

**AGING IN SOUTH CAROLINA:
BIOMEDICAL RESEARCH IN
THE PALMETTO STATE**

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C O N T E N T S

	Page
Opening Statement of Senator Susan M. Collins, Chairman	1
Opening Statement of Senator Tim Scott, Member of the Committee	3
Opening Statement of Representative Jeff Duncan	5

PANEL OF WITNESSES

Wayne Roper, President of South Carolina Biotechnology Industry Organization (SCBIO), Greenville, South Carolina	8
Martine LaBerge, Ph.D., Professor and Chair of Bioengineering, Executive Director of Clemson University Biomedical Engineering Innovation Campus (CUBEInC), Clemson University, Clemson, South Carolina	10
Joseph A. Helpern, Ph.D., Professor and Vice Chairman for Research of the Department of Radiology and Radiological Sciences, Medical University of South Carolina, Charleston, South Carolina	12
Reverend Jerry Welch and Nancy Welch, Retired Minister and Counselor diagnosed with early-onset Alzheimer's Disease, Anderson, South Carolina ..	14

APPENDIX

PREPARED WITNESS STATEMENTS

Wayne Roper, President of South Carolina Biotechnology Industry Organization (SCBIO), Greenville, South Carolina	29
Martine LaBerge, Ph.D., Professor and Chair of Bioengineering, Executive Director of Clemson University Biomedical Engineering Innovation Campus (CUBEInC), Clemson University, Clemson, South Carolina	37
Joseph A. Helpern, Ph.D., Professor and Vice Chairman for Research of the Department of Radiology and Radiological Sciences, Medical University of South Carolina, Charleston, South Carolina	42
Reverend Jerry Welch and Nancy Welch, Retired Minister and Counselor diagnosed with early-onset Alzheimer's Disease, Anderson, South Carolina ..	44

AGING IN SOUTH CAROLINA: BIOMEDICAL RESEARCH IN THE PALMETTO STATE

WEDNESDAY, SEPTEMBER 2, 2015

U.S. SENATE,
SPECIAL COMMITTEE ON AGING,
Washington, DC.

The Committee met, pursuant to notice, at 10:20 a.m., at the Strom Thurmond Institute at Clemson University, 230 Kappa Street, Clemson, South Carolina, Hon. Susan M. Collins, Chairman of the Committee, presiding.

Present: Senators Collins and Scott.

Also present: Representative Duncan.

OPENING STATEMENT OF SENATOR SUSAN M. COLLINS, CHAIRMAN

The CHAIRMAN. The Special Committee on Aging will come to order.

First, let me say what a great pleasure it is to be in the State of South Carolina with my great friend, Senator Tim Scott. I am Senator Susan Collins from the great State of Maine and I came all the way from Maine to be here today because Senator Scott and I share a deep commitment to issues that affect our seniors, so I want to begin this Special Field Hearing of the Senate Committee on Aging today by thanking Senator Scott for your leadership in requesting this field hearing to examine issues that are of crucial importance not only to seniors here in South Carolina, but throughout our Nation.

It is a pleasure to be in the Palmetto State to participate in today's hearing, and I want to also welcome Representative Jeff Duncan, who is joining us and whose district I believe we have the pleasure of being in.

It is interesting for me in just a short visit here to observe how much the Pine Tree State of Maine and the Palmetto State have in common. We most of all have very friendly people. We have traditions of forestry, farming, fishing, manufacturing, and in the winter, another thing that Maine and South Carolina have in common is a lot of Mainers. Many of our Mainers escape our winters by coming to South Carolina. We do not mind, if they do not stay too long and return to Maine, and we would encourage you to do the reverse.

It is a great pleasure to serve with Senator Scott on the Aging Committee. His commitments and contributions to the Committee's

work are many, and he is such a terrific Senator who cares deeply for his constituents. Today's hearing is a testament to his belief that more can and should be done to address the diseases that disproportionately affect our seniors.

One of the things that I enjoy most about serving as Chairman of the Senate Aging Committee is that we deal with what I call people issues, issues that truly affect people in their daily lives, and through the Committee, we have the opportunity to help improve the lives of our seniors, those who care for our seniors, and those who will one day be our seniors.

Among my highest priorities as Chairman is to highlight the importance of biomedical research for diseases like Alzheimer's and cardiovascular disease that take such a devastating toll on Americans and their families. Investments in biomedical research not only improve the health and longevity of Americans, but also provide ongoing benefits to our economy and the Federal budget.

