters ER expression and function in the lymph nodes, effecting tumor growth. These findings led Dr. Harrell to conduct further research in the field of breast metastasis during his postdoctoral work. Jim Hongjun of

the Battelle Memorial Institute received a postdoctoral award for the early detection of breast cancer using post-translationally modified biomarkers.

Dr. John Niederhuber, now the Director of the National Cancer Institute (NCI), said the following about the Program when he was Director of the University of Wisconsin Comprehensive Cancer Center in April, 1999:

Research projects at our institution funded by the Department of Defense are searching for new knowledge in many different fields including: identification of risk factors, investigating new therapies and their mechanism of action, developing new imaging techniques and the development of new models to study [breast cancer]...Continued availability of this money is critical for continued progress in the nation's battle against this deadly disease.

Scientists and consumers agree that it is vital that these grants continue to support breast cancer research. To sustain the Program's momentum, \$150 million for peer-reviewed research is needed in FY11

# Outcomes and Reviews of the DOD BCRP

The outcomes of the BCRP-funded research can be gauged, in part, by the number of publications, abstracts/presentations, and patents/licensures reported by awardees. To date, there have been more than 12,241 publications in scientific journals, more than 12,000 abstracts and nearly 550 patents/licensure applications. The American public can truly be proud of its investment in the DOD BCRP. Scientific achievements that are the direct result of the DOD BCRP grants are undoubtedly moving us closer to eradicating breast cancer.

The success of the DOD peer-reviewed Breast Cancer Research Program has been illustrated by several unique assessments of the Program. The IOM, which originally recommended the structure for the Program, independently re-examined the Program in a report published in 1997. They published another report on the Program in 2004. Their findings overwhelmingly encouraged the continuation of the Program and offered guidance for program implementation improvements.

The 1997 IOM review of the DOD peer-reviewed Breast Cancer Research Program commended the Program, stating, "the Program fills a unique niche among public and private funding sources for cancer research. It is not duplicative of other programs and is a promising vehicle for forging new ideas and scientific breakthroughs in the nation's fight against breast cancer." The 2004 report spoke to the importance of the program and the need for its continuation.

The DOD peer-reviewed Breast Cancer Research Program not only provides a funding mechanism for high-risk, high-return research, but also reports the results of this research to the American people every two to three years at a public meeting called the Era of Hope. The 1997 meeting was the first time a federally-funded program reported back to the public in detail not only on the funds used, but also on the research undertaken, the knowledge gained from that research and future directions to be pursued.

Sixteen hundred consumers and researchers met for the fifth Era of Hope meeting in June, 2008. As MSNBC.com's Bob Bazell wrote, this meeting "brought together many of the most committed breast cancer activists with some of the nation's top cancer scientists. The conference's directive is to push researchers to think 'out of the box' for potential treatments, methods of detection and prevention..." He went on to say "the program...has racked up some impressive accomplishments in high-risk research projects..."

One of the topics reported on at the meeting was the development of more effective breast imaging methods. An example of the important work that is coming out of the DOD BCRP includes a new screening method, molecular breast imaging, which helps detect breast cancer in women with dense breasts – which can be difficult using a mammogram alone. I invite you to log on to NBCC's website <a href="http://influence.stopbreastcancer.org/">http://influence.stopbreastcancer.org/</a> to learn more about the exciting research reported at the 2008 Era of Hope. The next Era of Hope meeting is being planned for 2011.

The DOD peer-reviewed Breast Cancer Research Program has attracted scientists across a broad spectrum of disciplines, launched new mechanisms for research and facilitated new thinking in breast cancer research and research in general. A report on all research that has been funded through the DOD BCRP is available to the public. Individuals can go to the Department of Defense website and look at the abstracts for each proposal at http://cdmrp.army.mil/bcrp/.

#### Commitment of the National Breast Cancer Coalition

The National Breast Cancer Coalition is strongly committed to the DOD BCRP in every aspect, as we truly believe it is one of our best chances for finding causes of, cures for, and ways to prevent breast cancer. The Coalition and its members are dedicated to working with you to ensure the continuation of funding for this Program at a level that allows this research to forge ahead. From 1992, with the launch of our "300 Million More Campaign" that formed the basis of this Program, until now, NBCC advocates have appreciated your support.

Over the years, our members have shown their continuing support for this Program through petition campaigns, collecting more than 2.6 million signatures, and through their advocacy on an almost daily basis around the country asking for support of the DOD BCRP.

Consumer advocates have worked hard over the years to keep this program free of political influence. Often, specific institutions or disgruntled scientists try to change the program though legislation, pushing for funding for their specific research or institution, or try to change the program in other ways, because they did not receive funding through the process, one that is fair, transparent and successful. The DOD BCRP has been successful for so many years because of the experience and expertise of consumer involvement, and because of the unique peer review and programmatic structure of the program. We urge this Committee to protect the integrity of the important model this program has become.

There are three million women living with breast cancer in this country today. This year, more than 40,000 will die of the disease and more than 240,000 will be diagnosed. We still do not know how to prevent breast cancer, how to diagnose it in a way to make a real difference or how to cure it. It is an incredibly complex disease. We simply cannot afford to walk away from this program.

Since the very beginning of this Program in 1992, Congress has stood with us in support of this important approach in the fight against breast cancer. In the years since, Chairman Dicks and Ranking Member Young, you and this entire Committee have been leaders in the effort to continue this innovative investment in breast cancer research.

NBCC asks you, the Defense Appropriations Subcommittee, to recognize the importance of what has been initiated by the Appropriations Committee. You have set in motion an innovative and highly efficient approach to fighting the breast cancer epidemic. We ask you now to continue your leadership and fund the Program at \$150 million and maintain its integrity. This is research that will help us win this very real and devastating war against a cruel enemy.

Thank you again for the opportunity to submit testimony and for giving hope to all women and their families, and especially to the 3 million women in the United States living with breast cancer and all those who share in the mission to end breast cancer.

# House Appropriations Committee Defense Subcommittee

# Witness Disclosure Form

Clause 2(g) of rule XI of the Rules of the House of Representatives requires nongovernmental witnesses to disclose to the Committee the following information. A non-governmental witness is any witness appearing on behalf of himself/herself or on behalf of an organization other than a federal agency, or a state, local or tribal government.

Your Name, Business Address, and Telephone Number:

FRANCES M VISCO 1101 17 <sup>TH</sup> STREET NW SUITE 1300 WASHINGTON, DC 20036 (202) 973-0583
Are you appearing on behalf of yourself or a non-governmental organization? Please list organization(s) you are representing.  NATIONAL BREAST CANCER COALITION
<ol> <li>Have you or any organization you are representing received any Federal grants or contracts (including any subgrants or subcontracts) since October 1, 2007?</li> <li>Yes No</li> </ol>
3. If your response to question #2 is "Yes", please list the amount and source (by agency and program) of each grant or contract, and indicate whether the recipient of such grant or contract was you or the organization(s) you are representing.
Signature: Marces Marco Date: 11 MAY 2010

Please bring this original form on the day of your testimony.

Mr. DICKS. We appreciate it. Now we will have Kendra Sharp, associate professor of mechanical, industrial and manufacturing engineering at Oregon State University. A great northwest school.

Ms. Sharp. Yeah. I just moved to the Pacific Northwest. Mr. Dicks. Some of my best friends went to Oregon State. Terry

Baker played there. A great quarterback.

Ms. Sharp. Okay. Great. I just moved there to the Pacific Northwest and I am quite pleased to have moved to that part of the

Mr. Dicks. Corvallis? You are in Corvallis, right?

Ms. Sharp. Yes.

Mr. DICKS. Thank you.

Thursday, May 20, 2010.

# ASME, DEPARTMENT OF DEFENSE TASK FORCE

## WITNESS

# KENDRA SHARP, ASSOCIATE PROFESSOR, MECHANICAL, INDUSTRIAL, AND MANUFACTURING ENGINEERING, OREGON STATE UNIVERSITY

Ms. Sharp. Mr. Chairman, Mr. Ranking Member and members of the committee, I am Kendra Sharp, associate professor at Oregon State University's mechanical, industrial, manufacturing and engineering. On behalf of the ASME Department of Defense task force, I am pleased to have the opportunity to testify on the fiscal year 2011 Department of Defense budget request. The American Society of Mechanical Engineers is a 120,000 member professional organization focused on technical, educational and research issues. Our Nation's engineers play a critical role in national defense through research discoveries and technology development for military systems. Therefore, my comments will focus on the DOD's science and technology budget. The administration has requested \$76.7 billion for the RDT&E portion of the fiscal year 2011 DOD budget, a 5.1 percent decline from last year. Of concern to our task force, funds for operational tests and evaluation function are still at reduced levels by historical standards.

And while the fiscal year 2011 request represents an improvement from recent years, even this amount does not represent the importance of OT&E as mandated by Congress. The administration's request for defense S&T of \$11 billion represents a 12.2 percent reduction from last year. Our task force strongly urges this committee to consider additional resources to maintain stable fund-

ing in the S&T portion of the DOD budget.

We note that up to \$16.4 billion would be needed for defense S&T funding to meet the 3 percent of total obligational authority guideline recommended by the National Academies and set in the 2001 Quadrennial Defense Review, recommendations which were broadly supported in Congress only a few years ago. The basic research 6.1 account supports programs which are crucial to fundamental scientific advances and for maintaining a highly skilled science and engineering workforce. Maintaining a skilled workforce is critical given the large turnover that will occur in the next few years in key science and engineering industries.

The National Science Foundation's 2010 Science and Engineering Indicators Report shows that the U.S. severely lags the rest of the world in both real terms and on a percentage basis in the granting of first degrees in engineering with only 4.5 percent of first university degrees being granted in engineering versus 12.6 percent for the European Union and over 21 percent across Asia. Combined with the NSF findings that the average age and retirement rate of the engineering workforce will continue to rise over the next several years, our task force reiterates the need for robust S&T programs at DOD as critical to our economic competitiveness and national security. Several of the proposed reductions to individual S&T program elements are dramatic and could have negative impacts on future military capabilities. While basic research accounts are properly weighted under the President's request, applied research, the 6.2 accounts would receive an 11.2 percent reduction. Applied research programs may involve laboratory proof of concept and are generally conducted at universities, government laboratories or by small businesses. Many successful demonstrations lead to the creation of small companies and 6.2 applied research has also funded the education of many of our best defense industry engineers. Failure to properly invest in applied research would stifle a key source of technological and intellectual development and stunt the creation and growth of small entrepreneurial companies. Advanced technology development, 6.3, would experience a dramatic 18.3 percent decline under the President's budget.

These resources support programs where ready technology can be transitioned into weapon systems. This line item funds research in a range of critical material technologies, including improved body armor to protect troops against IEDs and in developing lightweight armor for vehicle protection. With the problems faced in Iraq and Afghanistan with IEDs and the need for improved armor systems,

it does not seem wise to cut materials research.

Another key program for the defense S&T community is the university research initiative which supports graduate education in mathematics, science and engineering. Under the proposed budget, this program would see a 2.1 percent decrease to 335.9 million. Sufficient funding for the URI is critical to educating the next generation of engineers and scientists for the defense industry. A lag in program funds will have a serious long-term negative consequence on our ability to develop a highly skilled scientific and engineering workforce to build weapon systems for years to come.

Mr. DICKS. You have 1 minute.

Ms. Sharp. Thank you. While DOD has enormous current commitments, these pressing needs should not be allowed to squeeze out the small but very important investments required to create the next generation of highly skilled technical workers for the American defense industry.

In closing, I have three recommendations from our task force. The first is that we urge the subcommittee to support the President's request for the 6.1 basic research accounts for S&T programs. The second is that the task force recommends the subcommittee provide an additional \$563 million in support for the 6.2 applied research account function in order to ensure workforce and project stability in this critical area of defense research.

And third, we also recommend that the committee support the Pentagon's stated goal of devoting 3 percent of the department's baseline budget to Defense S&T program, 6.1, 6.2 and 6.3 accounts. I thank the committee for its ongoing support of defense science and technology. Our task force appreciates the difficult choices that Congress must make in this tight budgetary environment. We believe, however, that there are critical shortages in the DOD S&T areas, particularly in those that support basic research and technical education that are critical to U.S. military in the global war on terrorism and defense of our homeland. Thank you.
[The statement of Ms. Sharp follows:]



1828 L Street, N.W. Suite 906 Washington, D.C. 20036

Tel 202.785.3756 Fax 202.429.9417 www.asme.org

Position Statement on the Fiscal Year 2011 Budget Request for the Department of Defense Research, Development, Test and Evaluation (RDT&E) and Science and Technology (S&T) Programs

Submitted by the ASME Department of Defense Task Force

## April 15, 2010

## Introduction

The ASME Department of Defense (DOD) Task Force of the Inter Sector Committee on Federal Research and Development is pleased to comment on the Fiscal Year (FY) 2011 budget request for the Research, Development, Test and Evaluation (RDT&E) and the Science and Technology (S&T) portion of the Department of Defense budget request.

With 127, 000 members, ASME is a worldwide engineering society focused on technical, educational and research issues. It conducts one of the world's largest technical publishing operations, holds approximately 30 technical conferences and 200 professional development courses each year, and sets many industry and manufacturing standards. This testimony represents the considered judgment of experts from universities, industry, and members from the engineering and scientific community who contribute their time and expertise to evaluate the budget requests and policy initiatives the DOD recommends to Congress.

Our testimony addresses three (3) primary funding areas: Science and Technology (S&T); Engineering (RDT&E); and the University Research Initiative (URI). Our testimony also outlines the consequences of inadequate funding for defense research. These include a degraded competitive position in developing advanced military technology versus potential peer competitors that could harm the United States' global economic and military leadership.

Since World War II the United States has led the world in science, innovation, and defense technology. However, this lead is quickly eroding and within the next few years may be substantially reduced or may completely disappear in some areas. The National Academy of Science's landmark 2005 report entitled "Rising Above the Gathering Storm: Energizing and Employing America for a Brighter Economic Future," evaluated the position of the United States in several critical measures of technology, education, innovation, and high skilled workforce development. While the report indicated that the U.S. maintains a slight lead in research and discovery, the committee stated that it was "deeply concerned that the scientific and technological building blocks critical to our economic leadership are eroding at a time when many other nations are gaining strength." Proper attention should be given to the vital role that DOD S&T programs play in meeting this challenge.

## DOD Request for Science and Technology

The FY2011 budget request for Defense Science and Technology (S&T) is \$11.8 billion, which is \$1.65 billion less than the FY 2010 appropriated amount and represents a 12.2 percent

reduction. The FY2011 request, if implemented, would represent a significantly reduced investment in Defense S&T. We strongly urge this committee to consider additional resources to maintain stable funding in the S&T portion of the DOD budget. At a minimum, \$16.4 billion is needed for S&T to meet the three percent of Total Obligational Authority (TOA) guideline recommended by a National Academies study and set in the 2001 Quadrennial Defense Review, both of which were broadly supported in Congress.

A relatively small fraction of the Research Development Test & Evaluation (RDT&E) budget is allocated to S&T programs. While the FY 2011 S&T request represents only about 15 percent of the RDT&E total, these accounts support all of the new knowledge creation, invention and technology developments for the military. While funds for Basic Research (6.1) would receive an increase under the President's request, Applied Research (6.2) and Advanced Technology Development (6.3) are programmed for significant funding reductions.

Basic Research (6.1) accounts would increase from \$1.87 billion to \$1.99 billion, a 6.6 percent increase. While basic research accounts comprise only a small percentage of RDT&E funds, the programs that these accounts support are crucial to fundamental scientific advances and for maintaining a highly skilled science and engineering workforce. Maintaining a skilled workforce, in particular, is critical given the large turnover that will occur in the next few years in key science and engineering industries. The National Science Foundation's 2010 Science and Engineering (S&E) Indicators Report shows that the US severely lags the rest of the world – in both real terms and on a percentage basis – in the granting of first degrees in engineering, with only 4.5 percent of first university degrees being granted in engineering verses 12.6 percent for the European Union and over 21 percent across Asia¹. Combined with the NSF's findings that the average age and retirement rate of the engineering workforce will continue to rise over the next several years², the Task Force reiterates the need for robust S&T programs at DOD as critical to our economic competitiveness and national security.

Basic research accounts are used mostly to support science and engineering research and graduate education at universities in all 50 states. Almost all of the current high-technology weapon systems, from advanced body armor, vehicle protection system, to the global positioning satellite (GPS) system, have their origin in fundamental discoveries generated in these basic research programs. Proper investments in basic research are needed now, so that the fundamental scientific results will be available to create innovative solutions for future defense challenges. In addition, many of the technical leaders in corporations and government laboratories that are developing current weapon systems were educated under basic research programs funded by DOD. Failure to invest sufficient resources in basic, defense-oriented research will reduce innovation and weaken the future scientific and engineering workforce. Several of the proposed reductions to individual S&T program elements are dramatic and could have negative impacts on future military capabilities. The Task Force supports the President's request of \$1.99 billion for Basic Research (6.1).

Applied Research (6.2) would be reduced from \$5.03 billion to \$4.47 billion, an 11.2 percent reduction. The programs supported by these accounts apply basic scientific knowledge, often derived from basic research programs, to important defense needs. Applied research programs may involve laboratory proof-of-concept and are generally conducted at universities, government laboratories, or by small businesses. Many successful demonstrations led to the creation of small

http://www.nsf.gov/statistics/seind10/append/c2/at02-35.pdf

http://www.nsf.gov/statistics/seind02/c3/c3s3.htm; see also: http://www.nsf.gov/statistics/seind10/c3/tt03-b.htm

companies. Some devices created in these defense technology programs have dual use, such as GPS, and the commercial market far exceeds the defense market. However, without initial support by Defense Applied Research funds, many of these companies would not exist. Like 6.1 Basic Research, 6.2 Applied Research has also funded the education of many of our best defense industry engineers. Failure to properly invest in applied research would stifle a key source of technological and intellectual development as well as stunt the creation and growth of small entrepreneurial companies.

Advanced Technology Development (6.3) would experience an 18.3 percent decline, from \$6.5 billion to \$5.3 billion. These resources support programs where ready technology can be transitioned into weapon systems. Without the real system level demonstrations funded by these accounts, companies are reluctant to incorporate new technologies into weapon systems programs. This line item funds research in a range of critical materials technologies, including improved body armor to protect troops against improvised explosive devices (IEDs) and in developing light weight armor for vehicle protection. With the problems faced in Iraq and Afghanistan with IEDs and the need for improved armor systems, it does not seem wise to cut materials research. Fortunately in the past few years the United States Congress has recognized that such cuts are not in the best interest of the country, and has appropriated additional resources to maintain healthy S&T programs in critical technologies.

## DOD Request for RDT&E

The Administration requested \$76.7 billion for the Research, Development, Test and Evaluation (RDT&E) portion of the FY2011 DOD budget. These resources are used mostly for developing, demonstrating, and testing weapon systems, such as fighter aircraft, satellites, and warships. This amount represents a decline from last year's appropriated amount by 5.1 percent. Funds for Operational Test and Evaluation (OT&E) function are still at reduced levels by historical standards. The FY 2010 appropriated amount was \$188.2 million, a significant reduction from the 2005 appropriated amount of \$310 million. The FY 2011 request is \$194.9 million, an improvement from recent years. However, even this amount does not reflect the importance of OT&E as mandated by Congress to insure that weapon systems are thoroughly tested so that they are effective and safe for our troops.

## DOD Request for the University Research Initiative (URI)

The University Research Initiative (URI) supports graduate education in Mathematics, Science, and Engineering and would see a decline to \$335.9 million in FY 2011, a 2.1 percent decrease. While the Administration has requested an increase for a Navy URI, both the Army and Air Force received sizable reductions. Sufficient funding for the URI is critical to educating the next generation of engineers and scientists for the defense industry. A lag in program funds will have a serious long-term negative consequence on our ability to develop a highly skilled scientific and engineering workforce to build weapons systems for years to come. While DOD has enormous current commitments, these pressing needs should not be allowed to squeeze out the small but very important investments required to create the next generation of highly skilled technical workers for the American defense industry.

## Reduced S&T Funding Threatens America's National Security

Science and technology have played a historic role in creating an innovative economy and a highly skilled workforce. Study after study has linked over 50% of our economic growth over

the past 50 years to technological innovation. The "Gathering Storm" report places a "special emphasis on information sciences and basic research" conducted by the DOD because of large influence on technological innovation and workforce development. The DOD, for example, funds 40% of all engineering research performed at our universities. US economic leadership depends on the S&T programs that support the nation's defense base, promote technological superiority in weapons systems, and educate new generations of scientists and engineers.

Prudent investments also directly affect U.S. national security. There is a general belief among defense strategists that the United States must have the industrial base to develop and produce the military systems required for national defense. Many members of Congress also hold this view. A number of disconcerting trends, such as outsourcing of engineering activities and low participation of U.S. students in science and engineering, threaten to create a critical shortage of native, skilled, scientific and engineering workforce personnel needed to sustain our industrial base. Programs that boost the available number of highly educated workers who reside in the U.S. are important to stem our growing reliance on foreign nations, including potentially hostile ones, to fill the ranks of our defense industries and to ensure that we continue to produce the innovative, effective defense systems of the future.

#### Recommendations

In conclusion, we thank the committee for its ongoing support of Defense S&T. This Task Force appreciates the difficult choices that Congress must make in this tight budgetary environment. We believe, however, that there are critical shortages in the DOD S&T areas, particularly in those that support basic research and technical education that are critical to U.S. military in the global war on terrorism and defense of our homeland.

The Task Force recommends the following:

- We urge this subcommittee to support the President's request for the 6.1 Basic Research
  accounts for S&T programs. We are encouraged by the movement toward meeting the
  recommendations in the Rising Above the Gathering Storm report that called for a 10
  percent increase in defense basic research.
- 6.2 Applied Research funds are critical to bridging the 'valley of death' for defense researchers and entrepreneurs. The Task Force recommends that the subcommittee provide an additional \$563 million in support for the 6.2 Applied Research account function in order to ensure workforce and project stability in this critical area of defense research.
- We also recommend that the committee support the Pentagon's stated goal of devoting three percent of the Department's baseline budget to Defense S&T program 6.1 basic research, 6.2 applied research, and 6.3 advanced technology development.