According to many economic analyses, there is a roughly two-to-one return on investment for Federal support for biomedical research. Investments in research at the National Institutes of Health and other research centers spur job creation and are also critical to our competitiveness in the global research environment.

It is clear that South Carolina understands this. I look forward to learning more today about the collaborative and innovative research being done in this State in conjunction with NIH grant funding and public-private partnerships. In fact, your Lieutenant Governor, whom we are honored to have here today, talked to me about the collaboration that exists and the fact that the silos have been broken down so that there is more cooperation, and that is what is needed.

As the Senate Co-Chair of the congressional Alzheimer's Task Force, I am particularly interested in breakthroughs in Alzheimer's disease, which has had such a devastating effect on 5.2 million Americans and their families, including 81,000 South Carolinians. In addition to the suffering that Alzheimer's causes, it costs the United States more than \$226 billion annually, and Medicare and Medicaid pay 68 percent of that cost. Yet, we are spending less than three-tenths of one percent of this amount on research. We are now spending about \$600 million a year. Help is on the way. In the Appropriations Committee this year, we were able to secure another \$350 million, which will bring us closer to the billion dollar mark, and unless an effective treatment is developed before 2050, that cost will soar to \$1.1 trillion as the Baby Boom generation grows older. Clearly, Alzheimer's research funding is disproportionately low compared to its human and economic toll.

I look forward in this hearing to hearing about the hopeful research for Alzheimer's patients and their families and from two people who are personally affected by Alzheimer's, Reverend Jerry Welch and his wife, Nancy, who are here with us.

There are other illnesses of major concern to the people of this State. South Carolina has the unfortunate distinction as being part of the stroke belt, with unusually high rates of stroke and other forms of cardiovascular disease. I look forward to learning what we can do to better understand, prevent, and treat stroke and cardiovascular disease, and also to figure out why there is such a dis-

parity in the impact on African American citizens in this State versus Caucasian citizens, where African American citizens are 48 percent more likely to die from stroke than are Caucasian citizens.

The other issue that I hope we will touch on today and that I know Mrs. Welch can speak to is the role of caregivers. They have become so important as our population is aging, and yet there are fewer and fewer professional caregivers that are available, causing more of the burden to fall on family members. I have authored legislation to require the Secretary of Health and Human Services to develop a national strategy to recognize and support family caregivers. This will not cost us money. It can be done out of existing resources. It involves the kind of collaboration among all the agencies, private organizations, and listening to family caregivers.

Again, I am delighted for the opportunity to join you today and I will now turn the gavel officially over to my friend and colleague, Senator Tim Scott.

**OPENING STATEMENT OF SENATOR
TIM SCOTT, MEMBER OF THE COMMITTEE**

Senator SCOTT. Thank you, Senator. Thank you for making the time to be in our great State. There is no doubt that we are blessed by your presence, and as a member of the U.S. Senate, it has been my privilege to get to know you as a person and to understand and appreciate the value of your leadership. You have demonstrated the key components to leadership. You have compassion, you are always prepared, and you have been, as you know, one of my most cherished treasures in the U.S. Senate.

We certainly should give her a round of applause for taking the time to be here.

The CHAIRMAN. Thank you.

Senator SCOTT. Thank you.

Senator Collins has been committed to the issues surrounding aging for as long as I have known her. If you have been impacted by Alzheimer's or your family has been impacted by Alzheimer's or cardiovascular issues, would you please raise your hand.

[Show of hands.]

The CHAIRMAN. Wow.

Senator SCOTT. Take a look around the audience. One of the things that I believe is so important is that as we discuss the issues of Alzheimer's and cardiovascular disease, one of the things that becomes present for me is that almost every family is impacted by Alzheimer's or cardiovascular disease.

I think of my grandfather, who was either 94 or 95 last Tuesday, and the impact that his diseases have had on our family and, frankly, when you think about the caregivers, I think about my mother spending every other night at his house helping to provide care through the night, and then she goes to the hospital and works as a nurse's assistant, and my aunt does that every other night, as well, and so, just the stress and the challenge facing so many American families needs to be highlighted, and your legislation just seems the appropriate legislation for us to say thank you and also to provide ways to support those caregivers in a very powerful way.

I know that Reverend Welch has been doing that, as well. Even though he suffers from the disease, he is involved in organizations that provide assistance for those folks.

We know that Senator Collins will be back to the Palmetto State, for sure. That was a question as well as a statement.

The CHAIRMAN. Absolutely.

Senator SCOTT. We look forward to seeing you soon.

The CHAIRMAN. Thank you.

Senator SCOTT. I would also like to take the time to thank the audience and our witnesses for participating in today's panel and discussion. I know this will be a great opportunity for us to highlight all the wonderful work being done in my home State here in South Carolina, and it will also give us a chance to examine the ways our Committee, the Aging Committee, can be helpful to ensure the innovation in the field of aging can continue to flourish.

Whether it is the foothills of the Upstate, the broad rivers of the midlands, or the stunning beaches on the coast, not to mention the world's best food across our State, as reasons why so many seniors are moving to South Carolina. Currently, 15 percent of our residents are over the age of 65, with that number expected to increase over upcoming years as more and more seniors call South Carolina home.

Unfortunately, our State has some work to do in terms of managing the chronic conditions that impact our seniors. Over 71 percent of Medicare beneficiaries in our State have two or more chronic conditions. Unfortunately, we know that means higher cost and poorer health, as 94 percent of Medicare spending is spent on those seniors with at least two chronic conditions. However, all of this data puts our State in a unique position to conduct research and develop medical innovations that allow seniors to better manage chronic conditions and improve the way care is delivered, especially in a manner that allows seniors to remain in their homes and live their healthiest lives.

Our State is home to some pretty amazing medical institutions. We have got Clemson, the Medical University of South Carolina, the University of South Carolina, among others. These institutions have teamed up with our state's leading health care systems to provide and to develop coordinated solutions to ease the impact of the burden of disease in our State. I am looking forward to hearing from our witnesses about the work that is being done, what the future holds, and the role this Committee can play.

Before we proceed to our witnesses, I would like to take this opportunity to thank Clemson University for hosting us here at the Strom Thurmond Institute. Clemson University has been one of the Nation's leading research institutes in biomedical research for the past 50 years. In fact, Clemson is recognized as the birthplace of the field of biomaterials, things like heart valves and joint replacement, which has led to some truly remarkable advances in health care.

This campus is also home to the Clemson University Institute for Engaged Aging, led by Dr. Cheryl Dye, which provides the nexus for Clemson faculty to conduct research to promote quality of life for older adults, making it particularly fitting that we would be able to host this field hearing here.

Again, we are very grateful to have the opportunity to hold this hearing right here, at Clemson University, and thank you to President Jim Clements for being such a wonderful host.

It is also certainly appreciated that we have the attention and the time of our Lieutenant Governor, Henry McMaster, as well as South Carolina Representative Gary Clary.

Now, I am honored to introduce my good friend, Congressman Jeff Duncan. Today's hearing is particularly significant to Jeff, not just because Clemson University is your alma mater—

Mr. DUNCAN. Yes.

Senator SCOTT. You went here.

Mr. DUNCAN. I did.

Senator SCOTT. You played football here.

Mr. DUNCAN. I did, 1988 graduate.

Senator SCOTT. I thought it was 2007?

Mr. DUNCAN. No.

Senator SCOTT. I do need my glasses—Jeff is not only a member of the Class of 2010, but when we came into Congress together, Jeff and I were roommates, so I have a special affinity for Congressman Duncan, but more important, I wanted to dedicate this hearing in the honor of Jeff's father, John Duncan, who passed away recently of complications associated with Alzheimer's disease. It is important to note that today, September 2, would have been your father's birthday, so a timely hearing, a very important topic, and in honor of your father, thank you for being here. I am glad that we are tackling this issue together.

Representative Jeff Duncan.

OPENING STATEMENT OF REPRESENTATIVE JEFF DUNCAN

Mr. DUNCAN. Thank you, Senator Scott. Chairman Collins, thanks for coming to Clemson, South Carolina, in the Third District, and holding such a very valuable hearing that has personal interest to me and my family. I think it is timely and I want to thank you for doing that and allowing me to share the dais with you today to talk about something that is dear to—and something I have learned a lot about, really, just within the last 24 to 48 months, because my dad's dementia and Alzheimer's really progressed rapidly, and so, I look forward to hearing from the witnesses and learning more as we tackle this issue as a Nation.

I want to thank Clemson for the work that they have done, and the Office of Aging under the Lieutenant Governor's Office, because as the Senator said, South Carolina is seeing an influx of retirees, so our population as a State is getting older as a percentage of the population.

Biomedical research has increasingly become an important issue, touching the lives of all American citizens. As we delved into the 21st Century Cures Act this year, which passed the House—I am not sure where it stands on the Senate side—learned more and more about the impacts of a lot of different diseases, Alzheimer's being the one that I was interested the most, and the impact it has on the Federal Government, the impact it has on American taxpayers, the impact it has on the health care system, the impact it has on the retirement system, the impact it has on families and individuals.