This statement represents the views of the ASME Department of Defense Task Force of ASME's Technical Communities and is not necessarily a position of ASME as a whole.

## House Appropriations Committee Defense Subcommittee

## Witness Disclosure Form

Clause 2(g) of rule XI of the Rules of the House of Representatives requires nongovernmental witnesses to disclose to the Committee the following information. A non-governmental witness is any witness appearing on behalf of himself/herself or on behalf of an organization other than a federal agency, or a state, local or tribal government.

Your Name, Business Address, and Telephone Number: Kendra Sharp School of Mechanical, Industrial, and Manufacturing Engineering Oregon State University 204 Rogers Hall Corvallis, OR 97331 541-737-5246 (office)/814-571-1394 (cell)

1. Are you appearing on behalf of yourself or a non-governmental organization? Please list organization(s) you are representing.

American Society of Mechanical Engineers

2. Have you or any organization you are representing received any Federal grants or contracts (including any subgrants or subcontracts) since October 1, 2007?

Yes

3. If your response to question #2 is "Yes", please list the amount and source (by agency and program) of each grant or contract, and indicate whether the recipient of such grant or contract was you or the organization(s) you are representing.

The following federal contracts/grants were awarded to the Pennsylvania State University (former employer) with Prof. K. Sharp either as Principal Investigator (PI) or co-Principal Investigator. The remaining funding from the National Science Foundation, approximately \$50,000, is currently being transferred to the Oregon State University, again with Sharp as Principal Investigator.

- O August 2007–April 2010, International Research and Education in Engineering (IREE) Supplement to CAREER: Particle Effects in Microfluidics, National Science Foundation (NSF), CBET-0738388, \$31,250, PI 100%.
- May 2004—April 2010, CAREER: Particle Effects in Microfluidics, National Science Foundation (NSF), CTS-0348149, \$400,000, PI 100%.
- Ossilvation of Superiories of Superiories of Superiories (NEU) Supplement to CAREER: Particle Effects in Microfluidies, National Science Foundation (NSF), CTS-0532376, \$6,000, PI 100%.

O January 2006—September 2008, Turbulent Velocity Field Measurements for Propellant Manifolds, National Aeronautics and Space Administration (NASA), \$265,000, PI 50% with R. Santoro, S. Pal for this task.

Signature: Date:

Please bring this original form on the day of your testimony.

Mr. DICKS. Thank you very much. I appreciate your statement. John Boslego, M.D., director of the Vaccine Development Global Program, PATH. I am very glad to have you here today.

THURSDAY, MAY 20, 2010.

## **PATH**

## WITNESS

## JOHN BOSLEGO, M.D., DIRECTOR, VACCINE DEVELOPMENT GLOBAL **PROGRAM**

Dr. Boslego. Good morning, sir. My name is John Boslego and I am the director of the Vaccine Development Global Program at PATH. I would like to begin by thanking Chairman Norman Dicks and Ranking Member Bill Young for the opportunity to testify before the subcommittee. Chairman Dicks understands the mission at PATH, has been a strong supporter of PATH programs.

I speak for all of my colleagues at PATH when I thank him for

his support and key leadership on the issues that are critical to our work. PATH is an international NGO and creates sustainable, culturally relevant solutions enabling communities worldwide to break longstanding cycles of poor health. By collaborating with diverse public and private sector partners, we help provide appropriate health technologies and vital strategies that change the way people think and act. We wish to take this opportunity to recognize the specific and unique areas of expertise that the DOD brings to bear in advancing innovation that ensures people in low resource settings have access to lifesaving interventions and technologies. Through DOD, the U.S. Government is able to apply this core capacity to improving health throughout the world. The global health research efforts of DOD respond to diseases many Americans never see up close, but which military personnel stationed in developing worlds experience, alongside local communities. Medicines, vaccines and diagnostics for health threats that disproportionately affect the developing world are critical for their protection. Health is also an important factor in global stability and security. The heavy burden of disease in developing world hinders economic and social development, which in turn, perpetrates conditions that breed political instability

DOD health research therefore benefits not only the U.S. military but also has the potential to reduce this health burden, by doing so reduce the likelihood of physical conflict. PATH requests of fiscal year 2011 that the subcommittee provide robust support for DOD research and development programs aimed at addressing health challenges, particularly for military malaria vaccine development research, as well as for research at DARPA aimed at developing protective countermeasures and developing health care to military personnel and civilians in remote resource poor and unsta-

ble locations.

More than one-third of the world's population is at risk for malaria, with approximately 250 million cases each year. The most of nearly 1 million annual deaths from malaria are among children in Africa under the age of 5. According to the 2006 Institute of Medicine report, malaria has affected almost all military deployments

since the American Civil War and remains a severe and ongoing threat.

The same report noted that a vaccine would be the best method of averting the threat of malaria, given the likely increasing number of deployments to high-risk areas. Military researchers within the military infectious disease program are at the forefront of efforts to develop the malaria vaccine. One example of DOD's impact in malaria research is the most promising vaccine candidate in existence today. It is called RTSS. Research at Walter Reed contributed to the development of the vaccine candidate in early testing of RTSS created by GlaxoSmithKline was done in collaboration with the U.S. military.

Today thanks to innovative partnership between GSK Bio and PATH, the malaria vaccine initiative works to accelerate development of malaria vaccines and assure their availability and accessibility in the developing world. RTSS is now in a large-scale phase 3 trial, typically the last stage of testing prior to licensure. The U.S. Army is assisting in this trial by supporting one of the field sites in Kenya. Although the efficacy of RTSS in its current formulation is unlikely to prove adequate for military purposes despite its potential benefit to young children in Africa, it has shown that developing a vaccine against malaria is possible and paved the way for other development efforts that could ultimately allow the mili-

tary to vaccinate its men and women against malaria before deploying them to endemic regions.

Unfortunately, DOD's spending on military infectious diseases research in general and specifically on malaria research has been declining for several years from levels that were already comparatively small given the historic impact of malaria on overseas deployments. Current funding levels are nowhere near what is needed to develop urgently needed countermeasures against malaria. PATH requests that the subcommittee reverse this trend and provide the resources needed to develop the necessary tools, including vaccines to protect soldiers, sailors, airmen and Marines from this

deadly and debilitating disease.

Another program making great contributions to research and development is DARPA. DARPA has identified as a priority the development of technologies that can both help the U.S. military and be of use to DOD sponsored humanitarian relief operations. One example is the technology pioneered by DARPA that has led to electrochemical generators of chlorine that may be able to fulfill a community's need for effective disinfectants for water or surfaces by using just salt water and a simple battery source. PATH has partnered with Cascade Designs on a new generation of smart electrochlorinators that has the potential to expand the project initiated by DARPA to broader community reach for both military and civilian benefits.

The device effectively inactivates bacteria, viruses and some protozoa to create safe drinking water. Since the generators can be powered by solar-charged batteries, they are accessible to communities that do not have electricity infrastructure. The costs are significantly less than required for the current large scale community systems, putting this solution within reach of very poor and small communities. The defense threat reduction agency, DTRA, is also

doing groundbreaking work as it investigates innovations in vaccine and chemical reagent thermostabilization and point of care di-

agnostic tests for infectious diseases.

This has positive implications for global health and U.S. military support in low-resource settings. Such technologies will enable rapid pathogen identification in field and threat zones to more rap-

idly enlist target interventions.

In conclusion, in light of the critical role that DOD plays in global health research and development and the fact that the investments in this area have been falling, we respectively request that the subcommittee provide the resources to maintain this important core capacity. We thank you very much for your consideration.

Mr. DICKS. Let me ask you, the Gates Foundation is doing some

significant work on malaria; isn't that correct.

Dr. Boslego. Yes, sir.

Mr. DICKS. Are you involved with that as well?

Dr. Boslego. Yes, we are.

Mr. DICKS. That is what I thought. And you think that DARPA's role in this is constructive?

Dr. Boslego. Yes, sir, very much so. Although DARPA is not working on the malaria piece per se. They are working on some of these newer innovations that would help, in this case, the purification of water.

Mr. DICKS. On Homeland Security, we had some problems initially with vaccines and various other treatments for various things that could happen in that relationship. Has that relationship between Homeland Security and HHS improved or is it still pretty shaky?

Dr. Boslego. I cannot comment on that, sir. I am not familiar with those discussions.

Mr. DICKS. There was a significant problem there. Thank you. Any other questions? Okay. Thank you very much.

[The statement of Dr. Boslego follows:]

# Written Testimony Submitted to the House of Representatives Defense Appropriations Subcommittee Regarding FY 2011 Funding for DOD Research and Development April 15, 2010

PATH appreciates the opportunity to submit written testimony regarding Fiscal Year (FY) 2011 funding for global health research and development to the House Defense Appropriations Subcommittee. PATH is an international nonprofit organization that creates sustainable, culturally relevant solutions, enabling communities worldwide to break longstanding cycles of poor health. By collaborating with diverse public- and private-sector partners, we help provide appropriate health technologies and vital strategies that change the way people think and act.

We wish to take this opportunity to recognize the specific and unique areas of expertise that the Department of Defense (DOD) brings to bear in advancing innovation that ensures that people in low-resource settings have access to life-saving interventions and technologies. Through DOD, the US Government is able to apply this core capacity to improving health throughout the world.

The global health research efforts of DOD respond to diseases many Americans may never see up close, but which military personnel stationed in the developing world experience alongside local communities. Medicines, vaccines, and diagnostics for health threats that disproportionately affect the developing world are critical for their protection. Health is also an important factor in global stability and security. The heavy burden of disease in the developing world hinders economic and social development, which in turn perpetuates conditions that breed political instability. DOD health research therefore benefits not only the US military but also has the potential to reduce this health burden, and by doing so, reduce the likelihood of physical conflict.

PATH requests that in FY 2011, the Subcommittee provide robust support for DOD research and development programs aimed at addressing these health challenges, particularly two important programs. First, we request that the Subcommittee provide increased support for military malaria vaccine development efforts. Second, we request that the Subcommittee support research at the Defense Advanced Research and Projects Agency (DARPA) aimed at delivering health care to military personnel and civilians in remote, resource-poor, and unstable locations. PATH also requests that no funding cuts be made to DOD research and development.

## Malaria and Vaccines

Malaria is a parasitic infection transmitted by mosquitoes. More than one-third of the world's population is at risk of malaria, with approximately 250 million cases occurring every year. Most of the nearly one million annual deaths from malaria are among children in Africa under the age of five. A malaria vaccine is desperately needed to help prevent these deaths. While consistent use of effective insecticides, insecticide-treated nets, and malaria medicines saves lives, eradicating or even significantly reducing the impact of malaria will require additional interventions, including vaccines. Immunization is one of the most effective health interventions available. Just as it was necessary to use vaccines to control polio and measles in the United States, vaccines are needed as part of an effective control strategy for malaria. Furthermore, vaccines are typically the most efficient means of protecting military personnel from disease threats. When troops are deployed, and particularly under combat conditions, compliance with drug regimens or other disease-protection protocols can be difficult, if not impossible. Vaccination, in contrast, can be performed prior to deployment, and allows deployed personnel

to remain focused on mission success, rather than chemoprophylaxis, bed nets, or insecticide application.

## Malaria and the US Military

A 2006 Institute of Medicine (IOM) report\* found that "malaria has affected almost all military deployments since the American Civil War and remains a severe and ongoing threat." For this reason, the military has historically taken an active and leading role in the development of health technologies to protect military personnel from malaria, or to treat them if they become infected with the disease. This work includes a robust, cutting-edge program aimed at developing a highly-efficacious malaria vaccine, suitable for use by military personnel. The aforementioned IOM study noted "the fact that a vaccine would be the best method of averting the threat of malaria given the likely increasing number of deployments to high-risk areas." An effective vaccine would provide unparalleled protection to servicemen and women serving in malaria-endemic countries and regions, and would significantly reduce the impact of noncompliance, drug resistance, and other significant obstacles that currently limit the military's ability to provide protection from malaria. Military researchers within the Military Infectious Diseases Research Program, including the US Army Medical Research Institute of Infectious Diseases, US Naval Medical Research Center, and the Walter Reed Army Institute of Research (WRAIR), are at the forefront of efforts to develop a malaria vaccine.

Research at WRAIR, for example, contributed to the development of the most promising vaccine candidate in existence today, RTS,S. Early testing of RTS,S—created by GlaxoSmithKline Biologicals (GSK Bio)—was done in collaboration with the US military. Today, thanks to an innovative partnership between GSK Bio and the PATH Malaria Vaccine Initiative (MVI)—a PATH program that works to accelerate the development of malaria vaccines and ensure their availability and accessibility in the developing world—RTS,S is now in a large-scale Phase 3 trial, typically the last stage of testing prior to licensure. Although the efficacy of RTS,S is unlikely to prove adequate for military purposes—despite its potential benefit to young children in Africa—it has shown that developing a vaccine against malaria is possible and paved the way for other development efforts that could ultimately allow the military to vaccinate men and women against malaria before deploying them to endemic regions. Since its establishment in 1999, MVI has partnered with the military in a number of malaria vaccine development projects, including the preclinical development of an adenovirus-vectored malaria vaccine candidate developed by GenVec, Inc. that used a modified common cold virus to deliver multiple malaria antigens.

Unfortunately, DOD spending on malaria research has been declining for several years from levels that were already comparatively small given the historic impact of malaria on overseas deployments. PATH requests that the Subcommittee reverse this trend, and provide the resources needed to develop the necessary tools—including vaccines—to protect soldiers, sailors, airmen, and marines from this deadly and debilitating disease threat. This would make possible a continuation of the kind of collaboration—characterized by joint funding—that currently exists between MVI and the US Military Malaria Vaccine Program.

<sup>\*</sup> Battling Malaria - Strengthening the U.S. Military Malaria Vaccine Program. National Academy of Sciences Press, Washington, D.C. 2006

## DARPA

The Defense Advanced Research Projects Agency (DARPA) is DOD's primary research and development component and performs work on the cutting edge of multiple scientific disciplines, providing a wide range of critical new technologies and products for use by the military. DARPA has made and could make additional contributions in one area it has identified as a priority: developing health technologies that can both help the US military, and be of use in DOD-sponsored humanitarian relief operations in regions emerging from conflict. Military personnel operating in developing countries face many of the same challenges to health care delivery as do the residents of those countries: electricity and transportation interruptions that can threaten the integrity of temperature-sensitive medicines and vaccines; lack of access to trained medical personnel and facilities; and an absence of infrastructures and technologies that allow for the rapid manufacture and delivery of medicines and vaccines for the treatment of unexpected infectious disease threats. Increased support for this research would help the United States to more effectively assist developing countries that need vaccines and other basic health technologies, while ensuring that health products are delivered as efficiently as possible.

DARPA's investments in austere healthcare delivery systems—through their focus on disaster medicine in projects such as "Real World," "Rapid Altitude Climatization," and "SAVE II Ventilators"—represent a commitment to interventions that could have positive and profound health implications for populations in low-resource settings. For example, DARPA pioneered technology that has led to electrochemical generators of chlorine that may be able to fulfill a community's needs for effective disinfectants for water or surfaces by using just salt water and a simple battery source, such as a car or motorcycle battery.

The Smart Electrochlorinator provides a chlorine solution used to treat water from a variety of sources, bringing safe water into small-community households. The devices effectively inactivate bacteria, viruses, and some protozoa to create safe drinking water. Since the generators can be powered by solar-charged batteries, they are accessible to communities that do not have an electricity infrastructure. The only resources required are 75 g of table salt and 0.1 kWh per person per year, both potentially renewable. These costs are significantly less than required for the current large-scale community systems, resulting in break-even points that are within reach of very poor, small communities. PATH has partnered with Cascade Designs, Inc. on a new generation of smart electrochlorinator that has the potential to expand the project initiated by DARPA to broader community reach for both military and civilian benefit.

The Defense Threat Reduction Agency (DTRA) is also doing groundbreaking work as it investigates innovations in vaccine and chemical reagent thermo-stabilization and point of care diagnostic tests for infectious diseases that has positive implications for global health and US military support in low-resource settings. Such technologies will enable rapid pathogen identification in the field and threat zone to more rapidly enlist targeted interventions. PATH requests that the Subcommittee maintain funding for the DARPA and DTRA research aimed at developing solutions to these and other health challenges.

## Conclusion

In light of the critical role that at DOD plays in global health research and development, and the fact that investments in this area have been falling, we respectfully request that the Subcommittee provide the resources to maintain this important core capacity. We thank you for your consideration, and hope that you will consider PATH as a resource and partner on this issue.

## **CURRICULUM VITAE**

#### ı. PERSONAL DATA

John William Boslego, MD A. Name:

1800 K St NW, Suite 800 Washington, DC 20006 В. Work Address:

C. Work Telephone: 202.822.0033

D. Email: jboslego@path.org

#### **EDUCATION** H.

School George Washington University School of Medicine Washington, DC	<u><b>Date</b></u> 1975	<u>Degree</u> MD
United State Military Academy West Point, New York	1970	BS

#### PATH EMPLOYMENT HISTORY III.

From - To 2006 - present Title Director, Vaccine Development Global Program 1800 K Street NW, Suite 800 Washington, DC 20006

#### IV. NON-PATH EMPLOYMENT HISTORY

<u>Title</u> Executive Director, Biologics - Clinical Research Merck Research Laboratories, Merck & Co., Inc. West Point, PA	<u>From - To</u> 1999 - 2006
Senior Director, Vaccine Infectious Diseases, Clinical Research Merck Research Laboratories, Merck & Co., Inc. West Point, PA	1997 - 1999
Director, Vaccine Infectious Diseases, Clinical Research Merck Research Laboratories, Merck & Co., Inc. West Point, PA	1995 - 1997
Deputy Director Walter Reed Army Institute of Research Washington, DC	1992 - 1995
Commander	1989 - 1992

**US Army Medical Component** Armed Forces Research Institute of Medical Sciences APO AP 96546 (Bangkok, Thailand)

Infectious Diseases Officer 1982 - 1989 Department of Bacterial Diseases Division of Communicable Diseases and Immunology Walter Reed Army Institute of Research

Assistant Chief, Infectious Diseases Service 1980 - 1982 Walter Reed Army Medical Center Washington, DC

1971

Platoon Leader CO. A, 1<sup>st</sup> BN, 27<sup>th</sup> Infantry 25<sup>th</sup> Infantry Division United States Army

#### ٧. **ACADEMIC EXPERIENCE**

Washington, DC

Title From - To 1980 - 1989 Attending Physician Internal Medical and Infectious Diseases Services 1992 - 1995 Walter Reed Army Medical Center Washington, DC Assistant Professor 1980 - 1995 Department of Medicine Uniformed Services, University of the Health Sciences School of Medicine Bethesda, MD

#### **TRAINING and CERTIFICATION** VI.

<u>Date</u> Advanced Cardiac Life Support Certification: 1987 Advanced Trauma Life Support (Instructor) 1985 American Board of Internal Medicine Diplomate, Subspecialty of Infectious Diseases 1982 Diplomate, Internal Medicine 1978 Chief Resident, Department of Medicine Apr-June 1980 Walter Reed Army Medical Center Apr-May 1978 Washington, DC Fellow, Infectious Diseases 1978 - 1980 Walter Reed Army Medical Center Washington, DC

(Dr. Edmund C. Tramont)

Resident in Medicine Walter Reed Army Medical Center Washington, DC (Dr. Jerry Earll)	1976 - 1978
Rotating Internship Walter Reed Army Medical Center Washington, DC (Dr. Robert Modlin)	1975 - 1976
POCIETY MEMBERSHIPS	

## VII. SOCIETY MEMBERSHIPS

Fellow, Infectious Diseases Society of America	Current
Member, American Society for Microbiology	Current
Member, American Association for the Advancement of Science	Current

## VIII. ACADEMIC AND PROFESSIONAL HONORS

	Legion of Merit, US Army	1995
•	"A" Proficiency Designation in Infectious Diseases from the United States Army Surgeon General	1990
•	Meritorious Service Medals, US Army	1992, 1989
•	Joint Service Commendation Medal, United States Army	1983
•	Army Commendation Medal	1981
•	Expert Field Medical Badge, United States Army	1980
•	King-Kane Obstetrical Society (Scholarship in Ob/Gyn) George Washington University, School of Medicine	1975
•	Army Ranger Tab	1971
•	Army Parachute Badge	1970
•	Distinguished Cadet (top 5% of graduates) United States Military Academy	1970

## IX. PUBLICATIONS AND PATENTS

## **ARTICLES**

Tramont EC, Ciak J, **Boslego J**, McChesney DG, Brinton CC, Zollinger W. "Antigenic Specificity of Antibodies in Vaginal Secretions during Infection with *Neisseria gonorrhoeae*". *J Infect Dis* 1980; 142(1):23-31.

Zollinger WD, **Boslego JW**. "A General Approach to Standardization of the Solid-phase Radioimmunoassay for Quantitation of Class-specific Antibodies". *J Immunol Meth* 1981; 46:129-40.

Tramont EC, Sadoff JC, **Boslego JW**, Ciak J, McChesney D, Brinton CC, Wood S, Takafuji E. "Gonococcal Pilus Vaccine: Studies of Antigenicity and Inhibition of Attachment".

McChesney D, Tramont EC, **Boslego JW**, Ciak J, Sadoff J, Brinton CC. "Genital Antibody Response to a Parenteral Gonococcal Pilus Vaccine". *Infect Immun* 1982; 36(3):1006-12.

Boslego JW. "Nosocomial Pneumonia". J Nosocomial Inf 1984; 1:17-20.

Zollinger WD, **Boslego JW**, Frasch CE, Froholm LO. "Safety of Vaccines Containing Meningococcal Group B Polysaccharide". *Lancet* 1984; 2:166.

Tramont EC, Boslego JW. "Pilus Vaccines". Vaccine 1985; 3:3-10.