Disease has no party affiliation and distributes its devastating effects on humans equally. Though vast majorities are fortunate to escape the more devastating illnesses while young, all of us will, in one way or the other, require treatments for diseases that we once thought were incurable. Unfortunately, some of the most heart-wrenching diseases still have yet to be cured. Diseases like Alzheimer's will in some way touch every American and every family. I think the number of hands that were raised in the room when the question was asked earlier is indicative of how Alzheimer's, as one disease, touches the lives of so many Americans.

It is estimated that 5.3 million Americans are living with Alzheimer's today. As the size and proportion of the U.S. population age 65 or older continues to grow at greater rates every year, so will those living with this disease. It is interesting to note that by 2025, the number of people age 65 or older with Alzheimer's will reach 7.1 million. That is a 40 percent increase from where we are today. In South Carolina, 81,000 people are stricken with the illness. By 2025, the number will explode to 120,000 people estimated. That is a 48 percent increase, so as South Carolinians, we must confront this growing wave today before it consumes our friends and loved ones tomorrow.

A little bit about my situation. My father passed away April 14, dementia progressing to full-blown Alzheimer's. He died of complications as a result of Alzheimer's. I watched as my mom struggled with not having a power of attorney to access the funds that were going to be critical for taking care of my father. I watched as my father became more and more aggressive due to the Alzheimer's disease, which necessitated at some point in time him being moved out of the home. I watched as my mom struggled with making that decision to actually place my father in an assisted living facility, possibly separated from her. I watched as she struggled with the understanding that that would gobble up vast amounts of their retirement resources and what that may mean to her future. I watched as my dad became aggressive and required to be taken to the hospital against his will.

I share this with you because these are things that Americans face every day, families, caregivers face every day as they deal with this terrible disease. Hard decisions. I think everyone wants to keep loved ones in the home and be a caregiver, but if you look at the data, oftentimes, the caregiver dies first because of the physical toll that being a caregiver takes on that person. That is the unfortunate side of Alzheimer's that is not discussed enough in the statistics that we talk about. These are real struggles.

I was a proud supporter of the 21st Century Cures Act as we direct more of the NIH resources and other research resources from the Federal Government toward looking at these diseases that are going to be very, very costly for Americans. That is why hearings like this conducted by the House and the Senate are so important, so that we can educate ourselves as policymakers, but we can also educate average Americans on what the toll is to the Federal budget, what the toll is to the State budget, and what the toll is in the real human capacity and real human numbers and struggles that they have.

I appreciate Senator Scott holding this hearing in honor of my father, John T. Duncan, Senior, a 1961 graduate of Clemson University. He would have been proud that we were having this hearing today at his alma mater. He would be proud that Senator Scott and I—he loved him, as I do and we all do—he would be proud that Tim was holding this hearing today, as well, and he would be proud of me sitting on the stage delving into this, and so, his birthday was today. It is tough.

Tim, thank you so much for letting me be a part of this. Thank you.

Senator SCOTT. God bless you and your family.

Mr. DUNCAN. Thank you. God bless you.

Senator SCOTT. Now, I would like to take the time to introduce our panel of distinguished witnesses.

First, we will start with Mr. Wayne Roper. Mr. Roper is the President of SCBIO, an organization supporting South Carolina's life science industry, which connects companies, institutions, affiliates, sponsors, and founding members with life science industry programs. Mr. Roper brings a unique perspective as a witness due to his involvement in all areas of biomedical world in the State.

Prior to serving as the President of SCBIO, Mr. Roper served as the Chief of Staff for Congress member Bob Inglis, SC-4, so he is certainly familiar with the dysfunction—I mean, the work that needs to be done in Washington, DC, to ensure that innovation in this field is not stifled. Thank you, Mr. Roper, for being here with us today and I look forward to your testimony.

Next, we have Dr. Martine LaBerge—good?

Dr. LABERGE. Good.

Senator SCOTT. Okay, excellent. When it is French, you want to make sure that you get it right. Dr. LaBerge serves as a professor within the Department of Bioengineering at Clemson and, as well, as the Department Chair. She is also the Interim Dean of the College of Engineering and Science. As Department Chair, Dr. LaBerge has developed the South Carolina Translational Medical Technology Program, a collaboration between academic and research universities in the Bioengineering Alliance of South Carolina and partner hospitals developing clinically relevant medical technology.

Dr. LaBerge has also received numerous honors and awards, including the South Carolina Governor's Award for Scientific Awareness. We are thrilled to have her here with us today to represent Clemson's Department of Bioengineering, as it is widely recognized as a pioneer in the field of bioengineering and one of the oldest programs in the world.

Next, we have Dr. Joe Helpert from my hometown of Charleston. He is a Professor of Radiology and the Vice Chair for Radiology Research at the Medical University of South Carolina. Dr. Helpert is a North American Editor of the Nuclear Magnetic Resonance in Biomedicine, a member of the Scientific Advisory Board for the Institute for the Study of Aging, the Treasurer of the Executive Committee of the Experimental Nuclear Magnetic Resonance Conference, and has served on numerous NIH committees and study sections. He has authored and published more than 90 scholarly papers and has received numerous awards for his work.

Finally, we have Reverend Jerry Welch and his wife, Nancy. Reverend Welch and his wife, Nancy, also join us from Anderson, South Carolina. Reverend Welch was diagnosed with Alzheimer's about eight years ago, after his daughter, who works with Alzheimer's patients, noticed he began to exhibit some of the symptoms of the disease. He is an active participant in Rhodes Respite Care, a local faith-based program to help those with moderate memory impairment to exercise their minds and their bodies while giving a respite to their caregivers. I want to thank both Reverend Welch and his wife for being here to discuss the patient and caregiver perspective of such a challenging disease.

Without objection, any written statement you have prepared for today will be made part of the record.

I will recognize each of you for remarks in the same order in which I introduced you. Our preference is that you keep your presentation to five minutes—we will give you 30 seconds or so extra, if necessary—so we have time to get to your questions and have some dialog.

Mr. Roper, you are now recognized for the first five minutes.

**STATEMENT OF WAYNE ROPER, PRESIDENT OF
SOUTH CAROLINA BIOTECHNOLOGY INDUSTRY
ORGANIZATION (SCBIO), GREENVILLE, SOUTH CAROLINA**

Mr. ROPER. Thank you. Madam Chairman and members of the Committee, we welcome you to South Carolina, the Palmetto State. We appreciate the chance to discuss some of the country's most extensive aging research right here in South Carolina. This is taking place through private industry, entrepreneurs, research at our three research universities, and a lot of collaboration among all organizations.

I also want to say "hey" to our Senator, Tim Scott, and thank him for bringing the focus to our state's life science committee and for thinking twice about singing at my son's commencement at USC.

There clearly can only be one William "Wee Gee" Howard.

Senator SCOTT. Amen.

Mr. ROPER. This morning I mentioned, only in passing, promising research at the University of South Carolina and the Medical University of South Carolina in Charleston along with other organizations. Martine is going to cover Clemson very well, and she is a member of the SCBIO Board and certainly is a tremendous contributor to us as we try to work on some of these cures and therapies.

Our focus at South Carolina Biotech Industry Organization is private industry. SCBIO represents those entrepreneurs, researchers, and executives who are moving therapies to market to relieve suffering and improve lives. Research can be impressive, but it changes nothing until it gets to patients, and that is the focus of SCBIO. We are a non-profit business association dedicated to growing life science businesses and the full ecosystem it takes to move innovative therapies and cures to market.

Toward that end, I want to point to the most important streamlining of more than a decade of government regulated process to get therapies to patients and that is the House-passed 21st Cen-

tury Cures legislation which Congressman Duncan mentioned. H.R. 6 is a major legislative milestone and, in this day and age, an impressive bipartisan margin of 344 to 77. We strongly urge H.R. 6 as a model for how it modernizes clinical trials, brings patients at the center of treatment decisions, improves coordination between the regulating agencies, and importantly, increases funding for the National Institutes of Health and the Food and Drug Administration.

You know how critical the NIH is as a launching point for what has become an explosion of discovery in biomedical science and data-driven health care under the excellent leadership of Francis Collins. For the FDA, years have seen its mission expand and funding constrained, but it is critical to increasing a safe but efficient throughput of therapies and cures for startup companies. Neither of these agencies should ever again be put through sequestration.

In South Carolina, SCBIO members are launching new companies that are moving therapies to market. They include CreatiVasc, a company recognized by the FDA as one of three in the country with breakthrough technology for an arterial port system for kidney dialysis patients, an area where there has been no innovation in 40 years.