Zollinger WD, **Boslego JW**, Brandt B, Moran EE, Ray J. "Safety and Antigenicity Studies of a Polyvalent Meningococcal Protein-polysaccharide Vaccine". *J Microbiol* 1986; 52:225-8.

Hicks CB, Boslego JW, Brandt B.

"Evidence of Serum Antibodies to Neisseria gonorrhoeae Before Gonococcal Infection". J Infect Dis 1987; 155(6):1276-81.

**Boslego JW**, Tramont EC, Takafuji ET, Diniega BM, Mitchell BS, Small JW, Khan WN, Stein DC. "Effect of Spectinomycin Use on the Prevalence of Spectinomycin-resistant and of Penicillinase-producing *Neisseria gonorrhoeae*". *N Engl J Med* 1987; 317(5):272-8.

Swanson J, Robbins K, Barrera O, Corwin D, **Boslego J**, Ciak J, Blake M, Koomey JM. "Gonococcal Pilin Variants in Experimental Gonorrhea". *J Exp Med* 1987; 165:1344-57.

**Boslego JW**, Hicks CB, Greenup R, Thomas RJ, Weiner HA, Ciak J, Tramont EC. "A Prospective, Randomized Trial of Ofloxacin vs Doxycycline in the Treatment of Uncomplicated Male Urethritis". Sex Trans Dis 1988; 15(4):186-91.

**Boslego JW**, Tramont EC. "Spectinomycin and Resistant *Neisseria gonorrhoeae"*. *N Engl J Med* 1988; 318(5):325-6.

McChesney DG, **Boslego JW**, Khan WN. "Spectinomycin Disk Zone Diameter as a Predictor of Outcome in the Clinical Treatment of Gonorrhea".

Antimicrob Agents Chemother 1988: 32(5):775-6.

Swanson J, Barrera O, Sola J, Boslego J.

"Expression of Outer Membrane Protein II by Gonococci in Experimental Gonorrhea". J Exp Med 1988; 168:2121-2129.

Cruz C, Pavez, G, Aguilar E, Grawe L, Cam J, Mendez F, Garcia J, Ruiz S, Vicent P, Canepa I, Martinez M, Boslego J, Zollinger W, Arthur J, Caugant D. "Serotype-specific Outbreak of Group B Meningococcal Disease in Iquique, Chile". Epidemiology Infect 1990; 105:119-126.

Johnson SC, Chung RCY, Deal CD, **Boslego JW**, Sadoff, JC, Wood SW, Brinton CC, Tramont EC. "Human Immunization with Pgh3-2 Gonococcal Pilus Results in Cross-reactive Antibody to the Cyanogen Bromide Fragment-2 of Pilin". *J Infect Dis* 1991; 163:128-34.

**Boslego JW**, Tramont EC, Chung RC, McChesney DG, Ciak J, Sadoff JC, Piziak MV, Brown JD, Brinton CC, Wood, SW, and Ryan, JR.
"Efficacy Trial of Parenteral Gonococcal Pilus Vaccine in Men".
Vaccine 1991; 9:154-62.

Schneider H, Griffiss JM, **Boslego JW**, Hitchcock PJ, Zahos KM, Apicella MA. "Expression of Paragloboside-like Lipooligosaccharides May be a Necessary Component of Gonococcal Pathogenesis in Men". *J Exp Med* 1991; 174:1601-5.

Zollinger WD, **Boslego J**, Moran E, Garcia J, Cruz C, Ruiz S, Brandt B, Martinez M, Arthur J, Underwood P, Hankins W, Mays J, Gilly J, and the Chilean National Committee for Meningococcal Disease. "Meningococcal Serogroup B Vaccine Protection Trial and Follow-up studies in Chile". NIPH Annals 1991; 14(2):211-13.

Shanks GD, **Boslego JW**. "Treatment of Malaria Acquired in Southeast Asia". *Military Medicine* 1992; 157(1):4-6.

Van De Verg LL, Herrington DA, **Boslego J**, Lindberg AA, Levine MM. "Age-specific Prevalence of Serum Antibodies to the Invasion Plasmid and Lipopolysaccharide Antigens of *Shigella Species* in Chilean and North American Populations". *J Inf Dis* 1992; 166:158-61.

Clendennen TE, Echeverria P, Saengeur S, Kees ES, **Boslego JW**, Wignall FS. "Antibiotic Susceptibility Survey of *Neisseria gonorrhoeae* in Thailand". *Antimicrob Agents Chemother* 1992; 36(8):1682-87.

Innis BL, Snitbhan R, Kunasol P, Laorakpongse T, Poopatanakool W, Suntayakorn S, Suknantapong T, Safary A, **Boslego JW**.

"Field Efficacy Trial of Inactivated Hepatitis A Vaccine Among Children in Thailand" (an extended abstract). Vaccine 1992; 10(suppl 1):S159.

Russell RG, Wasserman SS, O'Donnoghue JM, Taylor DN, **Boslego J**, Moreno JG, Hopkins RJ, Detolla LJ, Morris Jr JG. "Serologic Response to *Helicobacter pylori* Among Children and Teenagers in Northern Chile".

Am J Trop Med Hyg 1993; 49(2):189-91.

Brown AE, Singharaj P, Webster HK, Pipithkul J, Gordan DM, **Boslego JW**, Krinchai K, Suarchawaratana P, Wongsrichanalai C, Ballou WR, Permpanich B, Kain KC, Hollingdale MR, Wittes J, Que JU, Gross M, Cryz SJ, Sadoff JC.

"Safety, Immunogenicity and Limited Efficacy Study of a Recombinant *Plasmodium falciparum* Circumsporozoite Vaccine in Thai Soldiers". *Vaccine* 1994; 12(2): 102-8.

Innis BL, Snitbhan R, Kunasol P, Laorakpongse T, Poopatanakool W, Kozik CA, Suntayakorn S, Suknuntapong T, Safary A, Tang DB, **Boslego JW**. "Protection Against Hepatitis A by an Inactivated Vaccine". *JAMA* 1994: 271(17):1328-1334.

Schneider H, Cross AS, Kuschner RA, Taylor DN, Sadoff JC, **Boslego JW**, Deal CD. "Experimental Human Gonococcal Urethritis: 250 *Neisseria gonorrhoeae* MS11mkC are Infective". *J Infect Dis* 1995; 172:180-5.

Ramsey KH, Schneider H, Cross AS, **Boslego JW**, Hoover DL, Staley TL, Kuschner RA, Deal CD. "Inflammatory Cytokines Produced in Response to Experimental Human Gonorrhea". *J Infect Dis* 1995; 172:186-91.

**Boslego J**, Garcia J, Cruz C, Zollinger W, Brandt B, Ruiz, S, Martinez J, Arthur J, Underwood P, Silva W, Moran E, Hankins W, Gilly J, Mays J and the Chilean National Committee for Meningococcal Disease. "Efficacy, Safety, and Immunogenicity of a Meningococcal Group B (15:P1.3) Outer Membrane Protein Vaccine in Iquique, Chile". *Vaccine* 1995; 13(9):821-9.

Nolan T; Hogg G, Darcy M-A, Skeljo M, Carlin J. **Boslego J.** "A Combined Liquid Hib (PRP-OMPC) Hepatitis B, Diphtheria, Tetanus and Whole-cell Pertussis Vaccine: Controlled Studies of Immunogenicity and Reactogenicity" Vaccine 2001; 19;2127-2137.

Markey P, Krause V, Boslego, JW, Coplan PM, Dargan JM, Kaplan KM.

"The Effectiveness of Haemophilus influenzae b Conjugate Vaccines in a High-risk Population Measured Using Immunization Register Data"

Epidemiology and Infection 2001; 126:31-36.

Schmidt KA, Schneider H, Lindstrom JA, Boslego, JW, Warren RA, Van De Verg L, Deal CD, McClain JB. Griffiss JM.

"Experimental Gonococcal Urethritis and Reinfection with Homologous Gonococci in Male Volunteers". Sexually Transmitted Diseases 2001; 28(10):555-564.

Kaplan KM, Rusche SA, Hassan DL, Bottenfield G, Guerra FA, Guerrero J, Keyserling H, Felicione E, Hesley TM, Boslego JW.

"Post-licensure Comparative Study of Unusual High-pitched Crying and Prolonged Crying Following COMVAX™ and Placebo versus Pedvax HIB™ and RECOMBIVAX HB in Healthy Infants" Vaccine 2002; 21:181-187.

Liese JG, Stojanov S, Berut F, Minini P, Harzer E, Jow S, Schödel F, Boslego J, Hoffenbach A, Kronwitter A, Belohradksy, BH, Munich Vaccine Study Group.

"Large Scale Safety Study of a Liquid Hexavalent Vaccine (D-T-acP-IPV-RVP~T-HBs) Administered at 2, 4, and 6 and 12-14 Months of Age". Vaccine 2002; 21:448-454.

Halperin S, Langley J, Hesley T, Zappacosta P, Radley D, Smith B, Hoffenbach A, Boslego J, Silber J. "Safety and Immunogenicity of Two Formulations of a Hexavalent Diphtheria-Tetanus-Acellular Pertussis-Inactivated Poliovirus-Haemophilus influenzae b Conjugate-Hepatitis B Vaccine in 15 to 18 Month-old Children

Human Vaccines 2005; 1(6): 245-250.

Vesikari T, Matson DO, Dennehy P, Van Damme P, Santosham M, Rodriguez Z, Dallas MJ, Heyse JF, Goveia MG, Black SB, Shinefield HR, Christie CDC, Ylitalo S, Itzler RF, Coia ML, Onorato MT, Adeyi BA, Marshall GS, Gothefors L, Campens D, Karvonen A, Watt JP, O'Brien KL, DiNubile MJ, Clark HF, Boslego JW, Offit PA, Heaton PM, for the Rotavirus Efficacy and Safety Trial (REST) Study Team. "Safety and Efficacy of Pentavalent Human-Bovine (WC3) Reassortant Rotavirus Vaccine". N Engl J Med 2006; 354:23-33.

Block SL, Vesikari T, Goveia M, Rivers S, Adeyi BA, Dallas MJ, Bauder J, Boslego JW, Heaton PM. "Efficacy, immunogenicity, and safety of a pentavalent human-bovine (WC3) reassortant rotavirus vaccine at the end of shelf life". Pediatrics 2007; 119:11-18.

Rodriguez Z, Goveia M, Stek J, Dallas M, Boslego J, DiNubile M, Heaton P.

"Concomitant Use of an Oral Live Pentavalent Human-Bovine (WC3) Reassortant Rotavirus Vaccine with Licensed Parenteral Pediatric Vaccines in the United States". Pediatric Infectious Disease Journal 2007; 26:221-227.

The Future II Study Group.

"Quadrivalent Vaccine against Human Papillomavirus to Prevent High-Grade Cervical Lesions." N Engl J Med 2007; 356:1915-1927.

Garland S, Hernandez-Avila M, Wheeler C, Perez G, Harper D, Leodolter S, Tang G, Ferris D, Steben

M, Bryan J, Taddeo F, Railkar R, Esser M, Sings H, Nelson M, **Boslego J**, Sattler C, Barr E, Koutsky L, for the FUTURE I Investigators.

"Quadrivalent Vaccine against Human Papillomavirus to Prevent Anogenital Diseases." N Engl J Med 2007; 356:1928-1943.

The Future II Study Group,

"Effect of Prophylactic Human Papillomavirus L1 Virus-like-particle Vaccine on Risk of Cervical Intraepithelial Neoplasia Grade 2, Grade 3, and Adenocarcinoma *in situ*: A Combined Analysis of Four Randomized Clinical Trials." *Lancet* 2007; 369:1861-1868.

Joura EA, Leodolter S, Hernandez-Avila M, Wheeler CM, Perez G, Koutsky L, Garland SM, Harper DM, Tang GWK, Ferris DG, Steben M, Jones RW, Bryan J, Taddeo FJ, Bautista OM, Esser MT, Sings HL, Nelson M, **Boslego J**, Sattler C, Barr E, Paavonen J.

"Efficacy of a Quadrivalent Prophylactic Human Papillomavirus (Types 6/11/16/18) L1 Virus-like-particle Vaccine Against High-grade Vulval and Vaginal Lesions: A combined Analysis of Three Randomized Clinical Trials."

Lancet 2007; 369:1693-1702.

Steinhoff MC for the Pneumococcal Vaccine Animal Model Consensus Group. "Animal Models for Protein Pneumococcal Vaccine Evaluation: A Summary." Vaccine 2007; 25:2465-2470.

WHO Expert Consultation on Serotype Composition of Pneumococcal Conjugate Vaccines for Use in Resource-poor Developing Countries, 26 – 27 October 2006, Geneva. Meeting report. *Vaccine* 2007; 25:6557-6564.

Goveia MG, Rodriguez ZM, Dallas MJ, Itzler RF, **Boslego JW**, Heaton PM, DiNubile MJ, for the REST Study Team.

"Safety and Efficacy of the Pentavalent Human-Bovine (WC3) Reassortant Rotavirus Vaccine in Healthy Premature Infants." *Pediatric Infectious Disease Journal* 2007; 26:1099-1104.

The Future II Study Group.

"Prophylactic Efficacy of a Quadrivalent Human Papillomavirus (HPV) Vaccine in Women with Virological Evidence of HPV Infection."

J Infect Dis 2007; 196:1438-1446.

Paavonen J, The Future II Study Group.

"Baseline Demographic Characteristics of Subjects Enrolled in International Quadrivalent HPV (types 6/11/16/18) Vaccine Clinical Trials." CMRO 2008; 24:1623-1634.

### Boslego J

"New Vaccine Technologies: Promising Advances May Save More Lives". *Global HealthLink* 2008; 148: 12-13 16.

Halperin SA, Tapiero B, Diaz-Mitoma F, Law BJ, Hoffenbach A, Zappacosta PS, Radley D, McCarson BJ, Martin JC, Brackett LE, **Boslego JW**, Hesley TM, Bhuyan PK, Silber JL.

"Safety and Immunogenicity of a Hexavalent Diphtheria-Tetanus-Acellular Pertussis-Inactivated Poliovirus-Haemophilus influenzae b Conjugate-Hepatitis B Vaccine at 2, 3, 4 and 12 to 14 Months of Age."

Vaccine 2009; 27:2540-2547.

Feavers I, Knezevic I, Powell M, Griffiths E, on behalf of the WHO Consultation on Serological Criteria for Evaluation and Licensing of New Pneumococcal Vaccines.

"Challenges in the Evaluation and Licensing of New Pneumococcal Vaccines, 7 – 8 July 2008, Ottawa,

Canada."

Vaccine 2009; 27:3681-3688.

Bhandari N, Sharma P, Kumar T, Rongsen-Chandola, T, Appaiahgari MB, Mishra A, Singh S, Vrati S, and The Rotavirus Development Group.

"A Dose Escalation Safety and Immunogenicity Study of Live Attenuated Oral Rotavirus Vaccine 116E in Infants: A Randomized, Double Blind Placebo Controlled Trial."

JID 2009: 200: 421-429.

Van Damme P, Minervini G, Liss CL, McCarson B, Vesikari T, **Boslego JW**, Bhuyan PK. "Safety, Tolerability, and Immunogenicity of a Recombinant Hepatitis B Vaccine Manufactured by a Modified Process in Healthy Young Adults." *Human Vaccines* 2009; 5(2): 92-97.

Manoff S, Liss C, Caulfield MJ, Marchese R, Silber J, **Boslego J**, Romero-Steiner S, Rajam G, Glass N, Whitney CG, Carlone GM for the Pneumococcal Revaccination Study Group. "Revaccination with 23-valent Pneumococcal Polysaccharide Vaccine Induces Elevated and Persistent Functional Antibody Responses in Adults > 65 Years of Age". *JID* 201; 525-533.

Diaz-Mitoma F, Halperin SA, Tapiero B, Law BJ, Hoffenbach A, Zappacosta PS, Radley D, McCarson BJ, Martin JC, Brackett LE, **Boslego JW**, Hesley TM, Bhuyan PK, Silber JL. "Safety and Immunogenicity of Three Different Fomulations of a Liquid Hexavalent Diptheria-Tetanus-Acellular Pertussis-Inactivated Poliovirus-*Haemophilus influenzae* b Conjugate-Hepatitis B Vaccine at 2, 4, 6 and 12 to 14 Months of Age. Manuscript in progress.

## **CHAPTERS**

**Boslego JW**. Book Review: <u>Immunoserology in the Diagnosis of Infectious Diseases</u>. Mil Med 1980; 145:328.

Boslego JW. "Bacterial Meningitis".

Conn's Current Therapy, Rakel R (ed). WB Saunders Co., Philadelphia, PA, 1985: 42-7.

Tramont EC, **Boslego JW**. "Pathogenesis and Management of Gonorrhea". <u>Urogenital Infections</u>, Bondi A et al (eds). Plenum Press, New York 1987; 117-126.

Tramont EC, **Boslego, JW**, Chung R, McChesney D, Ciak J, Sadoff, J, Piziak M, Brinton CC, Wood S, Bryan J. "Gonococcal Pilus Vaccine". <u>Bacterial Vaccines</u>, Robbins JB, Schneerson R, Klein D, Sadoff J, Hardegree MC (eds). Prager Publishers, New York 1987; 176-186.

Zollinger WD, **Boslego J**, Moran E, Brandt B, Collins H, Mandrell R, Altiere P, Berman S. "Bactericidal Antibody Response to a Polyvalent Meningococcal Protein-polysaccharide Vaccine". <u>Bacterial Vaccines</u>, Robbins JB, Schneerson R, Klein D, Sadoff J, Hardegree MC (eds). Prager Publishers, New York 1987; 245-261.

Brandt BL, Griffiss JM, Broud DD, **Boslego JW**. "Tetravalent Meningococcal Polysaccharide Vaccine: Relationship of Dose to Immunogenicity and Reactogenicity in Young Adults". <u>Gonococci and Meningococci</u>, Poolman JT et al (eds). Kluwer Academic Publishers, Dordrecht 1988; 33-37.

Zollinger WD, **Boslego J**, Froholm LO, Ray JS, Moran EE, Brandt BL. "Human Bactericidal Antibody Response to Meningococcal Outer Membrane Protein Vaccines". <u>Gonococci and Meningococci</u>, Poolman JT et al (eds). Kluwer Academic Publishers, Dordrecht 1988; 209-217.

Hitchcock PJ, **Boslego JW**, Joiner KA, Robinson EN. "Analyses of the Immunoaccessibility of H8 Antigen and of the Functionality of H8 Specific Monoclonal Antibody". <u>Gonococci and Meningococci</u>, Poolman JT et al (eds). Kluwer Academic Publishers, Dordrecht 1988; 543-52.

**Boslego JW**, Deal CD. "Gonorrhea Vaccines". <u>Vaccines and Immunotherapy</u>, Cryz SJ (ed). Pergamon Press, Inc. New York 1991; 211-24.

Tramont EC, **Boslego JW**. "Neisseria gonorrhoeae". <u>Infectious Diseases</u>, Gorbach SL, Bartlett JG, and Blacklow NR (eds). WB Saunders Company, Philadelphia 1992; 1443-1452.

**Boslego JW**, Tramont EC. "Neisseria meningitidis". Infectious Diseases, Gorbach SL, Bartlett JG, and Blacklow NR (eds). WB Saunders Company, Philadelphia 1992; 1452-1458.

Zollinger WD, **Boslego J**. "Immunologic Methods for the Diagnosis of Infections by Gram-negative Cocci". <u>Manual of Clinical Laboratory Immunology</u>, 4<sup>th</sup> Edition. Rose NR, Conway de Marcario E, Fahey JL, Friedman H, and Penn GM (eds). American Society for Microbiology, Washington, DC, 1992; 440-51.

Lawrence DN, Goldenthal KL, **Boslego JW**, Chandler DKF, LaMontagne JR. "Public Health Implications of Emerging Vaccine Technologies". <u>Vaccine Design: The Subunit and Adjuvant Approach</u>. Powell MF and Newman MJ (eds). Plenum Press, New York 1995; 43-60.

Zollinger, WD, **Boslego, J**. "Immunologic Methods for Diagnosis of Infections by Gram-negative Cocci". <u>Manual of Clinical Laboratory Immunology,</u> 5<sup>th</sup> Edition. Rose NR, Conway de Macario E, Folds JD, Lane HC, Nakamura RM (eds). ASM Press, Washington, DC, 1997; 473-83.

Tramont EC, **Boslego JW**. "Neisseria gonorrhoeae". <u>Infectious Diseases</u>; 2<sup>nd</sup> Edition. Gorbach SL, Bartlett JG, and Blacklow NR (eds). WB Saunders Company, Philadelphia, PA, 1998; 1758-1768.

Boslego JW, Tramont EC. "Neisseria meningitidis". <u>Infectious Diseases</u>; 2<sup>nd</sup> Edition. Gorbach SL, Bartlett JG, and Blacklow NR (eds). WB Saunders Company, Philadelphia, PA, 1998; 1769-1775.

**Boslego J**, Liu X, Frazer IH. "Vaccines Against Human Papillomavirus Infection". New Generation Vaccines; 3<sup>rd</sup> Edition. Levine MM, et al (eds). Marcel Dekker, Inc., New York, 2004: 977-87.

Paton JC, **Boslego JW**. "Protein Vaccines". <u>Pneumococcal Vaccines: the Impact of Conjugate Vaccines</u>. Siber GR, Klugman KP, and Mäkelä, PH (eds). ASM Press, Washington, DC, 2008; 421-435.

## **ABSTRACTS**

Tramont EC, **Boslego J**, Sadoff J, Zollinger W, Lobik A, Bryan J, Brinton C. Safety and immunogenicity study of gonococcal pilus vaccine (Abstract No. 505). The 19<sup>th</sup> Interscience Conference on Antimicrobial Agents and Chemotherapy (ICAAC), Washington, DC, American Society for Microbiology, 1979.

Tramont EC, Ciak J, McChesney D, **Boslego J**, Brinton C. Cross reactivity of gonococcal pill as determined by inhibition of epithelial cell attachment (Abstract No. 504). The 19<sup>th</sup> Interscience Conference on Antimicrobial Agents and Chemotherapy (ICAAC), Washington, DC, American Society for Microbiology, 1979.

**Boslego J**, McChesney D, Sadoff J, Ciak J, Tramont E. Human genital secretion antibody response to a gonococcal pilus vaccine (Abstract No. 420). The 20<sup>th</sup> Interscience Conference on Antimicrobial Agents and Chemotherapy (ICAAC), Washington, DC, American Society for Microbiology, 1980.

Tramont EC, Ciak J, McChesney D, **Boslego J**, Brinton CC. Inhibition of attachment of *N. gonorrhoeae* by antipilus antibodies induced by pilus vaccines (abstract). The 3<sup>rd</sup> International Meeting on Sexually Transmitted Disease, Antwerp, Belgium, 1980.

Tramont EC, McChesney DG, **Boslego JW**, Ciak J, Sadoff J, Brinton CC. Induction of local genital 11S antibody by a parenteral gonococcal vaccine (abstract). In: Clinical Research. Thorofare, NJ: American Federation of Clinical Research, 1981.

McChesney D, Woodbury D, **Boslego J**, Ciak J, Tramont E, Brinton C. Cross-reactivity of human genital antibodies from volunteers vaccinated with gonococcal pilus vaccine Pgh 3-2 (Abstract No. E65). The 81<sup>st</sup> Annual Meeting of the American Society for Microbiology (ASM), Washington, DC: American Society for Microbiology, 1981.

**Boslego, J**, Chung R, Sadoff J, McChesney D, Piziak M, Ciak J, Brown J, Caldwell W. Berliner D, Seitter G, Brinton C, Tramont EC. Efficacy trial of the purified gonococcal pilus vaccine (Abstract No. 294). The 24<sup>th</sup> Interscience Conference on Antimicrobial Agents and Chemotherapy (ICAAC), Washington, DC: American Society for Microbiology, 1984.

McChesney D, Chung R, **Boslego J**, Ciak J, Tramont EC, Brinton C. Cross-reactive pilus antibody levels in gonococcal pilus vaccine failures (Abstract No. E16). The 85<sup>th</sup> Annual Meeting of the American Society for Microbiology (ASM), Washington, DC: American Society for Microbiology, 1985.

Kahn WN, Piziak MV, Ahmad S, Leavy D, **Boslego JW**, Rodriguez WJ, Chung R, Tramont EC. Antibiotic susceptibility of *Neisseria gonorrhoeae* and PPNG isolated in the Republic of Korea and U.S.A. (Abstract). The 6<sup>th</sup> International Society for STD Research, Brighton, England, 1985.

McChesney D, **Boslego J**, Acebal M, Tramont EC. *In Vitro* susceptibility of spectinomycin resistant *N. Gonorrhoeae* to ofloxacin (Abstract No. A19). The 86<sup>th</sup> Meeting of the American Society for Microbiology (ASM), Washington, DC, American Society for Microbiology, 1986.

Chung R, Liu C, **Boslego J**, Tramont EC, Wood S, Brinton C. Volunteers protected against gonorrhea by a single pilus vaccine lack antibody to a proposed common binding domain (Abstract No. B5). The 86<sup>th</sup> Meeting of the American Society for Microbiology, 1986.

**Boslego J**, Hicks C, Greenup R, Thomas R, Weiner H, Ciak J. Tramont E. Comparative trial of ofloxacin versus doxycycline for the treatment of acute urethritis in males (Abstract No. 243). The 26<sup>th</sup> Interscience Conference on Antimicrobial Agents and Chemotherapy (ICAAC), Washington, DC, American Society for Microbiology, 1986.

**Boslego J**, Tramont EC, Takafuji E, Leary D, Ahmed S, Kahn W. Emergence of spectinomycin-resistant *Neisseria gonorrhoeae* (abstract). In: Clinical Research. Thorofare, NJ: American Federation of Clinical Research, 1986.

Zollinger WD, **Boslego J**, Froholm O, Moran EE, Ray JS, Brandt BB. Human antibody response to meningococcal outer membrane protein vaccines (Abstract I-41). The 5<sup>th</sup> International Pathogenic *Neisseria* Conference. Noordwijkerhout, The Netherlands, 1986.

Mandrell R, Sugai J, **Boslego J**, Chung R, Rice P, Griffiss JM. Human immune response to monoclonal antibody-defined epitopes on lipooligosaccharides of *Neisseria gonorrhoeae* (Abstract IV-95). The 5<sup>th</sup> International Pathogenic *Neisseria* Conference. Noordwijkerhout, The Netherlands, 1986.

Swanson J, Bergstrom S, **Boslego J**, Koomey M. Gene conversion accounts for pilin structural changes and for reversible pilation "phase" changes in gonococci *in vitro* and *in vivo* (Abstract II-63). The 5<sup>th</sup> International Pathogenic *Neisseria* Conference. Noordwijkerhout, The Netherlands, 1986.

Brandt BL, Griffiss JM, Broud DD, **Boslego JW**. Tetravalent meningococcal polysaccharide vaccine: relationship of dose to immunogenicity in young adults (Abstract I-6). The 5<sup>th</sup> International Pathogenic *Neisserai* Conference Noordwijkerhout. The Netherlands. 1986.

Schneider H, **Boslego JW**, Apicella MA, Hammack CA, Mandrell RE, Griffiss JM. *Neisseria gonorrhoeae* that cause urethral disease are clonal variants that share membrane glycolipids with human erythrocytes. The 28<sup>th</sup> Interscience Conference on Antimicrobial Agents and Chemotherapy (ICAAC), Washington, DC, American Society for Microbiology, 1988.

Hicks C, Lennox L, Southmayd L, Goerss M, Gilreath C, Michael R, **Boslego J**, Tramont E. Clinical efficacy trial comparing an enzyme immunoassay to gram stain and culture for the diagnosis of urethritis in men. The 28<sup>th</sup> Interscience Conference on Antimicrobial Agents and Chemotherapy (ICAAC), Washington, DC, American Society for Microbiology, 1988.

Van De Verg LL, Warren RL, Skillman D, Kenner J, Schmidt KA, Schneider H, **Boslego JW**. Antibody and cytokine production in human male volunteers infected with *Neisseria gonorrhoeae*. The 8<sup>th</sup> International Congress of Mucosal Immunology, San Diego, 1995.

Schmidt KA, Schainker, R, Balignot B, Lindstrom J, **Boslego J**, Van De Verg L, Warren R, Schneider H. Does urine pH affect experimental gonorrhea infections in male volunteers? Abstract Book, The General Meeting of the American Society for Microbiology, Washington, DC, American Society for Microbiology. 1996.

Schneider H, Lindstrom J, Schmidt KA, **Boslego JW**, Warren R, Van De Verg L. Does an experimental gonococcal infection protect human volunteers from subsequent reinfection? The 10<sup>th</sup> International Pathogenic *Neisseria* Conference, Abstract Book, Baltimore, MD, 1996.

Schmidt KA, Deal CD, Lindstrom J, **Boslego JW**, Van De Verg L, Warren R, Kwan M, Thattassery E, Schneider H. Opacity protein expression by organisms recovered from volunteers infected with transparent *Neisseria gonorrhoeae* MS11mkC. The 10<sup>th</sup> International Pathogenic *Neisseria* Conference, Abstract Book, Baltimore, MD, 1996.

West DJ, **Boslego JW**, Mendelman PM, Reisinger K, Daum R, Keyserling H. Concurrent administration of routine pediatric vaccines with COMVAX™ [Haemophilus b conjugate (meningococcal protein conjugate) and hepatitis B (recombinant) vaccine]. Pediatric Research 1997; 41(4):133A, Abstract No. 785

Fabre P, **Boslego J**, Wiens B, Bailleuz F, Blondea C, Mallete E. Immunogenicity of the fourth dose of a hexavalent fully liquid acellular pertussis combination vaccine given to infants at 12 to 14 months of age. Abstract Book, The 16<sup>th</sup> Annual Meeting of the European Society for Paediatric infectious Diseases (ESPID), Slovenia, 1998.

Clements-Mann ML, Eichelberger M, **Boslego JW**, Harro C, Evans RK, Ulmer JB, Friedman A, Chan ISF, Liu M, Donnelly JJ. Safety and immunogenicity of influenza hemagglutinin DNA vaccine alone or with aluminum adjuvant in adult volunteers. Abstract Book, The 17<sup>th</sup> Annual Meeting of the American Society for Virology, Vancouver, Canada, 1998.

Thaler S, Clements-Mann ML, Donnelly J, Eichelberger M, Chan I, Firedman A, **Boslego J.** Preliminary report on the safety and immunogenicity of Influenze hemagglutinin DNA vaccine alone or with aluminum adjuvant in adult volunteers. International Symposium on Influence and Other Respiratory Viruses, Maui, Hawaii, 1998.

Donnelly J, Ulmer J, Liu M, Evans R, **Boslego J**, Hastings J, Chan I, Mazurik, C, Thaler S, Clements-Mann ML, Eichelberger M, Harro C. Adjuvants for DNA vaccines. Abstract Book, Keystone Symposium on DNA Vaccines, Snowbird, Utah, 1999.

Stojanov S, Liese JG, Berut F, Minimi P, Harzer E, Jow S, Schödel F, **Boslego J**, Hoeffenbach A, Kronwitter A, Belohradsky bH. Safety profile of a liquid hexavalent vaccine given at 2, 4, 6 and 12 to 14 months of age. Abstract Book, The 37<sup>th</sup> Annual Meeting of the Infectious Diseases Society of America, Abstract No. 656, Philadelphia, PA, 1999.

Lagos R, del Rio R, Fabre P, Pines E, Barrand M. Salomon H, Chryssomalis G, Schödel F; **Boslego J** Hoffenbach A, Levine M. Safety and immunogenicity of 3 consistency lots of a liquid hexavalent vaccine given at 2, 4, 6 months of age. Abstract Book, The 37<sup>th</sup> Annual Meeting of the Infectious Diseases Society of America, Abstract No. 663, Philadelphia, PA, 1999.

Barr E, **Boslego J**, Chiacchierini L, Jansen K. HPV Vaccine: Where does it stand? The 7<sup>th</sup> International Society of Travel Medicine Congress (ISTM), Innsbruck, Austria, 2001.

**Boslego J.** Clinical trials of HPV and cervical cancer vaccines (Abstract No. 5.4). Proceedings of the 4<sup>th</sup> Global Vaccine Research Forum, Seoul, Korea, July 2003.

**Boslego J**. CSL – Investigational Pentavalent Human-Bovine Rotavirus Vaccine. Program and Abstracts Book, The 9<sup>th</sup> National Immunisation/1st PHAA Asia Pacific Vaccine Preventable Diseases Conference, Queensland, Australia, August 2004.

**Boslego J**. CSL – An Investigational Oka/Merck Varicella-Zoster Virus (VZV) Vaccine for the Attenuation or Prevention of Herpes Zoster (HZ) and Postherpetic Neuralgia (PHN). Program and Abstracts Book, The 9<sup>th</sup> National Immunisation/1st PHAA Asia Pacific Vaccine Preventable Diseases Conference, Queensland, Australia, August 2004.

Block SL, Goveia MG, Rivers S, Adeyi B, Dallas MJ, **Boslego J**, Heaton P. Efficacy, Immunogenicity, and Safety of a Polyvalent Rotavirus Vaccine (RotaTeq™) at Expiry Potency in Healthy Infants. Abstract Book, 39<sup>th</sup> National Immunization Conference, Washington, DC, March 2005.

Vesikari T, Matson D, Van Damme P, Heyse J, Dallas M, Goveia M, Black S, Shinefield H, Christie C, Rodriguez Z, **Boslego J**, Dennehy P, Marshall G, Gothefors L, Miller J, Campens D, and Heaton P for the REST Study Team. Incidence of Intussusception with the Pentavalent (Human-Bovine) Reassortant Rotavirus Vaccine (PRV) is Similar to Placebo. 23<sup>rd</sup> Annual Meeting of the European Society for Paediatric Infectious Diseases: Valencia, Spain; May 18-20, 2005.

Vesikari T, Matson D, Dennehy P, Santosham M, Rodriguez Z, Goveia M, Dallas M, Adeyi B, **Boslego** J, Heyse J, Miller J, Digilio L, and Heaton P for the REST Study Team. Protection Against Rotavirus Gastroenteritis of Multiple Serotypes by a Pentavalent (Human-Bovine) Reassortant Rotavirus Vaccine (PRV). 23<sup>rd</sup> Annual Meeting of the European Society for Paediatric Infectious Diseases: Valencia, Spain; May 18-20, 2005.

**Boslego J.** New Immunotherapies – A Global Approach. Program Book, BIO 2005 Annual International Convention, Philadelphia, PA, June 2005.

**Boslego J.** New, Innovative Adolescent Vaccines Create Immunization Opportunities. Program Book, BIO 2005 Annual International Convention, Philadelphia, PA, June 2005.

Rodriguez Z, Goveia M, Stek J, Dallas M, **Boslego J**, DiNubile M, Heaton P. Efficacy of a Pentavalent Human-Bovine (WC3) Reassortant Rotavirus Vaccine when Administered Concomitantly with Licensed Pediatric Vaccines. 43rd Annual Meeting of the Infectious Disease Society of America (IDSA), San Francisco, CA, October 2005.

Goveia M, Hastings P, Rodriguez Z, Dallas M, **Boslego J**, Heaton P. Safety and Efficacy of a Pentavalent Human-Bovine (WC3) Reassortant Rotavirus Vaccine (RotaTeq™) in Premature Infants. 40th National Immunization Conference, Atlanta, GA. March 2006.

Manoff S, Liss C, Caulfield M, Marchese R, Silber J, **Boslego J**, Romero-Steiner S, Rajam G, Glass N, Whitney C, Carlone G, and the Pneumococcal Revaccination Study Group. Elevated and persistent functional antibody responses in adults ≥65 years of age after a second dose of a 23-valent pneumococcal polysaccharide vaccine. Program and Abstract Book, 5th International Symposium on

Pneumococci and Pneumococcal Diseases, Alice Springs, Australia. April 2 - 6, 2006.

Rodriguez Z, Goveia M, Stek J, Dallas M, **Boslego J**, DiNubile M, Heaton P. Concomitant Use of Pentavalent Rotavirus Vaccine (PRV) With Acellular Pertussis Vaccine: A Resassessment of Antibody Responses. 2006 Infectious Diseases Society of America Annual Meeting, Toronto, Canada. October 12-15, 2006.

Halperin, SA, Tapiero B, Diaz-Mitoma F, Law BJ, Hoffenbach A, Zappacosta PS, Radley D, McCarson BJ, Martin JC, Brackett LE, **Boslego JW**, Hesley TM, Bhuyan PK, Silber JL. Safety and Immunogenicity of a Hexavalent Diphtheria-Tetanus-Acellular Pertussis-Inactivated Poliovirus-*Haemophilus influenzae* b Conjugate-Hepatitis B Vaccine at 2, 3, 4 and 12 to 14 Months of Age. 11<sup>th</sup> Annual Conference on Vaccine Research, Baltimore, MD. May 5-7, 2008.

**Boslego J.** Multi-valent pneumococcal vaccine – exploring the challenges and the role of public-private partnering in the clinical and product development of a truly global vaccine. Phacilitiate Vaccine Forum, Washington, DC. January 26-28, 2009.

Caulfield, M.J., Payne, A.M., Indrawati, L., Heinrichs, J.H., Przysiecki, C.T., Penny, M., Mast, T.C., Straus, W.L., Dargan, J.M., **Boslego, J.** Retrospective Study of *N. meningitidis* Serogroup B-specific SBA Activity in Sera from Peruvian Infants Vaccinated with PedvaxHIB or ActHIB. 11<sup>th</sup> Annual Conference on Vaccine Research, Baltimore, MD. April 27-29, 2009.

				Address of the Party of the Par			
			Award Start Award	Award			
OrigAwardID Funder	Funder	Awd_title	Date	End Date	End Date   Agreement Type	Budget	Obligated
	ELIZABETH GLASER PEDIATRIC						
EGP, 1483-01	EGP.1483-01 AIDS FOUNDATION	HIV CAPACITY BUILDING - KENYA YR 2	30-Sep-09	30-Sep-14	30-Sep-09   30-Sep-14   Cooperative Agreement		
		EVIDENCE-BASED HEALTH GLOBAL HEALTH					
		INTERVENTIONS FOR MOTHERS AND CHILDREN -					
TUL. 1514-00	TUL. 1514-00   TULANE EDUCATIONAL FUND	ARGENTINA	01-Oct-09   29-Aug-14   Agreement	29-Aug-14	Agreement		
	US AGENCY FOR INTL.				Cost Plus Fixed Fee		
AID.1470-Q0	AID.1470-Q01 DEVELOPMENT (USAID)	TB IQC TASK ORDER 1	29-Oct-09   30-Oct-14   Contract	30-Oct-14		58,389,014.00 5,323,000.0	5,323,000.0
	US AGENCY FOR INTL.	AIDSTAR TASK ORDER # 3 - Democratic Republic of Congo			Cost Plus Fixed Fee	*****	
AID 1365-00	AID 1365-ORS DEVELOPMENT (USAID)	(CRC)	19-Mar-10   30-Sep-10   Contract	30-Sep-10	Contract	44 873 203 00 6 688 923 (	6 688 923

			Award Start Award	Award			-
OrigAwardID Funder		Awd_title	Date	End Date	End Date   Agreement Type	Budget	Obligated
FHI.1312-00	HINTERNATIONAL	PROVIDE FEMALE CONDOMS FOR CLINICAL STUDY IN SOUTH AFRICA	01-Oct-07	05-Jun-12	ig.	317.00	32.317.00
NIH.1327-00	NATIONAL INSTITUTES OF HEALTH (NIH)	IMPROVEMENT OF CO2-BASED CRYOTHERAPY	01-Oct-07	30-Sep-08	30-Sep-08 Fixed Price Contract	24 711 00	
FAMI	FAMILY HEALTH INTERNATIONAL	1 1 1 1 1 1 1 1 1 1 1 1 1 1 1 1 1 1 1					
ENG.1322-00	ENDERHEALTH	APHIA II: NYANZA PROJECT	01-0cf-07	30-Sep-08	30-Sep-08 Indefinite Quantity Contract	1 257 061 00	084 858 00
JHP.1318-00		KENYA APHIA II: EASTERN PROVINCE	Τ	30-Sep-11	30-Sep-11 Cooperative Agreement	1 851 506 00	1 582 179 00
INP.1463-00	INTERNATIONAL PARTNERSHIP FOR MICROBICIDES (IPM)	FELLOWS, ZAMBIA ADVOCACY & SRH CONFERENCE	_	29-Sep-10	Cooperative 29-Sep-10 Agreement/Fixed Price	300 000	300 000 00
TUL.1401-00	TULANE UNIVERSITY	INTERPERSONAL COMMUNICATION FOR ITN USE IN ZAMBIA		31-May-09 Grant	Grant	659.244.00	438.898.00
AID.1344-00	U.S. AGENCY FOR INTERNATIONAL DEVELOPMENT (USAID)	TASC 3	01~Jun-08	31-Mav-09	31-May-09 Indefinite Quantity Contract	25,000,00	
AID.1470-00	USAID/M/OAA/GH	TUBERCULOSIS INDEFINITE QUANTITY CONTRACT (TB IQC)	1	01-Jun-09	01-Jun-09 Indefinite Quantity Contract	58.389.014.00	5 323 000 00
EGP.1270- Q02A	ELIZABETH GLASER PEDIATRIC AIDS FOUNDATION	CALL TO ACTION/HEART TO 2A: NUTRITION TECHNICAL ASSISTANT (GLOBAL)	01-Jul-08	30-Jun-09	30-Jun-09 TASK ORDER	38,624.35	
EGP.1270-00	EGP.1270-00 AIDS FOUNDATION	CALL TO ACTION/HEART: STRENGTHEN NUTRITION AND INFANT FEEDING PROGRAMS	01-Jul-08	90-Jun-09	COST REIMBURSEMENT 30-Jun-09 CONTRACT	3.300.000.00	1 032 630 00
EGP.1270- Q02B		CALL TO ACTION/HEART TO 2B: NUTRITION TECHNICAL ASSISTANT (GLOBAL)	01-Jul-08	30-Jun-09	30-Jun-09 TASK ORDER	87 055 00	
CDC.1421-00	CENTERS FOR AND PREVENTI	YEAR 1: SEASONAL INFLUENZA VACCINE DISEASE CONTROL EFFECTIVENESS IN A TROPICAL DEVELOPING AFRICAN ON	01-Aug-08	31-Jul-09	Grant	2,694,728.00	1,105,929.00
EGP.1270- Q01	LASER PEDIATRIC	CALL TO ACTION/HEART TO 1: COTE DIVOIRE NUTRITION WORK PLAN	01-Aug-08	30-Apr-10	COST REIMBURSEMENT	35 000 00	
CRE.1316-00	CRE.1316-00 CARE/KENYA	MAGNET THEATRE TRAINING		30-Jul-09		5,000.00	
AID.1365-00	U.S. AGENCY FOR INTERNATIONAL DEVELOPMENT (USAID)	AIDSTAR SECTOR I IQC - UMBRELLA AWARD	15-Sen-08	14-Sen-13	15-Sep-08 14-Sep-13 Indefinite Quantity Contract Ro 872 548 00 55 348 202 00	80 872 518 00	85 918 209 00