In diabetes, Perle Bioscience of Charleston is moving to clinical trial a combination therapy that hopes to eliminate the need for insulin shots for certain Type one diabetes, and Neuro-Quest, it is an Israeli-based technology with North American headquarters right here in South Carolina with a promising technology for an affordable early diagnostic blood test for Alzheimer's disease, before the symptoms ever become clinically apparent. As you know, Alzheimer's can be progressing for 12 to 13 years before they are observable in a clinical setting. There are many drugs which are making an impact, but the fact is, they are making an impact on a disease that has been a decade in ongoing. If we can get earlier intervention, those drugs may be more effective.

Increasingly, we are seeing an explosion of health IT companies developing smart phone apps for compliance, monitoring, and real-time information that is going to be the heart of the new health care industry and wellness industry and is the greatest hope for quality of life for elderly citizens being able to live at home.

South Carolina truly has distinguished work in stroke-related therapies and neurotechnology. At MUSC, Dr. Robert Adams chairs the SmartState Center of Excellence in Stroke Treatment and the Center for Biomedical Research Excellence in Stroke Therapies. His REACH MUSC network now puts 80 percent of South Carolinians within an hour's drive of advanced Internet-based stroke intervention. They are now able to quickly fly, because of this, fly certain stroke patients to MUSC to remove the arterial blockage in time to stop a lot of stroke damage.

All you have to do is look at aging research in South Carolina and know the importance of NIH funding, nearly \$80 million in South Carolina, and what a significant effort is being made in all facets.

At the University of South Carolina, more than \$35 million from the NIH and other agencies support more than eleven centers and specific projects on aging, and these include Dr. Sue Levkoff's

SmartHOME Center, working across disciplines to extend healthy independent living, and the Assisted Robotics and Technology Lab to develop improved robotic and assistive technologies. USC also has one of the most extensive registries of Alzheimer's patients. At MUSC, the Center of Aging is one of the longest established at the University, with \$33 million in research among 68 affiliated faculty members from all six colleges.

South Carolina's collaborative prowess is also evident in what is a one-of-a-kind, really, in the Health Sciences South Carolina, one of the Nation's first statewide data warehouse systems. It includes all seven of the largest health care systems and the research universities partnering together to bring data to the research in health care outcomes. HSSC is now partnering with North Carolina in a \$15 million study funded by Duke Endowment on using data-driven innovations to improve health outcomes in our states' high rates of diabetes, stroke, obesity, and heart disease.

Further detail I have on the efforts here are in written remarks.

The CHAIRMAN. Thank you, Mr. Roper.

Next, we will hear from Dr. LaBerge.

**STATEMENT OF MARTINE LaBERGE, PH.D., PROFESSOR AND
CHAIR OF BIOENGINEERING, EXECUTIVE DIRECTOR
OF CLEMSON UNIVERSITY BIOMEDICAL ENGINEERING
INNOVATION CAMPUS (CUBEInC), CLEMSON UNIVERSITY,
CLEMSON, SOUTH CAROLINA**

Dr. LABERGE. Chairman Collins, Senator Scott, and Representative Duncan, welcome to Clemson University. This is a privilege and honor to speak before you this morning. I thank you for the opportunity to provide testimony about the impact of the exciting research led by my colleagues to ensure that older Americans can fulfill a longer, healthier, and independent life.

As South Carolina's land grant institution, Clemson University has tackled the socio-economic burden of aging through an integrated approach. The result is significant with impactful outcome, economic development, and workforce education.

Clemson presents an extensive portfolio of research programs and partnerships for aging-related research. We partner with the Medical University of South Carolina, the University of South Carolina, and the Greenwood Genetic Center, along with the Greenville Health System. As you can see, there are a lot of people here in this agenda.

Clemson is at the forefront of medical device and technology research. Our Department of Bioengineering, as Senator Scott mentioned, is recognized worldwide as the leader of biomaterials and its birthplace, so for more than 50 years, our bioengineers have developed technologies improving artificial joints, implant fixation, fracture fixation, and heart valve replacements currently used in patients worldwide.

Clemson develops innovation to meet special needs of the aging population. More than 600,000 knees are replaced, or the replacement is performed yearly in the United States. By 2030, this number will exceed three million. Our Engage Knee System, developed by Dr. Desjardins and his team, is designed to address problems

of the elderly. Along with diseases of the mind and diseases of the cardiovascular system, arthritis is also a very debilitating disease.

Who does not know, as you mentioned, a family member, a friend, a neighbor who suffers from heart disease? My mother passed away from congestive heart failure in the recent months. Heart disease is the leading cause of death in the United States. One in four Americans dies of heart disease yearly. Our researchers developed new technology to increase a lifetime of medical devices, such as heart valve, endovascular stents, and blood vessels, among many others.