			Award Start Award	Award			
OrigAwardID Funder	Funder	Awd_title	Date	End Date	End Date   Agreement Type	Budget	Obligated
AVC.1134-02	AVC.1134-02 ARBOR VITA CORPORATION	DEVELOP RAPID STRIP TEST FOR CERVICAL CANCER VIA HPV-E6 DETECTION	29-Sep-08	29-Sep-13 GRANT	GRANT	287,139.00	287,139.00
AID.1307-00	USAID/CAUCASUS	STRENGTHENING SURVEILLANCE, INFORMATION, EDUCATION, COMMUNICATION, AND PROCUREMENT CAPACITY TO ADDRESS AVIAN FLU IN GEORGIA	30-Sep-08	29-Sep-09	COOPERATIVE 29-Sep-09 AGREEMENT	400 000 00	400 000 00
PRB.1275-00		ACTIVITIES TO SUPPORT THE ABANDONMENT OF FEMALE GENITAL CUTTING	30-Sep-08	29-Sep-09	29-Sep-09 SUBCONTRACT	12.000.00	
PRB.1082-09	POPULATION REFERENCE BUREAU (PRB)	FOLLOW-UP TO THE 2002 GENDER-BASED VIOLENCE TECHNICAL UPDATE	01-Oct-08	29-Mar-10	29-Mar-10 CONTRACT	12,000.00	
AID.1365-Q01	US AGENCY FOR INTL. AID.1365-Q01 (DEVELOPMENT (USAID)	AIDSTAR-TO#1 - ORPHANS & VULNERABLE CHILDREN CAREGIVER TRAINING AND CHILD PROTECTION	01-Oct-08	Cost Plu 30-Jun-13 Contract	Cost Plus Fixed Fee Contract	9,999,315.00	3,600,000,00
GEO.1227-00	GEORGETOWN UNIVERSITY/INSTITUTE FOR GEO.1227-00 REPRODUCTIVE HEALTH	EVALUATE LOCAL PRODUCTION OPPORTUNITIES FOR CYCLEBEADS	01-Oct-08	31-Dec-09 GRANT	GRANT	83,473.81	<
SAV.1247-00	SAVE THE CHILDREN SAV.1247-00 FEDERATION, INC.	ASSIST WITH MIDTERM RÉVIEW MEETING FOR ASPHYXIA IN CIREBON PROJECT	19-Dec-08	15-Feb-09	15-Feb-09 CONTRACT		
AID 1346-00	USAID/KENYA	APHIA II: WESTERN PROVINCE	01-Jan-09	30-Sep-09	30-Sep-09 Cooperative Agreement	42,972,465.00 31,660,000.00	31,660,000.00
ORC.1441-00	ORC MACRO INTERNATIONAL, INC.	TO SUPPORT THE 2008/2009 HIV/AIDS AND MALARIA ORC.1441-00 ORC MACRO INTERNATIONAL, INC. INDICATOR SURVEY PROJECT IN UGANDA	22-Feb-09	Cost Plu 30-Apr-10 Contract	Cost Plus Fixed Fee Contract	20,000.00	
EGP.1270- Q06	ELIZABETH GLASER PEDIATRIC AIDS FOUNDATION	CALL TO ACTION TASK ORDER #6	01-Apr-09	31-Mar-14 Task Order	Task Order	33,933.00	
WHO.1525-00	WHO.1525-00 WORLD HEALTH ORGANIZATION	TB TECHNICAL ASSISTANCE IN TANZANIA	03-Apr-09	31-Mar-14 Agreement	Agreement		
02	JSI.1335-Q02 JOHN SNOW, INC.	DELIVER II: TASK ORDER 2	01-Jun-09	31-May-10 Task Order	Task Order	522,916.00	370,878.00
EGP.1270- Q12	ELIZABETH GLASER PEDIATRIC AIDS FOUNDATION	CALL TO ACTION: TASK ORDER #12 - SOUTH AFRICA	04-Jun-09	30-Apr-10 Task Order	Task Order	386,083.00	386,083.00
AID.1329-00	US AGENCY FOR INTL. DEVELOPMENT (USAID)	INFANT YOUNG CHILD NUTRITION PROGRAM (IYCN)	10-Jun-09	31-Mar-11	31-Mar-11 Cooperative Agreement	45,996,032.00 16,103,000.00	16,103,000.00
AID:1303-00	USAID/KIEV	PURCHASE ORDER FOR EQUIPMENT AND SUPPLIES TO SUPPORT USAID'S AVIAN FLU RESPONSE	01-Jul-09	30-Jun-10	30-Jun-10 PURCHASE ORDER	150,000.00	
JSI.1060-Q17	JSI.1060-Q17 JOHN SNOW, INC.	DELIVER T.O.#17: JORDAN QUALITY ASSURANCE TECHNICAL ASSISTANCE	01-Jul-09	30-Jun-10	30-Jun-10 TASK ORDER	31,427.60	

			Award Start Award	Award			
OrigAwardID Funder		Awd_title	Date	End Date	Agreement Type	Budget	Obligated
CHE 1507-00	TERNATIONAL INC	PRIVATE SECTOR MOBILIZATION FOR FAMILY HEALTH PROJECT PHASE 2 (PRISM)	01-Jul-09	30-Jun-10 Contract	Cost Reimbursement Contract		
PCH.0826-	를	FOR CHILD HEALTH BASICS III TO# 2: CAMBODIA CHILD SURVIVAL AND					
002	CARE, INC.	NEWBORN HEALTH PROGRAM	01~Jul-09	30-Sep-09	30-Sep-09 Task Order	00.7/3,101	23,474.00
		MEASURE PHASE III - DEMOGRAPHIC AND HEALTH			Cost Plus Fixed Fee		
ORC.1164-01	ORC.1164-01 [MACRO INTERNATIONAL, INC.	SURVEYS	13-Jul-09	12-Jul-14	Contract	4,875,778.00	544,861.00
	CENTERS FOR DISEASE CONTROL	YEAR 2: SEASONAL INFLUENZA VACCINE EFFECTIVENESS IN A TROPICAL DEVELOPING AFRICAN					
CDC.1421-02	NO	COUNTRY	01-Aug-09	31-Jul-10	Grant	1,412,877.00	1,412,877.00
ORC.1278-00	ORC.1278-00 ORC MACRO INTERNATIONAL, INC. PROJECT	PROVIDE RESEACH ASSISTANT FOR LINKAGES PROJECT	01-Aug-09	31-Jul-10	TIME AND MATERIALS SUBCONTRACT	16,474.00	
PSC.1279-00	PSC.1279-00 MANAGEMENT LLC	SUPPLY CHAIN MANAGEMENT SYSTEM PROJECT	01-Sep-09	31-Aug-11	31-Aug-11 Task Order	541,222.00	541,222.00
CHE.1288-00	CHE 1288-00 CHEMONICS INTERNATIONAL INC.	HEALTH POLICY INITIATIVE IQC	01-Sep-09	31-Aug-11	INDEFINITE QUANTITY 31-Aug-11 SUBCONTRACT	5,000,000.00	1,000.00
		FY09 ENHANCING INFLUENZA VACCINE DEVELOPMENT					
DHH.1485-00	DHH.1485-00 HUMAN SERVICES (DHHS)	IN VIETNAM	01-Sep-09	01-Aug-12	01-Aug-12 Cooperative Agreement	7,900,000.00	7,900,000.00
CDC 1328-01		SURVEILLANCE AND RESPONSE TO AVIAN/PANDEMIC INFLUENZA (YEAR 2)	01-Sep-09	31-Aug-12	31-Aug-12 Cooperative Agreement	710.455.00	710.455.00
	NATIONAL INSTITUTES OF HEALTH	ITUTES OF HEALTH CENTER TO ADVANCE POC DIAGNOSTICS FOR GLOBAL					
NIH.1374-01	(ZIZ)	HEALTH	30-Sep-09	29-Sep-10	29-Sep-10 Cooperative Agreement	1,689,979.00	1,689,979.00
CDC 1328-02	CEC 1328-02 AND PREVENTION	DISEASE CONTROL  SURVEILLANCE AND RESPONSE TO AVIAN/PANDEMIC   INFLUENZA (YEAR 3)	30-Sep-09	29-Sep-10	29-Sep-10 Cooperative Agreement	479,359.00	479,359.00
		YEAR 1 PROVISION OF TECHNICAL ASSISTANCE.					
		FINANCIAL SUPPORT AND CAPABILITY BUILDING FOR					
		HIV PREVENTION, CARE AND TREATMENT FOR					
		DISEASE CONTROL MEMBERS OF THE NON-MILITARY UNIFORMED					
CDC.1423-00	CDC.1423-00 AND PREVENTION	SERVICES OF KENYA	30-Sep-09	29-Sep-10	29-Sep-10 Cooperative Agreement	500,000.00	500,000.00
	CENTERS FOR DISEASE CONTROL	CENTERS FOR DISEASE CONTROL SURVEILLANCE AND RESPONSE TO AVIAN/PANDEMIC					
CDC.1328-03	CDC.1328-03 AND PREVENTION	INFLUENZA (YEAR 4)	30-Sep-09	29-Sep-11	29-Sep-11   Cooperative Agreement	519,177.00	519,177.00
		YEAR 2: PROVISION OF TECHNICAL ASSISTANCE,					
		FINANCIAL SUPPORT AND CAPABILITY BUILDING FOR					
		HIV PREVENTION, CARE AND TREATMENT FOR					
	CENTERS FOR DISEASE CONTROL	CENTERS FOR DISEASE CONTROL MEMBERS OF THE NON-MILITARY UNIFORMED	******				
CDC.1423-01	CDC.1423-01 AND PREVENTION	SERVICES OF KENYA	30-Sep-09	29-Sep-14	29-Sep-14 Cooperative Agreement	2,966,685.00	2,966,685.00 2,966,685.00

## House Appropriations Committee Defense Subcommittee

## Witness Disclosure Form

Clause 2(g) of rule XI of the Rules of the House of Representatives requires nongovernmental witnesses to disclose to the Committee the following information. A non-governmental witness is any witness appearing on behalf of himself/herself or on behalf of an organization other than a federal agency, or a state, local or tribal government.

Your Name, Business Address, and Telephone Number:

Dr. John Boslego

	1800 K St. NW, Suite 800 Washington, DC 20006 202.822.0033
1.	Are you appearing on behalf of yourself or a non-governmental organization? Please list organization(s) you are representing.  On behalf of PATH.
2.	Have you or any organization you are representing received any Federal grants or contracts (including any subgrants or subcontracts) since October 1, 2007?  No  No
3.	If your response to question #2 is "Yes", please list the amount and source (by agency and program) of each grant or contract, and indicate whether the recipient of such grant or contract was you or the organization(s) you are representing.  Please see list attached.  PATH is the recipient of all listed grants and contracts.
5	Signature Date: 5/19/2010  Please bring this original form on the day of your testimony.

Mr. DICKS. Sherry S. Galloway, registered nurse, board member of ZERO, the project to end prostate cancer.

Thursday, May 20, 2010.

## **ZERO**

#### WITNESS

# SHERRY GALLOWAY, R.N., BOARD MEMBER, ZERO, THE PROJECT TO END PROSTATE CANCER

Ms. Galloway. Mr. Chairman, members of the committee, thank you very much for the opportunity to speak to you today about the Prostate Cancer Research Program and the congressionally directed medical research programs at the Department of Defense. Many people can speak to you effectively about the research this program has done or is doing, about its history, funding levels and accomplishments. But I want to talk to you about how we can affect the future of prostate cancer research by looking at two men in my life who fought this deadly disease. My husband, Tom, and my son, Jeremy. When we leave here today, I hope you understand why I hold out hope for the future that research promises to give us and why I ask you to increase prostate cancer research funding so that the PCRP can lead us there.

My name is Sherry Galloway. I am a nurse, a mother, a wife and a sister. I have a personal relationship with prostate cancer after watching its horrific impact on both my son and my husband. My husband's diagnosis was made when he was 54 and that made a little more sense at that age to me, although that is not old. And we do think of this disease often as an old man's disease. The treatment my husband received was not without side effects. His nerve-sparing prostatectomy left him impotent. While that persists today at 60, he is alive and cancer free. I would give anything to have my son alive and cancer free. Jeremy's prostate cancer was diagnosed 4 years after my husband's and he was 35 years old. 18 months later he was dead.

When he was 34, Jeremy complained of back pain that would not subside. He was fit, he was healthy and strong. He turned 35 in Burma where he was delivering medicine to villages there. When he returned home, he felt tired and he was still in unremitting pain. He was having night sweats. So he went to an infectious disease specialist thinking maybe he had caught something in the jungle or in the forest. They did blood tests and found that he was walking around with almost no platelets. They sent him to the ER. His own physician reviewed his MRI, saw that he had no platelets and they immediately thought of lymphoma, which is more typical in young men. And both are very treatable. His first bone biopsy revealed cells that were suspicious of prostate cancer, however the oncologist couldn't believe that. So they continued to test him, transfuse him and look for everything else. And finally they called in a urologist. At that time, my son's DRE was normal and ultrasound of his prostate was normal. His PSA was 441. When repeated, it was more like 460. At that time, he was diagnosed with advanced metastatic hormone refractory prostate cancer. Three

months later—actually the hormones after 3 months. It was hormone refractory. The hormones did not work.

When you looked at his CAT scan, his bone scan, all you saw was black throughout his axial skeleton and his clavicle with little spots on his brain. That was all tumor. So his back pain was due to his metastasis, not due to the prostate cancer which was asymptomatic, completely. Jeremy was married on a Saturday in September of 2006 and 2 days after his wedding he started chemotherapy. Things began to slip for him about a year after his diagnosis. There were nights when he would sit in a hot tub with Epsom salts and just sob because he was in pain and he was depressed and scared.

And I would just sit by the tub. There was nothing I could do but listen. On good days, he dedicated time to research. He discovered numerous prostate cancer research projects, each one of which became a source of hope for us. He was started in the Provenge trials, clinical trials. Unfortunately he was in the control group. So he never received the Provenge which today is an accepted treatment for advanced metastatic prostate cancer. That was a huge disappointment.

Later he was accepted into an experimental treatment at the University of Oregon in which he would have received a mini allogenic total bone marrow transplant. Fortunately, the approval of this came about 3 days before he died. So he was unable to get this. Jeremy accepted being experimented on with grace, even when elephant doses of pain medication did not work. He was in excruciating bone pain 24/7. He couldn't sit, he couldn't stand, he couldn't lay down anywhere without pain. He slept through most of his first wedding anniversary because he was so highly drugged and in so much pain. And his wife had to sit there alone and sometimes with me because Jeremy couldn't play, although he tried to remain positive about his life.

For 33 years, Jeremy was healthy and he worked tirelessly for human rights and environmental sustainability. Among his many accomplishments was a special award given to him while he was sick by the Rain Forest Action Network. He also brokered an agreement between several guitar companies and Greenpeace whereby no old growth forest trees would be used in the manufacture of guitars. Six weeks before his death, I literally had to kidnap him from the hospital so he could go get his award. We had to cover up our dress clothes with hospital gowns and sneak out of the hospital and go in a rickety RV to get him to these awards. I wheeled him down the aisle to a standing ovation of over 300 people.

Then he stood up on the stage and spoke with such power that during those moments, it was hard to imagine that he was so sick. After receiving his award and returning to the hospital, the staff came in and spoke with him and his wife and then his father and I were asked to join them while they gave the talk about preparing for the end of life. It was the speech where they kindly ask you whether you want to just continue with treatment that isn't going to work or you want to go home. Jeremy and Beth decided that Jeremy would die at home. During the final weeks of his life, Jeremy was in agony. There were no comfortable positions. He vomited and retched repeatedly and with extreme force because of all the radi-

ation treatments he had had that went through his abdomen to affect his spine to keep from paralyzing him. He took medication for pain, nausea, constipation, appetite, anxiety and sleep. He began to wander at night, even on medication, and maybe because of it.

His friends organized into teams so 2 or 3 of us would be with Jeremy around the clock. I slept so little that Jeremy's friends nicknamed me "zombie mom." Jeremy's morphine pump wasn't working and he became incontinent of stool and urine. My proud, strong, beautiful son would stand docile at the toilet while his wife or I wiped a continuing stream of stool that was running down his legs until it stopped and we could put a diaper on him. We had diapers, we had clothing, we had water and medication with us at all times if we did go outside. Jeremy's ankles became so swollen and

painful that he could barely walk.

In Jeremy's final days, his diet consisted largely of mashed potatoes, which is all he wanted most of the time. He also ate his favorite cookies that I baked for him and special granola that his stepsister made for him. He slept on a hospital bed in his living room and at night he would pull himself up and with help shamble into the bedroom to kiss his wife goodnight. When he could, he would sit at his computer and try to do a little work. There are some pictures here of him healthy and also in these final stages that I will pass around for you to look at. He tried to do a little e-mail. And then finally he just opted to stop. He just stopped eating, stopped drinking and asked the hospice nurses to up his morphine so he could sleep his last days away. It was Thanksgiving week of 2007 and he slept but was restless. He had fallen out of bed a week earlier when friends couldn't stay awake and he was in constant pain every time he even moved in bed. He began to have that nauseatingly sweet smell of ketosis that has when your body is wasting. The day before Thanksgiving, he woke up in the afternoon and told my husband and I very clearly I am dying, but it is all right.

And he had a smile on his face. He said some very loving things to us and went back to sleep. That night he actually awoke and sang and chanted with his friends. That was the last time he woke up. On Thanksgiving day, he did not wake up again, although his eyes were slightly open at all times and his mouth was hanging open. But he was not conscious. On Friday, the day after Thanksgiving, my sister's 50th birthday, the autumn weather was gentle and the space was quiet, respectful. We sang and read to Jeremy. We wandered around. We were tired, we were exhausted and wandering and waiting. That night at about 7:00, I could tell that his breathing had changed and I knew the end was coming. He died peacefully, his wife holding his right hand and me holding his left as I had promised. His dad, step-dad, siblings and friends were all

there as were my sister and best friend.

A helium balloon that had been floating about the room for several days slipped out the window and floated skyward. Jeremy had a peaceful look on his face for the first time in months. We send our sons off to war and they may not come back or they come back less than whole when they left home. We send them off to college not knowing where they will go from there but still we have hope for their futures. We have hope for their lives. My son chose a dangerous path. He was an activist. He was shot at, he was threat-

ened, he was in jungles. He was not safe. I knew this and I feared for him, but at the same time I was proud. I never expected that prostate cancer would kill him. Prostate cancer took away my hope. I learned that it is an old man's disease and I know that it is not. 300 men die each year in the United States under the age of 40. If that is not enough for you to fund research, then look at the almost 30,000 men that will die this year alone in the United States from prostate cancer. We need to increase funding. What I have described to you today is the life of someone dying of a highly aggressive form of prostate cancer. This is not rare. His own oncologist is the same age and has lost 4 young men to prostate cancer and many more older men. Perhaps if a more accurate test for prostate cancer existed, my child would have known about his cancer earlier and he could be here talking to you himself.

I will never know because there just aren't enough funds to do all the research that needs to be done. Perhaps had the research been done on newer techniques, my husband would not be impotent. It is because of the research we know that it does not work. There is no question that the PSA is not a good enough diagnostic test but it is all we have. There is no question that there are aggressive cancers that we cannot watch and wait. Prostate cancer kills more men than any cancer except lung cancer and has a mortality rate comparable to breast cancer. Each month, I read another article about the inadequacy of the PSA test and each day I wait for a better test. And every day I question why more and more funding seems to go to a few types of cancer, none of which are the greatest killer of men in this country. It is one thing to criticize the test we currently have to screen men for this insidious killer and quite another to find a viable solution.

Unless you increase funding for the Prostate Cancer Research Program, I fear good research will be left unfunded. No one is asking you to make the same sacrifice Jeremy made. No one is asking you to go through the pain that my son went through, the embarrassment, the deterioration and a very horrific and painful death. All I ask is that you consider increasing funding for prostate cancer research so that no more mothers, children, husbands, wives have to suffer the way my family has. Thank you for your time.

[The statement of Ms. Galloway follows:]

#### STATEMENT BY

# SHERRY S. GALLOWAY, R.N. BOARD MEMBER, ZERO – THE PROJECT TO END PROSTATE CANCER

#### REGARDING

# THE PROSTATE CANCER RESEARCH PROGRAM OF THE CONGRESSIONALLY DIRECTED MEDICAL RESEARCH PROGRAMS

BEFORE THE
HOUSE COMMITTEE ON APPROPRIATIONS
SUBCOMMITTEE ON DEFENSE

May 20, 2010

Mr. Chairman, Members of the Committee, thank you for the opportunity to speak to you about the Prostate Cancer Research Program (PCRP) and the Congressionally Directed Medical Research Programs (CDMRP) at the Department of Defense (DOD). Many people can speak effectively about the research this program has done or is doing, about its history, funding levels, and accomplishments, but I want to talk to you about how we can affect the future of prostate cancer research by looking at the personal stories of those impacted by this insidious disease. Today, I want to tell you about the two men in my life who fought prostate cancer — my husband, Tom and my son, Jeremy. When we leave here today, I hope you understand why I hold out hope for the future that research promises to give us and why I ask you to increase prostate cancer research funding so that the PCRP can lead us there.

I am a nurse, a mother, a wife and a sister. I have a personal relationship with prostate cancer after watching its horrific impact on both my son and my husband. My husband's diagnosis made a little more sense to me – he was 54. Our understanding of prostate cancer is that it affects older men – although I challenge the idea that 54 is old. The treatment my husband received was not without side effects – his nerve sparing prostatectomy left him impotent and while that persists, today at 60, Tom is alive and cancer free.

I would give anything to have my son alive and cancer free. Jeremy's prostate cancer was diagnosed 4 years after my husband's diagnosis – he was 34, and 18 months later, he was dead.

As I speak today, I do so to stand up for my son, Jeremy, and to tell you what he has given to prostate cancer research. On November 23, 2007, my sister's 50th birthday, my son gave his greatest gift to prostate cancer research. His very wasted body, no longer in pain, went to UCSF to be used for prostate cancer research at his request. Once the necessary cells were harvested, Jeremy's body was cremated and his ashes scattered beneath his beloved Golden Gate Bridge in San Francisco. Jeremy was 36 years old at the time of his death. Jeremy had one life and one body to give to prostate cancer research. He gave it all. It would be impossible for you to match the contribution he made to research an end to this disease. I simply ask as Jeremy would, for

you to invest for more prostate cancer research so that you can make a difference to other mothers, wives, sisters and daughters.