Approximately 25 percent of Americans over age 60 have diabetes. In 2012, the direct cost of diabetes was \$176 billion, largely attributed to glucose monitoring. Clemson bioengineering students Kayla Gainey, Tyler Ovington, and Alex Devon developed a new, inexpensive type of test strip so that diabetics can be provided with low-cost testing equipment they need to manage their blood sugar.

In partnering with the State, we built the Clemson University Biomedical Engineering Innovation Campus. CUBEInC is located on the campus of Greenville Health System. At CUBEInC, we translate our clinically relevant technology to help patients finding new ways of treating their illness associated with aging. This is where actually we are doing the economic development that Clemson has a very large arm for in South Carolina. Clemson and CUBEInC play a key role in the growth of South Carolina's biotech industry.

The Clemson University Institute for Engaged Aging, as you mentioned, Senator Scott, in your introduction, led by Dr. Dye, has definitely provided a platform and a nexus to promote quality of life for elderly adults. Faculty explore aging from the cellular level to the built environment from the cell to the house so that you can have aging individuals who are living more independent life. They are working through the South Carolina SeniorSMART program, supporting mobility, activity, rehabilitation, and technology.

Dr. Dye and her team have developed and implemented projects using community volunteers as health coaches. Health coaches mentor peers in self-management of chronic conditions. These efforts have yielded improvements in the health of elders with hypertension and in the knowledge and skill of health care providers.

Today at Clemson University, more than 150 researchers and scientists are conducting biomedical research that relates to aging. The cited examples are few, but they all have something in common, the quest for funding. Federal support for biomedical technology and aging research must keep up with inflation, as you mentioned, and Federal support for translational research and accelerated innovation must be given priority in addition to basic science.

In closing, I thank you for the opportunity we were given to share with you our engagement and truly our excitement for health-focused research. We are committed to transform economic development and develop the workforce needed to assure the competitiveness of the United States and, obviously, South Carolina in health care. South Carolina is the ultimate aging in place destination. We are daily reminded of the potential impact of our work.

You must know that this is not in my text, but I am doing within my five minutes—that Maine has the largest number of individuals with 65 years and older. Following that is South Carolina, Georgia, Florida, and Arizona, so they migrate to South Carolina, and then our counties that are the most populated with elderly are very close to here—Oconee County, Beaufort, and you also have Georgetown in Senator Scott's districts. As you see, we are very well positioned to understand the needs of our citizens.

Senator SCOTT. Thank you very much.

Dr. LABERGE. We look forward to working with you and meeting the agenda of the Special Committee on Aging. Thank you for this great opportunity.

Senator SCOTT. Thank you very much.

Dr. Helpern.

**STATEMENT OF JOSEPH A. HELPERN, PH.D., PROFESSOR
AND VICE CHAIRMAN FOR RESEARCH OF THE DEPARTMENT
OF RADIOLOGY AND RADIOLOGICAL SCIENCES,
MEDICAL UNIVERSITY OF SOUTH CAROLINA,
CHARLESTON, SOUTH CAROLINA**

Dr. HELPERN. Chairman Collins, Senator Scott, and Congressman Duncan, thank you for inviting me here today to speak to you and the audience about aging research in South Carolina.

If I may, I would like to take a moment to provide a brief framework of the topic that we are discussing here today. This may seem like an obvious statement to many, but the incidence of many diseases increases rapidly with aging. In fact, 65 percent of all the people who will die today in the world will die of age-related diseases. In the United States, this percentage is closer to 90 percent. The problem is that aging is a co-factor in many diseases, including cancer, heart disease, Type two diabetes, hypertension, and the most obvious one, Alzheimer's disease.

Within this broad definition of aging, MUSC has an equally broad portfolio of aging-related research. Of course, NIH plays a significant role in supporting this research, with grants ranging from traditional individual investigator, R01s, they are called, to larger center grants. However, our aging research is also supported by the Alzheimer's Association, the American Heart Association, the American Cancer Society, the U.S. Army, as well as numerous other corporations and various other foundations.

Our total aging research portfolio of approximately \$33 million in direct costs is divided almost evenly between NIH, corporate, and other agencies. These grants span all colleges within MUSC, with the College of Medicine being the largest, at 86 percent, and the College of Nursing being the fastest growing.

In aging-related research, MUSC's NIH portfolio provides approximately \$11.7 million in total direct costs. This NIH support is critical for our research mission for several reasons, but it has been on the decline over the past few years due to pressures on the availability of NIH funds. Competition for NIH grant funding is fierce, with the success rate for competitive grants being a significant challenge and near an all-time low. The level of NIH funding also affects our ability to recruit top scientists to MUSC, as NIH funding is used as a means of ranking a university.