The recent celebration of Mother's Day makes this the perfect time for me to share the story of my only child with you, because he made me what I am today; his life and legacy are the reasons I am here. My sweet, smart, passionate and beautiful son is dead, so I must speak for him, because, to quote poet Robert Browning, "Motherhood: Love begins and ends with it."

When he was 33 years old, Jeremy complained of back and hip pain that would not subside. He was fit, healthy and strong. He was a climber, hiker and cyclist. A vegetarian since high school, Jeremy did not smoke, drank very little alcohol and had no other symptoms or physical complaints. His physician did an MRI of Jeremy's spine and sent him for physical therapy and acupuncture. Because my son kept such an active schedule – he was constantly working and travelling – a back injury seemed a reasonable explanation for the pain. While I suggested Jeremy receive some laboratory testing, his doctor saw no need.

Jeremy turned 34 in Burma, where he led a small group of volunteers into the jungle to deliver medicine to villages there. When he returned home, he felt tired and was still in unremitting pain. He was having night sweats, so he saw a specialist in infectious diseases, thinking his time in various jungles and forests might have given him some kind of infection or virus. Blood tests revealed that Jeremy had almost no platelets; it was a miracle Jeremy was upright, much less feeling just a little tired. His primary physician took a closer look at Jeremy's previous MRI after being notified about Jeremy's laboratory results and sent Jeremy immediately to the emergency room.

Early on, doctors thought testicular cancer or lymphoma may have been the culprit, as both are common in younger men and treatable. It is because of the lack of prostate cancer research that doctors saw little or no reason to expect prostate cancer was to blame. Jeremy's first bone biopsy revealed cells that looked like prostate cancer cells. After this, Jeremy was transfused

several times, tested for everything at all related to his symptoms and, only as a last resort did the oncologist on his case call in a urologist for consultation.

The results from the urologist's DRE were normal. This had always been the case. An ultrasound revealed a normal looking prostate, but Jeremy's PSA was 441. His very painful prostate biopsy revealed prostate cancer cells, but his Gleason score was unclear. He bled for days and could barely walk due to pain more than weakness.

A bone scan was conducted that showed nice, white bone in his arms and legs and black tumor throughout Jeremy's entire axial skeleton, with spots on his skull. Jeremy's pelvis was just tumor. My only child was diagnosed with advanced metastatic prostate cancer at the end of March 2006.

Once we had a diagnosis, we spent several days calling and cajoling, doing whatever we needed to have Jeremy seen at UCSF in the Department of Urological Oncology. Jeremy was finally transferred to UCSF, and thus began what I call "Jeremy time." I returned home to Albuquerque, packed some clothing, quit my job, kissed my husband, and returned to California to face the unknown with my son. Jeremy was released from the hospital and began outpatient treatment with Dr. Charles "Chuck" Ryan. Jeremy was started on oral Casodex daily and Lupron injections monthly. This combination initially brought his PSA down; however, by June, these medications no longer worked and the side effects made Jeremy miserable.

By July 2006, Jeremy was newly engaged to be married, looking and feeling good, exercising and hopeful. He spent the summer of 2006 building his strength for the start of chemotherapy treatment. He was married on a Saturday in September and later that month started treatment with taxotere.

Throughout his ordeal, Jeremy would be treated with various combinations of taxotere and other chemotherapy agents. His UCSF team treated him aggressively and passionately. Although his initial PSA on diagnosis was 441, it went down to 6.5 almost immediately upon treatment. It

then gradually doubled upon itself over and over until it surpassed its original number close to Jeremy's death. Unfortunately for Jeremy, much of the research into diagnosis and treatment lagged behind the progression of his disease.

The 18 months following Jeremy's diagnosis were full of night sweats, pain, nausea, treatment, and sadness. But Jeremy refused to let this disease get the best of him. Although he could not sit for long periods due to his pelvic pain, he continued to enjoy meals out, good movies and his work. We took long walks, picking berries in late summer; we worked on reducing the amounts of money due for medical bills and slogged through copious amounts of insurance paperwork. Jeremy started an acupuncture internship and published an article about prostate cancer treatment with concurrent alternative therapy as an adjunct.

Things began to slip for Jeremy about a year after diagnosis. There were nights he would sit in a hot tub with Epsom salts and sob with pain and desolation. All I could do was sit with him.

On good days, he dedicated time to research. Jeremy discovered numerous prostate cancer research projects – each one of which became a source of hope. Throughout Jeremy's battle with prostate cancer, we consistently found hope in the unseen. We celebrated when Jeremy was approved to participate in the clinical trial of the drug Provenge. We had high hopes for this promising drug, which were well founded given that Provenge was recently approved for use in the treatment of advanced metastatic prostate cancer patients. Jeremy was approved to participate in this trial after hormone treatment ceased to be effective and early chemotherapy treatment was failing. Our hopes were dashed when we discovered that Jeremy was in the control group and did not actually receive Provenge. We found another reason to hope for Jeremy's future when we discovered an experimental treatment at the University of Oregon. He was accepted into this program which would have provided a mini-allogenic total marrow transplant. Of course, the approval came months after we sought this course of treatment and only days before Jeremy's death.

In September 2007, he had surgery on his spine when tumors put too much pressure on the spinal cord. Doctors put a morphine pump in his abdomen to pump morphine sulfate directly into his hip and low spine, which was most painful.

He had a few days where he could sit and move about without pain. He was surrounded by friends and family. He played his guitar, ate, and wrote. After two weeks in the hospital, the staff of the ward managed to get Jeremy into one of two special rooms, large enough for a guest to sleep in and appointed much like a hotel room. We knew that patients were put in those rooms so they could die surrounded by loved ones. We were assured that this was not the case with Jeremy; he was just so well-known and beloved after his several hospital stays. We were able to remain in denial a little longer; this was the palliative care floor, after all.

Jeremy learned to accept being experimented on with grace, even when elephant doses of powerful pain relievers did not touch the amount of excruciating bone pain that he was experiencing at all hours every day. He slept through most of his first wedding anniversary weekend, unable to take part in the celebration with his wife. Still, he worked hard to remain positive.

This is how my son was. He was a tireless worker – even in death. For the 33 years he was healthy on this earth, he worked tirelessly for human rights and environmental sustainability. He brokered an agreement between several guitar companies and Greenpeace whereby no old growth wood will go into the manufacturing of future guitars. He was known by his friends and co-workers as a compassionate, loving and generous man. If you Google his name, among many of his accomplishments, you see that he was given a special award to honor him by the Rainforest Action Network.

Six weeks before his death, I literally had to sneak him out of the hospital and wheel him up to the stage so that he could be honored. After a standing ovation of more than 300 people, Jeremy stood and spoke with such power that we forgot, for a moment, how weakened his body was by tumor and treatment. At his living wake, just a few weeks later, Jeremy could barely stay awake

as people came up to the dais upon which he reclined to give testimonials to him. Yet, when he spoke, he was focused upon the need for change in our world. His speech was selfless and full of gratitude toward the hundreds of people who had showed up to honor him.

After receiving his award at the ceremony and returning to the hospital, the staff came and spoke with him, his wife, his father and me about preparing for his end of life. It was the speech where they kindly ask if you want to spend the rest of your life in the hospital, being probed, prodded and kept alive painfully, or at home, with friends and comfort. Jeremy and Beth made their choice – he wanted to go home.

During the final weeks of his life, Jeremy was in agony. There were no comfortable positions that didn't cause pain. He vomited and retched repeatedly and with extreme force as the radiation treatments to prevent the tumors on his spine from paralyzing him had also affected his abdomen. He took medication for pain, nausea, constipation and appetite, anxiety and sleep. His mouth hurt. He began to wander at night, even on medication and maybe because of it. His friends organized into teams so that two or three of us would be with Jeremy around the clock. I slept so little that Jeremy's friends nicknamed me "Zombie Mom." Jeremy's morphine pump wasn't working and he also was incontinent of stool and urine. My proud, strong son would stand, docile, at the toilet while his wife or I wiped a continuing stream of stool running down his legs until it stopped so that we could put a fresh diaper on him. On excursions outside, we had diapers, a change of clothing, medication and water all packed up to go with us. Jeremy's ankles became so swollen and painful that he could barely move, although he still wanted to wander at night.

In Jeremy's final days, his diet consisted largely of mashed potatoes, which is all he wanted most of the time. He also ate his favorite cookies that I baked for him and a special granola that his step sister made for him. He slept on a hospital bed in his living room, provided by hospice. He would pull himself up and, with help, shamble on swollen feet into the bedroom to kiss his wife goodnight. In lucid moments, he would sit at his computer and try to do a little work or e-mail.

Finally, he opted to stop taking in food and asked hospice to increase his morphine so that he could sleep away his last days.

It was Thanksgiving week of 2007. None of us were feeling particularly thankful. Jeremy did sleep, but was restless much of the time. He had fallen out of bed a week earlier when the friends with him couldn't stop the fall in time and his neck hurt every time he shifted in bed. He began to have that nauseatingly sweet smell of ketosis as his already thin body wasted in front of our eyes. The day before Thanksgiving, he woke up in the afternoon and told my husband and I very clearly that he was dying and "it was alright." He said some loving things to each of us and then went back to sleep.

Later that evening, when friends were singing and playing music, he actually got up and sang, and was with us for a short time. On Thanksgiving, he did not wake up. His eyes remained lidded, not completely closed and his mouth hung open. I rarely left his side. My daughter-in-law ordered a feast from Whole Foods and we all tried to eat. No one had much appetite and we were all exhausted. There were beautiful flowers and candles decorating the space and there was, at every instant, so much love in the room. And we waited. On Friday, my sister's 50<sup>th</sup> birthday, the autumn weather was gentle and the space was quiet and respectful. We read to Jeremy, we sang to him, we wandered around tired, sad, wondering and waiting. That evening, at about 7:00 p.m., Jeremy's breath changed and I knew instinctively that this was it. He died peacefully, his wife holding his right hand and I holding his left, as I had promised him. His dad, stepdad, step-siblings and friends were all there, as were my sister and best friend. A helium balloon that had been floating about in the room for several days slipped out the window and floated skyward. Jeremy had a peaceful look on his face for the first time in months. His forearms felt solid, like always, although his gaunt face belied his frail state.

We send our sons off to war knowing they may not come back, or they may come back less whole than when they left home. We send them off to college, not knowing where they will go from there. But still, we have hope for their futures. We have hope for their lives. My son chose a dangerous path, an activist, he was threatened, shot at and he was often in jungles,

forests and other isolated locations. He was not safe. I knew this and feared for him, but at the same time I was proud. I was proud and I had hope for his future and the future of the world he was helping to create for his children.

Prostate cancer robbed me of that hope and that future. I learned in nursing school that prostate cancer is an "old man's disease." I know it is still perceived that way by most. About 1-percent or 300 men under the age of 40 die annually from prostate cancer. There should be none. If 300 doesn't sound like a large enough number for you to focus on increased research funding – if the 300 mothers like me who have to spend the rest of their lives wondering why they outlived their children aren't enough to motivate you to increase funding – please think about the 27,360 men who will die this year from prostate cancer. That makes prostate cancer the second-leading cause of male cancer-related death in the United States.

It is because of research that we know what does not work. There is no question that the PSA is not a good enough diagnostic tool, but it's currently all that we have. There is no question that there are aggressive cancers that we cannot "watch and wait". Prostate cancer kills more men than any cancer except lung cancer and has a mortality rate comparable to breast cancer in women.

What I have described to you today is the life of someone dying of a highly aggressive form of prostate cancer. His cancer was aggressive, but not rare. His own oncologist is the same age as Jeremy and in his practice has already treated – and lost – four patients under the age of 40. Too many YOUNG men are dying of prostate cancer. Too many MEN are dying of prostate cancer. In 2010, more than 27,000 men – fathers, brothers, husbands and sons, will die from prostate cancer in the United States. Perhaps if a more accurate test for prostate cancer existed, my child would have known about his cancer earlier and he could be here talking to you, himself; I'll never know because there just aren't enough funds to do all of the research that needs to be done. Perhaps, had the research been done on newer prostatectomy methods, my husband would not be impotent. Again, I do not know. All I know is the reality I deal with every day.

Each month I read another article about the inadequacy of the PSA as a screening test for prostate cancer and every day I wait for a better test. And every day I question why more and more funding seems to go to a few types of cancer – none of which are the largest killer of men in this country. It's one thing to criticize the test we currently have to screen men for this insidious killer – and quite another to find a viable solution. Unless you increase funding for the Prostate Cancer Research Program, I fear good research is being left unfunded.

No one will ever ask you to make the type of sacrifice that Jeremy made for prostate cancer. No one will ask you to put your families through the type of agony we came to know in watching our baby boy suffer through pain, embarrassment, shame and deterioration. I come to you today, representing my son's legacy, representing families who have lost loved ones and representing those who have not yet experienced the tragedy that is living through prostate cancer, to ask you to allocate additional funding to research this deadly disease. The sacrifice I ask of you is a painless one – and one that will make a difference in the lives of so many.

Thank you for your time.

House Appropriations Committee Defense Subcommittee

#### Witness Disclosure Form

Clause 2(g) of rule XI of the Rules of the House of Representatives requires nongovernmental witnesses to disclose to the Committee the following information. A non-governmental witness is any witness appearing on behalf of himself/herself or on behalf of an organization other than a federal agency, or a state, local or tribal government.

Your Name, Business Address, and Telephone Number: Sherry 5. Galloway Central NM City College (505)224-3080 Student Heal Th Ceinter 525 Buena Vista Drive. Albuguergue, NM 87106
1. Are you appearing on behalf of yourself or a non-governmental organization? Please list organization(s) you are representing.  myself and ZERO-The Project To End  Prostate Cancer
2. Have you or any organization you are representing received any Federal grants or contracts (including any subgrants or subcontracts) since October 1, 2007?
Yes No
3. If your response to question #2 is "Yes", please list the amount and source (by agency and program) of each grant or contract, and indicate whether the recipient of such grant or contract was you or the organization(s) you are representing.
Si

Please bring this original form on the day of your testimony.

Mr. DICKS. Thank you for your very compassionate statement. We appreciate it very much. Any questions? Thank you. Jonathan W. Simons, Prostate Cancer Foundation. Welcome.

Thursday, May 20, 2010.

#### PROSTATE CANCER FOUNDATION

#### WITNESS

### JONATHAN SIMONS, M.D., PRESIDENT AND CHIEF EXECUTIVE OFFICER, PROSTATE CANCER FOUNDATION

Dr. SIMONS. Thank you very much. I am Dr. Jonathan Simons. I am the President and chief executive officer of the Prostate Cancer Foundation. Nothing I can say can be as profound or as important as what Ms. Galloway said about her son. I am just speaking on behalf of the other 27,000 families that aren't here right now from 2009 that could not articulate the pain and the courage of the

experience of human prostate cancer.

În the last 22 years, I have been involved myself as an oncologist and the scientist funded by the American taxpayer in the care of over 1,000 prostate cancer patients. Today I lead a foundation that in its 17-year history has raised over \$400 million through the Prostate Cancer Foundation and actually funded 1,200 laboratories around the United States and America and the world in order to see a cure for prostate cancer and eradicate death and suffering. Our single and total goal is to put ourselves out of business as a foundation and end suffering from prostate cancer. What the committee doesn't know is that probably in the entire history you have been briefed—certainly Chairman Murtha was briefed this quietly—last year we reduced deaths from prostate cancer since projected from 1993.

In fact, a 30 percent reduction in deaths doesn't bring back Jeremy Galloway. But actually between 1993 and 2010, 180,000 American men have not died from prostate cancer who were projected to through a concerted effort of earlier detection, advocacy, better care and biomedical research supported by the defense appropriations committee, the National Cancer Institute, the Prostate Cancer Foundation. If we did nothing more except for never except the unacceptable, by 2013, with that reduction in death rate, we would have saved more American men's lives than have died in the history of American warfare on the battlefield from Bunker Hill to the Persian Gulf, which is actually a pretty remarkable statement, which I expect the committee has not heard either. But if you save the half a million American lives by 2039 with the current effort, you would still be losing an American man, whether young or old by your definition, every 19 minutes around the clock, 365 days a year.

Prostate cancer is a molecular form of terrorism and one of the greatest threats to the lives of the citizens of the American people. Now, it is true that prostate cancer is complicated. The committee will learn in July at a press conference we will hold that out of Ann Arbor there are 24 kinds of prostate cancer. The American people's investment in the human genome research has actually brought us a very interesting and complicated story. Unlike breast cancer, un-

like colon cancer, there are 24 kinds of prostate cancer. You can see it in the DNA and it is unique to prostate cancer. What would that mean? One, it would mean you have gotten a huge return on your investment out of this committee. Because after our foundation, which has put over \$8 million into it, the second leading funder of this research has been the Department of Defense, a congressionally mandated research program. The understanding of these genes has come from the National Cancer Institute and the NIH. It is a concert, a symphony concert of public-private partnership and biomedical research but where American people are giving philanthropically, paying taxes and actually medical scientists and patients like the Galloways and their families have all come together.

July of this year is one of the most important months in the history of over 50 years of concerted prostate cancer research. If there are 24 kinds of prostate cancer, what could that mean? Well, it could mean that there is a kind of prostate cancer that will never take your life and it will probably show up when you are 80. There is a kind of prostate cancer that can strike you down by 50. And actually there ought to be a test for everyone. When we indict the PSA test as being an insufficient test, which it is, we are actually only indicting our ignorance in our inability to sort of prosecute, so to speak, molecular diagnostics.

But now we have this ability and actually the DOD has the program in place, which I will discuss in a second, to actually fast forward progress. The other thing is I have no personal relationship with Don Berwick and CMS. But if I were running CMS in August, one of the most important contributions in diagnostics for cancer would have actually come out of the DOD. This test of 24 clona types or what kind of clone it is should change forever the future

of prostate cancer care.

I cannot speak to the pain and suffering of Sherry Galloway, but I can actually make a specific set of recommendations for the committee to consider. In my testimony, I have asked the committee to consider \$40 million over the additional 80 million to fast forward three things that would improve the lives of families like the Galloways in the future. One would be to simply put \$10 million into fast forwarding this new kind of test. It is cancer specific. It is prostate cancer specific and the DOD already has that infrastructure. Secondly, the committee has probably not been briefed, but there are four drugs up for FDA approval this year, Provenge, the vaccine which did not work for Jeremy Galloway, which was just FDA approved; Abiraterone, which was just in license by Johnson & Johnson up for phase III review.

There is also going to be Ipilimumab and there will be MDV3100. All four of these new medicines in phase III trials came through the Department of Defense prostate cancer clinical trials program in cities like Portland, Seattle, Baltimore, Ann Arbor. Actually through an early clinical trials network which is not supported by the National Cancer Institute but actually is funded by your appropriation, run by the doctors, the same doctors that are NCI cancer centers. This is widely unappreciated as well. But again, prostate cancer has been largely underappreciated in American life historically. All this being said, there is a lot more work to do in biomedical research. The public debate around PSA is really a debate

about a better test and I submitted the data to your taxpayers money and mine.

We actually have real hope for patients if we can fast forward that kind of research. What is interesting, though, is also that the DOD congressionally mandated research program asks scientists like myself and doctors like myself to do three things that are unusual in NCI funding or NIH funding which are largely under-

appreciated.

When I had the occasion to talk with Chairman Murtha last year, he squinted and he said why don't we know more about this. What he is referring to is that when you get a grant which I have gotten several in my career at Emory University, and before that on the faculty of Johns Hopkins from the DOD from this program, you are expected to provide milestones and actually endpoints and contingencies just in the same kind of culture that logistics and procurement are a part of life in the military.

And since I am the son of the greatest generation GI Bill father, I kind of got it although at first when I was asked to provide timelines for my research I said this is not your NIH as I knew it. If you want to put patients on clinical trials, if you want to study how vaccines work, if you wanted to define genes and you are held somewhat accountable to simply report your progress, it has turned out that most cancer scientists and physicians like myself enjoy it, welcome it because the program also incentivizes high-

er performance.

It is the first Federal program for biomedical research where actually some of the culture of excellent tactics in the field are rewarded in cancer research. Completely unexpected as a consequence of giving Captain Kami or others actually in the Pentagon

control the program. It is not a workaround.

It is a new invention in cancer research. And I would recommend to the committee that it ought to be reviewed as it actually may be better practice for certain aspects of our NIH right now. Lastly, with the 24 kinds of prostate cancer, there are a significant number of new medicines that might be developed for a Jeremy Galloway. In fact, if you have a disease that is now 24 diseases but it looks like one under the microscope, it is no different than saying if you have 24 diseases you have 24 treatments. For our biotech and pharmaceutical industry there is a huge opportunity and most practically in terms of asking for 20 million to fast forward new medicines, 10 million for a new better test than the PSA, 10 million for additional clinical trials—yeah, go ahead.

Mr. DICKS. You have 1 minute.

Dr. SIMONS. I have got it. In addition to doing all these things, I cannot emphasize enough the courage of the patients and families that participate in these clinical trials, Mr. Chairman. Without DOD funding, the progress I reviewed for you today would not have happened. Thank you.

Mr. DICKS. Thank you. Another very compelling case.

Ms. KILPATRICK. Mr. Chairman. Mr. DICKS. Yes, Ms. Kilpatrick.

Ms. KILPATRICK. Thank you, Mr. Chairman. Why would the National Cancer Institute not approve a DOD project for their doctors

and researchers to participate in as well? Is it competition or is it who is the best or-

Dr. Simons. It is just that NCI doesn't fund it. In prostate cancer, early clinical trials, there is not a program at NCI for early-

Ms. KILPATRICK. So they don't-

Dr. SIMONS. The DOD funds it.

Ms. KILPATRICK. Right. So they fund it, but you ought to be partners in the illness because it is catastrophic.

Dr. Simons. I agree, Ms. Kilpatrick. But the last time that prostate cancer research was reviewed, I was on the panel, was in the Clinton administration for coordination between the DOD. After 9/ 11, a lot of things happened in this country. But a research strategy for American medical research did not take place in the lastwe haven't—our government hasn't actually looked at our strategy in prostate cancer for 10 years.

Ms. KILPATRICK. Thank you.
[The statement of Dr. Simons follows:]



STATEMENT BY

JONATHAN W. SIMONS, MD

BEFORE

HOUSE APPROPRIATIONS COMMITTEE
DEFENSE SUBCOMMITTEE
U.S. HOUSE OF REPRESENTATIVES

SECOND SESSION, 111th CONGRESS

MAY 20, 2010

Chairman Dicks, Ranking Member Young and distinguished members of the Subcommittee: thank you for the opportunity to appear here today. My name is Jonathan Simons, and I am a prostate cancer oncologist and physician-scientist. I currently serve as the President and Chief Executive Officer of the Prostate Cancer Foundation (PCF). PCF is the world's leading private funder of prostate cancer research. In the past 17 years, PCF has raised over \$400 million<sup>2</sup> and funded an exceptionally innovative set of research projects that have changed prostate cancer research and improved patient care.

PCF is not just a biomedical research funding charity. PCF board members led the bi-partisan advocacy effort with prostate cancer survivors to create the Department of Defense Prostate Cancer Research Program (PCRP). Congress approved this DOD program of prostate cancer research in late 1996.<sup>3</sup> Several of my own patients contributed hundreds of hours to strengthen this unique partnership between Congress, the military, prostate cancer survivors, clinicians and scientists. As a consequence of their collective efforts, since 1997 Congress has appropriated a total of nearly \$1.1 billion (B) in funding for prostate cancer research, including the fiscal year (FY) 2010 appropriation of \$80 million (M).<sup>4</sup>

The Department of Defense Prostate Cancer Research Program has played a pivotal role in accelerating progress for patients. It would be hard to overstate its impact. Let's make it simple. Fewer US men are dying of prostate cancer than the day the Defense Department's program of prostate cancer research was created. In fact, there has been a 30 % reduction in US deaths from prostate cancer in the last decade from the projections of 1996. <sup>5</sup> That is the largest reduction of projected deaths for cancer for the "tragic big four" cancers: lung, breast, colon and prostate cancer. If you do the arithmetic using statistics on incidence rates and survival, 187,1326 US men who were projected to die from prostate cancer from 1993 to 2000 either were cured or lived with prostate cancer. While many factors including research progress, better patient education, earlier detection, better care have all been

<sup>&</sup>lt;sup>1</sup> For more information about the Prostate Cancer Foundation, visit http://www.pcf.org

<sup>&</sup>lt;sup>2</sup>Data Sources: Prostate Cancer Foundation, "About PCF: Milestones,"

http://www.pcf.org/site/c.leJRIROrEpH/b.5880617/k.27D7/Milestones.htm

<sup>&</sup>lt;sup>3</sup> Moore, Geoffrey E. A Call to Action (Santa Monica: The Prostate Cancer Foundation, 2005),53

Data Source: CDMRP Prostate Cancer Research Program http://cdmrp.army.mil/pubs/pips/pcpip.pdf
 Data sources: U.S. Cancer Statistics Working Group. United States Cancer Statistics: 1999–2006

Incidence and Mortality Web-based Report. Atlanta (GA): Department of Health and Human Services, Centers for Disease Control and Prevention, and National Cancer Institute; 2010. Available at: http://www.cdc.gov/uscs. American Cancer Society Statistics, 2007, 2008, 2009

http://www.cancer.org/docroot/stt/stt\_0.asp

<sup>&</sup>lt;sup>6</sup> See Appendix 1

important to saving lives, this kind of progress in cancer research is unprecedented and largely underappreciated in oncology and in American life.

Let us say we maintain the status quo, having reduced deaths-but not eliminated them-and that we do nothing further to fast-forward research in earlier detection, prevention, and targeted new medicines that eradicate metastatic disease. By 2039 all of us involved in prostate cancer research funding and care will have saved 576,4867 US men from lethal prostate cancer deaths. That figures represents a greater number of US men whose lives have been saved from strides against a common cancer—than all the lives lost in all US battle deaths from Bunker Hill through the Civil War, WWII, up until the Persian Gulf War.8 At the same time, without doing anything further to amplify our research efforts, we will still lose a US man to prostate cancer every 19 minutes around the clock in 2039 - exactly as we are in 2010. 9 For anyone considering the favorable impact of appropriations in saving the lives of citizens, our status quo could not be considered satisfactory. An estimated 27,000 US men will die from lethal prostate cancer this year, while two million American men and their families battle this disease. Even as we continue to push the death toll downwards, prostate cancer still occurs in 1 in 6 American men. We can call prostate cancer research in the past decade measurable, dramatic, and palpable medical research progress, but no one would call it an unconditional victory.

Towards the ultimate goal of conquering prostate cancer as a cause of death, in my testimony today, I am respectfully asking the subcommittee to consider increasing the \$80 M per year by an additional \$40M in three high-priority areas for intensified research investment. My subject will be not only the real progress we have made, but also the positive steps we need to take to raise the flag of victory, and bring about a day when death and suffering from prostate cancer have been eradicated. In brief, we need more research funding to

 identify new prostate-cancer specific biomarkers that could one day make the PSA test obsolete;

26 27

28

29

30

31

32 33

34

35 36

37

38 39

40

41

42 43

44

45

46 47

48

49 50

51

52

<sup>&</sup>lt;sup>7</sup> See Appendix 1

<sup>8</sup> Data Source: PBS "U.S. Casualties in Major Wars"

http://www.pbs.org/greatwar/resources/casdeath\_pop.html

Data Source: The latest American Cancer Society estimates for prostate cancer in the United States are for 2009: about 192, 280 new cases of prostate cancer will be diagnosed and 27,360 men will die of prostate cancer: "What are the key statics about prostate cancer"

 $http://www.cancer.org/docroot/CRI/content/CRI\_2\_4\_1X\_What\_are\_the\_key\_statistics\_for\_prostate\_cancer\_36.asp~See~Appendix~2$ 

- fast-forward discovery of new targeted medicines and vaccines and antibodies against the 24 distinguishable types of human prostate cancer;<sup>10</sup> and
- increase access of US men, especially the underserved who carry an undue disease burden, to innovative new experimental treatments in early clinical trials by creating a better geographical distribution of clinical study centers.

53 54

55

56 57

58

59

61

62

63 64

65

66 67

68

69 70

71

72

73

74

75

76

77

78

79

80

81

American men are told that perhaps 40 percent of surgery and radiation procedures conducted are not necessary in curing a patient's prostate cancer, but we do not yet have a ideal way of discerning which man has which type of cancer. Increased DOD support, in partnership with the current NCI basic research investment and biomedical funding foundations, is vital to fast-forwarding research progress addressed to what is perhaps the largest US public health comparative effectiveness question in adult oncology. That question is: on biopsy, which patient with prostate cancer has a lethal disease necessitating surgical or radiation therapeutic intervention with curative intent and, on the other hand, which patient can be spared the morbidity of surgery or radiation and saved from the primary treatment of a life-threatening neoplasm. Our field needs new funding on research in unique genetic, blood and tissue-based "actionable" biomarker approaches to defining men with early-stage prostate cancer who are appropriate for watchful waiting as opposed to surgery or radiation. In other words, we need to identify new biomarkers that could one day make the PSA test obsolete. PCF has estimated that overtreatment of prostate cancer may cost over \$1 billion<sup>11</sup> each year in the United States - not to mention the significant emotional toll on men who experience side-effects from unneeded treatment.

Lately, public debate has focused mostly on the limitations of the PSA blood test as "the problem," but we have heard very little about the "solution," the research task ahead to create a better test for at-risk patients using our new genomic understanding of prostate cancer. Although researchers have an honest debate on the usefulness of PSA testing for patients, there is unanimous agreement that that we need a more sophisticated and cancerspecific means of detection. The American Cancer Society has stepped forward to respond

<sup>10</sup> See Appendix 3

<sup>11</sup> Prostate Cancer Foundation "Experts to Men: Controversy Aside, PSA Test Can Still Save Your Life" http://www.pcf.org/site/c.leJRIROrEpH/b.5957251/k.9A2B/Experts\_to\_Men\_Controversy\_Aside\_PSA\_Test\_Can\_Still\_Save\_Your\_Life.htm

to the problem of overtreatment by revising its prostate cancer screening guidelines and NCI has notably funded intense basic science on prostate cancer biology; 12 however, neither has made adequate provisions for a "Manhattan Project" type private-public research effort to fast-forward a better test than PSA to the clinic.

For example, the American Cancer Society, kindly provided the Prostate Cancer Foundation with a listing of current ACS prostate cancer grants in force. An impressive \$29.6 million<sup>13</sup> has been committed to multi-year research projects on prostate cancer research. Of these grants, only \$4.1 million<sup>14</sup> in ACS funding addresses finding a better means of detection. This research commitment amounts to less than half of one percent of the \$1 billion<sup>15</sup> in ACS 2009 expenditures. We gratefully acknowledge the American Cancer Society's critical program services to support the men and women battling all cancers. At the same time, we must all recognize that we need not only to improve screening guidelines, but also to model our research leadership on the exceptional research leadership shown by the DOD CDMRP. Historically, CDMRP has led the effort to prioritize the need to fast-forward new medicines through the clinical, and they have also supported efficient and effective university research project management.

Why would the Defense Departments PCRP be a "part of the future PSA test solution?" Actually, it is already part of the solution. PCRP currently supports research testing the biotechnology of circulating tumor cells as a new class of biomarkers. In fact, the ability to diagnose a lethal prostate cancer at the molecular level from indolent prostate cancer is one of two goals stated in PCRP's programmatic vision for FY10 (the other stated goal is the development of effective treatments for advanced disease). 16 The DoD PCRP has a mechanism that is not duplicative at all with the National Cancer Institute through its "first in man" clinical trials consortium to identify biomarkers that have the potential to help guide therapeutic intervention. In fact the DOD PCRP fills a research space that the National Cancer Institute has not substantially entered.

82 83

84 85

86

87

88

89

90 91

92

93

94 95

96

97

98

99

100

101

102

103 104

105

106 107

<sup>12</sup>http://www.cancer.org/docroot/NWS/content/NWS\_1\_1x\_Revised\_Prostate\_Cancer\_Screening\_Guideli nes What Has--and Hasnt--Changed.asp

Data Sources: ACS List provided by Otis Brawley, MD, CMO in e-mail message to Jonathan W. Simons, MD. See Appendix 5

14 See note 13

<sup>15</sup> American Cancer Society 2009 Annual Report

http://www.cancer.org/docroot/AA/content/AA\_1\_7\_American\_Cancer\_Society\_2009\_Annual\_Report\_1

<sup>.</sup>asp <sup>16</sup> See note 16 above

New, fundamental knowledge has emerged in the last few months, providing the first comprehensive molecular classification system for prostate cancer. This system changes everything. At the DNA-level, 24 kinds of human prostate cancer were found in the clinic. With a decade of lead funding from PCF and key funding from the Department of Defense and the National Cancer Institute, Professor Arul M. Chinnaiyan, M.D., Ph.D. and his team at the University of Michigan, Ann Arbor developed new software and molecular probes enabling them to identify the "Achilles heels" of prostate cancer, gene fusions responsible for 24 clonal types of prostate cancer. At PCF, we propose that the US needs more robust research funding to develop new medicines designed specifically to interdict against the survival of each of these 24 types of prostate cancer clones based on investigations of how these "fusions" work. In charting the course for a research and development pathway towards new prostate cancer medicines, we look to targeted anti-DNA fusion medicines like Gleevec (imatinib), a therapy which targets a gene fusion that has dramatically improved the survival rates of patients with Chronic myelogenous leukemia cancers.

We need a "Manhattan Project of Medicines against Prostate Cancer DNA Fusions." My Foundation has pledged to raise additional millions around the problem, but we cannot do it alone. These new anti-fusion therapies would not resemble last century's chemotherapy. They would be personalized, based on working against the genetic code wiring diagram of what makes a prostate cancer cell run and what makes it lethal. The Department of Defense can play a key role in priming the pipeline in NCI cancer centers strong in prostate cancer research and that discovery pipeline could then flow into biotech and pharma.

Before I discuss the third clinical research area where increased funding is needed, I'd like to provide some historical background on the existing public-private partnership between the Department Defense Prostate Cancer Research Program and the Prostate Cancer Foundation to illustrate how our work together has amounted to new FDA drug approvals for men with advanced prostate cancer. The PCF has been philanthropically active in trying to venture fund US clinical research for prostate cancer drug development since our founding. In 1995, the PCF board authorized forming a PCF Therapy Consortium at over \$1M per year. It subsequently became a network of US academic medical oncology clinical investigators at NCI cancer centers involved in early clinical trials of new treatments for advanced prostate cancer where the NCI had no mechanism of funding. A milestone in private-public partnership was achieved in 2005 when the DOD Prostate Cancer Research Program, influenced by multiple discussions with PCF and PCF Therapy Consortium Principal

143 144

145

146 147

148

149

150

151

152

153

154 155

156

157

158 159

160 161

162

163 164

165

166

167

168

169

Investigators, recognized the early achievements of the PCF Therapy Consortium. The DOD decided to provide a \$10 million grant over three years to develop the clinical trial systems for further prostate cancer drug development, representing a 2-fold increase in total therapeutic clinical investigation funding in 2005. This DOD consortium is called the Prostate Cancer Clinical Trials Consortium (PCCTC) and was initially funded in January, 2006.<sup>17</sup>

Today, both the PCRP and PCF continue to sponsor this congressional directive to fund the Prostate Cancer Clinical Trials Consortium (PCCTC), which is now a robust network of 13 institutions dedicated to rapid accrual to early-phase, multicenter studies in prostate cancer. Each year, PCF, as a partner, funds \$3.2 million of the consortium and the DOD funds \$5 million of the consortium. The DOD 2005-2013 total commitment to the Consortium is \$41.3 million. Study sites receive \$300,000 per year. The Coordinating Center, which is Memorial Sloan-Kettering Cancer Center, receives \$1.8 million per year. 18 In this way, the PCCTC constitutes the world's most comprehensive clinical trials network for new medicines for advanced prostate cancer. Over 1,700 patients have been recruited through the network, and the Consortium has tested over 60 novel early-phase studies investigating over 30 new therapies for prostate cancer. 19 Of new therapies tested in the Consortium, three are currently in the final stage of FDA review for approval, and the Provenge vaccine has recently been approved. All four of these new medicines saw their first testing in men with prostate cancer through the DOD-PCF partnership for early clinical trials. These promising new therapies for patients would not have been moved forward without the early clinical trials mechanism in place through PCRP. In this unique respect, this subcommittee oversees—through direction of funding administered through the DOD entry of new medicines into the clinic for men with advanced prostate cancer.

What was going on before this network was formed? Little. Prior to the Consortium formation, fewer than 3 early phase clinical trials were even conducted per year in prostate cancer research. In the late 1990s, the trials performed were often single-institution trials, which were slow to be completed. Additionally, complex administrative processes in NCI-sponsored cooperative clinical trial groups often slowed activation of trials, a problem that

<sup>&</sup>lt;sup>17</sup> PCF Therapy Consortium Strategic Plan (2008)

<sup>&</sup>lt;sup>18</sup> These numbers are total costs and therefore include direct and indirect costs

<sup>&</sup>lt;sup>19</sup> House Committee on Oversight and Government Reform, Prostate Cancer: New Questions About Screening and Treatment, 111th Cong., 2nd sess. Carolyn Best, PhD

has persisted. The Institute of Medicine in 2010 recently reported that, "the NCI program is falling short of its potential to conduct the timely, large-scale, innovative clinical trials needed to improve patient care."

Through the unique partnership of the Military, Congress, and the public, the Prostate Cancer Clinical Trials Consortium of the DoD has achieved an unmatched level of "patients on trial" and now "trials in front of the FDA" success. As a funding mechanism, the PCRP, with its inextricable ties to patient advocates, has focused on reducing bottlenecks, cutting down delays as paperwork is exchanged, and accelerating the responsible selection, prioritization, and clinical evaluation of new drug candidates for treatment of advanced prostate cancer. Key improvements have been made in the areas of cross-institutional communication, project management, informatics systems, contracting, shared information systems, reporting of results, and findings regarding the speed of publication and dissemination of clinical research. It is a model of its kind that we would respectfully suggest the National Cancer Institute might study.

At this time, I am proposing that the Subcommittee consider increasing resources for the expansion of existing study centers in the Consortium beyond 13 institutions. This would not only be a priority for increasing the output of clinical trial results, but also for reaching underserved prostate cancer patients who do not have access to new and innovative experimental treatments. A better geographical distribution of centers is needed, especially for those who experience a greater burden of prostate death and suffering. Increased access to the experimental treatments offered by clinical trial centers will not only alleviate the burden on currently underserved populations through the benefit to the individual patients granted access to the trials, but also through the resulting research that can be used to understand the epidemiological differences observed in disproportionately affected populations.

The drive to increase the geographical distribution of the consortium's centers is in harmony with current DOD funded initiatives to serve underserved populations, such as the landmark study of the North Carolina-Louisiana Prostate Cancer Project (PCaP), which has created a critical mass of research for disproportionately affected prostate cancer patients such as African American men. Through this study, leading institutions in New York, North Carolina, and Louisiana have been responsible for creating and maintaining the largest

<sup>&</sup>lt;sup>20</sup> A National Cancer Clinical Trials System for the 21st Century: Reinvigorating the NCI Cooperative Group Program Released: April 15, 2010 http://www.iom.edu/Reports.aspx

sample repository of specimens from underserved prostate cancer patients.<sup>21</sup> This bank of specimens will support research that aims to better serve this population for a decade. With additional resources, the Clinical Trials Consortium will, like PCaP, be poised to make a major impact on the lives of underserved prostate cancer patients.

203 204 205

206

207

208

209

210 211

200 201

202

Before I summarize, I'd like to take a moment to bring your attention to The Center for Prostate Disease Research (CPDR) at Walter Reed, which was established in 1991 by the United States Congress to provide state-of-the-art translational clinical research and patient care for 7,900 plus military beneficiaries annually, including 300 newly-diagnosed cases of prostate cancer each year.<sup>22</sup> Due to the equal access system in the military, and the military's emphasis on yearly exams, CPDR diagnoses significant prostate cancer in men between 40 and 50 years of age. The Center for Prostate Disease Research maintains a clinical trial portfolio treating all stages of prostate cancer from prevention to late stage-disease.<sup>23</sup>

212 213 214

215

216

217

218

219

220

221

The CPDR at Walter Reed is a national resource. It has also been the primary resource of clinically documented biospecimens (blood and urine) with an average of a 7year follow-up history for all patients. The patients' specimens are consented and are under protocols in the CPDR Basic Science Research Program (BSRP). Biospecimens are also shared under protocols with outside collaborators in cooperative research projects. These state-of-the-art integrated resources combined with high throughput technologies have led to discovery of several new prostate cancer associated genes with biomarker or therapeutic potential. This may be one of the most valuable "banks" to confirm identification of a better biomarker than PSA, and it was funded by the Department of Defense.

222 223 224

225

226 227

228

At the Walter Reed Army Medical Center (WRAMC) alone, 95% of men being treated for prostate cancer participate in the CPDR National Database. Many of these CPDR studies have influenced how prostate cancer is managed and treated on national and international levels. The CPDR Clinical Research Center maintains a clinical trial portfolio treating all stages of prostate cancer from prevention to late stage-disease. The CPDR is

<sup>&</sup>lt;sup>21</sup> http://www.ncla-pcap.org/layabstract.html

<sup>&</sup>lt;sup>22</sup> The Center for Prostate Disease Research (CPDR) – USUHS (2010) "Selected Accomplishments" http://www.cpdr.org/ <sup>23</sup> See note 22

credited with over 300 research publications, numerous awards, and patents. Among scientific breakthroughs, the CPDR team has been at the forefront of the discovery of ERG alterations as the most prevalent oncogenic defect described thus far in prostate cancer. <sup>24</sup> Noteworthy is the fact that CDPR is integrated in an extramural patient care and research collaboration with the National Cancer Institute (NCI) and provides a unique interface for both programs.

At this time, I would like to suggest that the subcommittee invite Col. David G. McLeod, M.D., J.D., USA (ret) to tell you what the Walter Reed Army Medical Center has underway to address solving the prostate cancer problem. Dr. McLeod is the Director of the Center for Prostate Disease Research, a congressionally directed medical research program, and is the former Program Director in Urology and Chief of Urologic Oncology at Walter Reed Army Medical Center, Washington, DC. I have been inadequate in highlighting the assets at Walter Reed that could be brought together in a "Manhattan Projects" for a better test than PSA and for discovering new medicines targeting the DNA fusions of prostate cancer.

In my 22 years as a medical scientist and medical oncologist, I have been involved in the care of over 1,000 patients. Today, as President and CEO of PCF, I am mindful of all our sacred responsibilities to approximately two million American men affected by prostate cancer to use our best science and common sense in public policy. So I have tremendous respect for what you and your staff do through the Subcommittee as you serve the entire American public. You learn courage from the patients and families. You also learn to a sense of gratitude and appreciation for the opportunity to perform research on behalf of the American people when they fund you. I was taught at Johns Hopkins always to remember that research money granted to us was never ours. We understand in the research community of which I am a part that the money you appropriate is the people's money, and that it is precious and finite. So I want to thank the Subcommittee for supporting the responsible use of the people's money in the form of \$80M per year to support hundreds of researchers, including my colleagues and myself, in our effort to accelerate medical research solutions for prostate cancer patients.

<sup>&</sup>lt;sup>24</sup> See note 22

<sup>&</sup>lt;sup>25</sup> ACS Statistics 2009

I was also taught that, if I ever had the opportunity to take a small role in the formation of public policy, that you first "tell them," but then I was to "tell them again, what I tried to tell them." So, now that I have told you where the opportunities are, please bear with me while I "tell you again" succinctly four ideas that I think could change the course of medical history.

First, I hope I have been able to outline how stunningly well the Department of Defense Prostate Cancer funding has been spent for our people with prostate cancer since 1997. Fewer men have died from prostate cancer since DOD funding started and we have more US men on early phase I/II clinical trials thanks to the DOD's invaluable support – and with respect – in the absence of a major NCI investment in early clinical trials – than anytime in the history of American cancer research. As a direct consequence of the DOD's 2005-2010 investment in prostate cancer clinical research, we have I FDA approval and 3 more unique classes of medicines (Abiraterone, MDV3100, and Denosumab) for advanced prostate cancer disease going in front of the FDA this year. This has only been possible thanks to the DOD Prostate Cancer Clinical Trials Consortium's capacity for fast-forwarding clinical research. These trials were led by US oncology experts who enabled American men to receive treatments in the following cities where there were clinical study centers: New York, NY, Ann Arbor, MI, Detroit, MI, Portland, OR, Boston, MA, Chicago, IL, New Brunswick, NJ, Houston, TX, Seattle, WA, Baltimore, MD, Madison, WI, Durham, NC, and San Francisco, CA.

Second, I would be remiss not to remind you that many US cities with populations over a million—such as Dallas, Philadelphia, and Los Angeles—still do not have federal support at the level needed to permit fast-forwarding the testing of promising new medicines in early clinical trials for advanced prostate cancer. One of the greatest problems that the field of US prostate cancer oncology now faces is limited access to trials. There are not enough great clinics with open doors that a man with metastatic prostate cancer and his family can walk through to get a new investigational medicine. Incidentally, we solved that access infrastructure for new medicines in early clinical trials for American children with leukemia in the 1970s. With respect, we just have not finished the job for their fathers and grandfathers; but the PCF in partnership with the DOD got us going in the right direction in the late 1990s. I am happy to provide the Subcommittee with additional data and detail. As a

<sup>&</sup>lt;sup>26</sup> See Appendix 2

cancer scientist I ask to be forgiven for providing you not only with footnotes with all of the sources of the facts I provided today, but also with additional information as an appendix.

Third, if past is prologue, a modest increase in prostate cancer research funding, to about that currently spent for breast cancer funding, <sup>27</sup> could save the lives of thousands of men in the years ahead. Above the \$80M of last years appropriation, I understand that \$40 million of additional appropriation is "real money" and so when I refer to it as a modest increase, I mean in proportion to the number of lives that will be saved by making this investment. Of course you hear that all the time—so what is different about prostate cancer research? The main difference is that it is working to save lives we can measure. It is a fact that since the entrance of DOD funding for prostate cancer research in the public-private partnership with the advocacy of patients and the PCF, we actually have reduced deaths from 1993 projections by an estimated 187,132 American men's lives.<sup>28</sup>

Oncology is a hopeful field, filled with both hopeful science and family tragedies and triumphs. I am not here promising a cure by a certain date, but, in the public record, I am staking my entire scientific and medical reputation to say that with the discovery in Ann Arbor of the 24 clonotypes from "fusions of DNA" in human prostate cancer cells, and the genetic blueprints of the engines that allow those cells to survive in metastatic sites and take the lives of men from men, we have the harbinger of solutions that will extend the lives of people who were told they were terminally ill.

I recognize in research we often sound entitled, so it is with great humility now that I say that we really do know in research today what to do next with what we have learned from Ann Arbor. We know what the DOD could do expertly, with the expectations of milestones and support of logistics to get work done, and with the support of project management to propel it to the clinic and fast-forward progress. Our field of oncology really has done that with Chronic myelogenous (or myeloid) leukemia (CML)—a disease of DNA fusions—in your lifetime and mine, right through the tumult of the post-9/11 world. If you remember nothing else, remember that human prostate cancer, like CML, has been taken from a fatal disease to a chronic disease in under a decade. It is also a disease of chromosomal diseases. In a way, human prostate cancer may be a leukemia engine we can treat in the chassis of a prostate cancer cell. I am fairly certain we would not have known that by now, were it not for the DOD research support.

<sup>27</sup> See Appendix 6

<sup>&</sup>lt;sup>28</sup> See Appendix 1

321	
322	Fourth and finally, if we now show concerted action, with the game-changing
323	discoveries from the University of Michigan and other DOD funded centers, we can reduce
324	the prostate cancer death rate to under a thousand deaths per year from 27,000 per year today.
325	But accomplishing that will take a public-private partnership that leverages all the effort.
326	The fulcrum—for the high-risk lead foundation research we at PCF support, and the NIH
327	basic science we all support as taxpayers—is the DOD investment in the existing
328	infrastructure the Department of Defense Prostate Cancer Research Progress has created. We
329	would advocate that this era of fiscal responsibility calls upon not only to maintain
330	investment at the current level, but also to direct greater resources to solving the problem of
331	minority disparities in incidence and mortality, overtreatment due to imperfect diagnostic
332	tests, and more targeted therapies around the 24 clonal subtypes of prostate cancer.
333	
334	My respectful recommendation is that the Subcommittee should consider the courageous step
335	forward in increasing PCRP research funding in the next fiscal year by \$40 million in the
336	following three ways:
337	
338	1) \$10 million to support biomarker research for a better PSA test given the Ann
339	Arbor discovery and other new prostate cancer unique candidate biomarkers
340	2) \$20 million to further accelerate university laboratory discovery of agents that would
341	be matched against 24 distinguishable types of human prostate cancer
342	3) \$10 million to support the expansion of centers in the Therapy Consortium and the
343	recruitment of more patients with particular emphasis in reaching more US cities and
344	the underserved patients, especially African American and other minority populations
345	through the existing NCI Cancer Centers system.
346	
347	Mr. Chairman and Members of the Subcommittee, thank you for the opportunity to serve as a
348	public witness today. I would be pleased to respond to any questions you may have.

#### Appendix 1

1993 NCI Data on ACS Statistics

$$\frac{\binom{\text{Death}}{\text{Year}}}{\binom{\text{Incidence}}{\text{Year}}} = 0.212$$

2009 ACS Statistics

$$\frac{\binom{\text{Death}}{\text{/}_{\text{Year}}}}{\binom{\text{Incidence}}{\text{/}_{\text{Year}}}} = 0.142$$

1993-2009 Incidences \* .212 = projected # deaths at 1993 rate

Projected # of deaths - Actual Deaths = Lives saved due to reduction in death rate

=187,132 US Men saved 1993-2009

576 039 (battle deaths US Wars) - 187 132 (prostate cancer live saved from 1993) = 388 907

 $40\ 786.66664 - 27\ 360 = 13\ 426.6666$  Difference between actual deaths in 2009 and deaths had death rate remained at 1993 level

388 907 / 13 426 = 28.9667064

13,426 \* 29 = 389,354

389,354 + 187,132 = 576 486

576, 486 = US men projected to die alive in 2039, if death rate reduction by 30% remains the same

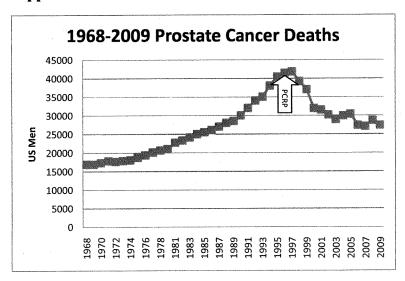
387

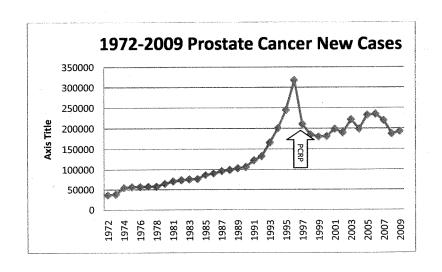
Appendix 2a: Table of Prostate Cancer New Cases and Deaths

		New
<u>Year</u>	<u>Deaths</u>	Cases
1968	16848	
1969	16836	
1970	17252	
1971	17772	da a company de la company
1972	17600	36000
1973	17800	38000
1974	18000	54000
1975	18700	56000
1976	19300	56000
1977	20100	57000
1978	20600	57000
1979	21000	64000
1981	22700	70000
1982	23300	73000
1983	24100	75000
1984	25000	76000
1985	25500	86000
1986	26100	90000
1987	27000	96000
1988	28000	99000
1989	28500	103000
1990	30000	106000
1991	32000	122000
1992	34000	132000
1993	35000	165000
1994	38000	200000
1995	40400	244000
1996	41400	317100
1997	41800	209900
1998	39200	184500
1999	37000	179300
2000	31900	180400
2001	31500	198100
2002	30200	189000
2003	28900	220900
2004	29900	198100
2005	30350	232090
2006	27350	234460
2007	27050	218890
2008	28660	186320
2009	27360	192280

National Center for Health Statistics - Mortality Data NCI Factbooks (Original Data from ACD) 2007,2008,2009 ACS Cancer Statistics

Appendix 2b: Charts - Prostate Cancer Deaths and New Cases

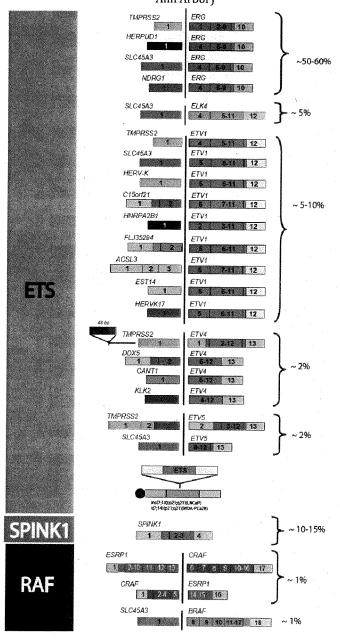




#### **Appendix 3: 24 Types of Prostate Cancer in Clinic**

Figure provided by Arul M. Chinnaiyan, M.D., Ph.D (University of Michigan, Ann Arbor) to Jonathan Simons, M.D. (Prostate Cancer Foundation)

Schematic Developed by Christopher Maher, Ph.D. (University of Michigan, Ann Arbor)



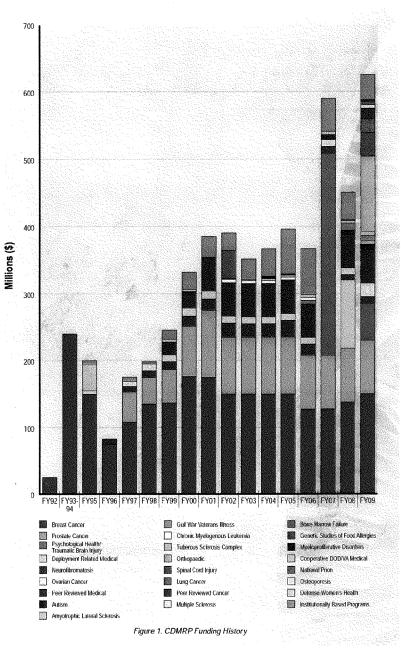
Title	Institution	Award Code	Period	Award	
Prostatic Neuroendocrine Differentiation in Different Ethnic Groups	University of Southern California	RSG-06-104-01	07-01-06 to 06-30-	\$	720,000
TR4 Orphan Receptor, A Longevity Assurance Gene in Cancer	University of Rochester	RSG-06-123-01	10 07-01-06 to 06-30- 10	\$	720,000
Regulation of Cell Proliferation and Differentiation by SWI/SNF and Gem	Washington University, St. Louis	RSG-06-148-01	07-01-06 to 96-30- 10	S	710,000
Functional Analysis of a Novel Tumor Suppressor, BRITT in Prostate Cancer	M.D. Anderson Caneer Center, University of Texas	RSG-06-192-01	07-01-06 to 06-30- 10	S	949,000
Novel Mechanisms Regulating Integrin Trafficking in Migrating Tumor Cells	University of Iowa	RSG-07-043-01	01-01-07 to 12-31- 10	S	703,000
Vascular Endothelial Growth Factor-C and Prostate Cancer	Mayo Clinic Rochester/Foundation	RSG-07-044-01	01-01-07 to 12-31- 10		720,000
ntegrin alpha 5 and Notch Signaling During Zehrafish Somite Morphogenesis	Yale University	RSG-07-050-01	01-01-07 to 12-31- 10	\$	720,000
Regulation of Hedgehog Distribution and Signaling	Cincinnati Children's Hospital Medical Center	RSG-07-051-01	01-01-07 to 12-31- 10	S	720,000
Activation of the Hedgehog and Wnt Pathways in Tumorigenesis	University of Texas Southwestern Medical Center, Dallas	RSG-07-062-01	01-01-07 to 12-31- 10	s	667,000
Genetic Regulators of Transcriptional Signatures in Cancer	Stanford University	RSG-07-084-01	01-01-07 to 12-31- 10	5	770,000
Mechanisms of Regulator of G-protein Signaling 2 (RGS2) in Prostate Cancer	Creighton University	RSG-07-090-01	01-01-07 to 12-31- 10	\$	720,000
Neuroendocrine Differentiation and IL-8 Signaling in Prostate Cancer	University of Rochester	RSG-07-092-01	01-01-07 to 12-31- 10	\$	800,000
Nutrition, Stem Cells and Cancers: The Drosophila Ovary as a Model System	Vanderbilt University Medical Center	RSG-07-182-01	07-01-07 to 06-30- 11	S	720,000
Effector T Cell Function in Androgen- independent Prostate Cancer	Wake Forest University	RSG-07-196-01	07-01-07 to 06-30- 11	S	720,000
Understanding Cellular Epigenetic Heterogeneity in Cancer	University of California, Los Angeles	RSG-07-206-01	07-01-07 to 06-30- 11	\$	800,000
Androgen Signaling Axis as Targets of Scienium Action	Tulane University	RSG-07-218-01	07-01-07 to 06-30-	\$	707,000
Directed Evolution of Cancer Ligands	Vanderbilt University Medical Center	RSG-07-238-01	07-01-07 10-06-30- 11	\$	720,000
Hedgehog Signaling and Vertebrate Germ Cell Migration	Stanford University	RSG-08-041-01	01-01-08 to 12-31- 11	\$	709,000
Dendritic Cell Surface Calreticulin/TLR4 as Receptors for NY-ESO-1	University of California, Los Angeles	RSG-08-070-01	01-01-08 to 12-31- 11	\$	919,000

					19,637,500
Health Care Access and Prostate Cancer Treatment in North Carolina: HCaP- NCUniversity of North Carolina, Chapel Hill	University of North Carolina, Chapel Hill	RSGT-08-008-01	01-01-08 to 12-31- 11	S	926,000
Physician Variations in Care and the Impact on Cancer Care Disparities	University of California, Los Angeles	RSGT-07-231-01	07-01-07 to 06-30- 11	\$	767,000
Overcoming Pro-survival Akt Through Tumor Suppressor Control of Metabolism	University of Cincinnati	RSG-08-293-01	07-01-08 to 06-30- 12	s	720,000
Mechanism of ATF5 Pro-survival Function in Cancer Cells	Pennsylvania State University	RSG-08-288-01	07-01-08 to 06-30- 12	\$	720,000
The Role of the WWP1 E3 Ubiquitin Ligase in Human Breast Cancer	Albany Medical College	R5G-08-199-01	07-01-08 to 06-30- 12	·s	960,000
Improving Cancer Radiotherapy by an SR- A-silenced Dendritie Cell Vaccine	Health Research Inc., Roswell Park Cancer Institute	RSG-08-187-01	07-01-08 to 06-30-	\$	720,000
Molecular Analysis of Hsp90: A Specialized Chaperone in Signal Transduction	University of Massachusetts Medical School	RSG-08-173-01	07-01-08 to 06-30- 12	\$	720,000
Flucidating the Molecular Mechanisms That Regulate Stem Cell Number In vivo	New York University	RSG-08-163-01	07-01-08 to 06-30- 12	\$	720,000
Genomic and Epigenetic Characterizations of Prostate Cancer	University of Pittsburgh	RSG-08-137-01	07-01-08 to 06-30- 12	S	724,000
Curcumin Inhibition of mTOR Signaling	Louisiana State University in Shreveport	RSG-08-135-01	07-01-08 to 06-30- 12	\$	720,000
Deciphering the Degron Code - Transcription Regulation by Ubiquitination	Baylor College of Medicine	RSG-08-090-01	01-01-08 to 12-31- 11	5	720,000

Note: Green indicates funding relevant to research on finding a better means of detection

392

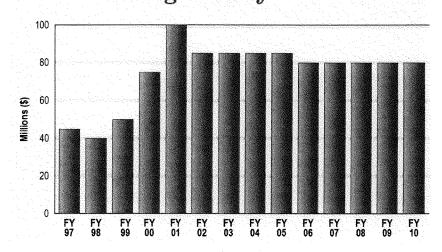
Appendix 6a: CDMRP Funding History



SOURCE: Congressionally Directed Medical Research Programs Annual Report http://cdmrp.army.mil/annreports/2009annreport.pdf

Appendix 6b: PCRP Funding History

## **PCRP Funding History**



SOURCE: Prostate Cancer Research Program Booklet http://cdmrp.army.mil/pubs/pips/pcpip.pdf

#### House Appropriations Committee Defense Subcommittee

#### Witness Disclosure Form

Clause 2(g) of rule XI of the Rules of the House of Representatives requires nongovernmental witnesses to disclose to the Committee the following information. A non-governmental witness is any witness appearing on behalf of himself/herself or on behalf of an organization other than a federal agency, or a state, local or tribal government.

Your Name, Business Address, and Telephone Number:
Jonathan W. Simons, MD
Prostate Cancer Foundation
Suite 360
1250 Fourth Street Santa Monica, CA 90401
(310) 570-4712 (office)
Are you appearing on behalf of yourself or a non-governmental organization? Please list organization(s) you are representing.
I am appearing on behalf of a non-governmental organization: the Prostate Cancer Foundation.
Have you or any organization you are representing received any Federal grants or contracts (including any subgrants or subcontracts) since October 1, 2007?  Yes  No
3. If your response to question #2 is "Yes", please list the amount and source (by agency and program) of each grant or contract, and indicate whether the recipient of such grant or contract was you or the organization(s) you are representing.
Signature: Jaman W. Jimas MP Date: 4 May 2010
Signature Coman W- firmers MP Date: 4 May 2010

Please bring this original form on the day of your testimony.

Mr. Dicks. The committee is adjourned until early June when testimony will be provided by the head of the U.S. Special Operations Command. Thank you.

[The following organization, Aplastic Anemia & MDS International Foundation did not appear before the committee but submitted testimony for the record:]

#### Testimony before the Public Witness Hearing of the Subcommittee on Defense House Committee on Appropriations

 $\mathbf{B}\mathbf{v}$ 

#### John Huber Executive Director Aplastic Anemia & MDS International Foundation

On behalf of the tens of thousands of Americans suffering from bone marrow failure diseases, I would like to thank Chairman Norman Dicks (D-WA) and Ranking Member C.W. Bill Young (R-FL) for giving me the opportunity to testify before the Public Witness Hearing of the Defense Appropriations Subcommittee. I am here today to testify in support of the Bone Marrow Failure Disease (BMFD) research initiative, which has been funded by the Subcommittee for three consecutive years through the Congressionally Directed Medical Research Program at the Department of Defense (DoD).

Acquired bone marrow failure diseases consist primarily of three disorders: myelodysplastic syndromes (MDS), aplastic anemia, and paroxysmal nocturnal hemoglobinuria (PNH), all of which occur when stem cells inside the bone marrow stop making enough healthy blood cells. These disorders can strike any person of any age, of any gender and any race, in any neighborhood, anywhere in the world. They are life-threatening diseases that currently affect tens of thousands of men, women, and children every year.

Although all of the causes are still unknown, BMFDs have been linked to toxins and viruses that we are in contact with every day. One particular culprit that we know about is the chemical "benzene," which was an ingredient used in Agent Orange during the Vietnam War. Our Foundation – the world's largest patient advocacy organization for BMFD patients and family members – has seen a growing number of Vietnam veterans receiving diagnoses for MDS, aplastic anemia and PNH. We are also starting to hear from a younger generation of members of the military – including those who were deployed to Iraq or Afghanistan – who have been diagnosed with a BMFD, perhaps through exposure to environmental factors in these theaters of operation. The Veterans Administration maintains a database of more than 30,000 veterans who are suffering from BMFDs, and they receive an estimated 4,000 new cases per year.

Due to this connection between BMFDs and military service, Representatives Doris Matsui (D-CA) and Jim McGovern (D-MA) first approached this subcommittee in fiscal year 2008 to request appropriations for a new DoD research initiative focused on BMFDs. We are deeply thankful for their leadership, and for the Subcommittee's decision to launch a new Congressionally Directed Medical Research Program for BMFD in the amount of \$1 million. In fiscal years 2009 and 2010, the Subcommittee appropriated \$5 million and \$3.75 million, respectively, to continue this initiative.

On March 18, 2010, 16 members of the House signed on to a letter circulated by Representatives Matsui and McGovern in support of \$7.5 million for the BMFD program at DoD. This much-needed funding has given investigators a stable source of support to augment our basic understanding of these diseases. By studying military personnel who have been diagnosed with these disorders, we can gain a much better understanding of what may be causing them. Most important, we can also begin to understand how to protect and treat members of the Armed Forces—and the general public—who contract these life-threatening diseases.

The Aplastic Anemia & MDS International Foundation appreciates the hard work of this committee in funding cutting edge research for diseases that affect both active duty and retired members of the Armed Forces. We look forward to working with you to invest in the next generation of bone marrow failure disease research that will ultimately lead to a cure for these devastating diseases.

#### WITNESSES

	Page
Bauman, Carlea	299
Berman, Dr. Josh	247
Boslego, John	329
Clarke-Pearson, D. L	265
Fenton-Ambrose, Laurie	203
Finney, Sally	249
Galloway, Sherry	354
Galvanek, Michelle	288
Green, Lieutenant General (Dr.) C. B	1
Gunsul, Karen	227
Huber, John	396
Janies, Dan	179
Keith, David	240
Mason, Karen	258
Mitchell, M. F	278
O'Reilly, Lieutenant General P. J	125
Riach, Steve	188
Rice, Dr. C. L	1
Robinson, Vice Admiral A. M., Jr	1
Schoomaker, Lieutenant General Eric	1
Sharp, Kendra	320
Simons, Jonathan	369
Visco, Fran	308
Weinstock, M. A	234
Wheeler Word	179