One challenge for MUSC in securing additional NIH funding, especially in the area of Alzheimer's disease and aging in general, is the lack of an Alzheimer's disease research center in the State of South Carolina. Such a center—it is called ADRC—would make MUSC significantly more competitive in funding from the National Institutes on Aging, as it would provide the necessary clinical focus for the recruitment and management of research subjects. NIH provides funding specifically for ADRCs. However, we would need to first seed such a center at MUSC for several years before applying for such funding, as a proven track record is critical for successful NIH funding.

I am going to interject a personal story here. I moved from New York University, where I was the Vice Chair of the Department of Radiology—NYU is the largest private university in the United States—where I had two NIH-funded grants, and I moved them to South Carolina, to MUSC. One of them was focused on ADHD and one of them was focused on AD. I am now, the first time in my career, not funded by NIH at all. I am on the front line of training graduate students and training post-docs and I find myself without any NIH funding. Part of the problem is the infrastructure that we have here at the university with regard to recruiting patients. My latest grant review stated it was one of the most productive groups in the field of AD research, but they did not believe we could recruit the research patients at MUSC. This is a heartbreaking finding.

Back to the written statement, research funding in the area of aging-related diseases has a positive impact on the citizens of South Carolina. Aside from providing a means for our citizens to participate in the latest advances in aging research, a focus on aging research also attracts top clinicians and scientists to work at MUSC.

With the current pressures of securing research funding, particularly in the beginning of an individual's career, we have had to think creatively to develop alternative revenue streams for supporting research, including philanthropy. In an attempt to address this challenge, approximately one year ago, a colleague of mine from New York and I established something called Donor's Cure Foundation. Donor's Cure Foundation is a 501(c)(3) charitable foundation, now licensed in almost all 50 states. It provides a mechanism to engage the public in supporting research through crowdfunding.

Donor's Cure attempts to at least partially fill the gap in funding important medical research, particularly for pilot projects and for early career scientists. Researchers use Donor's Cure to explore new creative ideas that they can eventually fund through a larger grant mechanism, such as NIH.

Donor's Cure teaches researchers to share what they do with non-scientists, an often overlooked but important skill set, and communications, I believe, between scientists and the general public needs to be improved. The general public needs to understand more about the importance of medical research, and I think if they did, they would support an additional funding for medical research.

As a result, non-scientists get a glimpse into what research is really like and can be personally invested in finding a cure. In this

way, we open the communication line between researchers and the general public, making donors partners, not just check writers.

Currently, our supporting institutions include MUSC, the Foundation for Research Development, the Medical College of Wisconsin, the State University of New York Upstate, Harvard and Massachusetts General Hospital, the University of California, and the University of Washington in St. Louis.

Thank you for inviting me today.

Senator SCOTT. Thank you.

Reverend Welch and Mrs. Welch, you have your five minutes now.

**STATEMENT OF REVEREND JERRY WELCH AND NANCY
WELCH, RETIRED MINISTER AND COUNSELOR
DIAGNOSED WITH EARLY-ONSET ALZHEIMER'S
DISEASE, ANDERSON, SOUTH CAROLINA**

Reverend WELCH. Five minutes?

Senator SCOTT. Yes, sir.

Reverend WELCH. I think my time would be best used if you just asked me some pointed questions. I have had Alzheimer's for years. I have been in treatment. I have been very fortunate in my treatment, and I do not want to waste your time, so if you have any—and you cannot ask me anything too personal.

Senator SCOTT. Sounds great.

Reverend WELCH. Have you got any questions? Has anybody got any questions?

Senator SCOTT. In a few minutes, we will have an opportunity to ask each panelist questions, so we will get you the questions. We are currently in the opening comments from the witnesses, so if you have no opening comments—Mrs. Welch, do you have any before we head to the questions?

Mrs. WELCH. Any comments? Well, is this on?

Senator SCOTT. Yes, ma'am, it is.

Mrs. WELCH. Okay. First of all, I owe you an apology and thank you all for coming. The reason you do not have any comments from me is because—confession, I did not probably get back to your aide as quickly as I needed to at all.

Senator SCOTT. No problem.

Mrs. WELCH. Anyway, I was listening to Congressman Duncan saying that he had—his father had Alzheimer's and what a difficult time his mother had had. I have not had that experience because we did have long-term care insurance and also because my parents had died earlier and then we got, you know, for each of us, so we did not have that experience, but I just cannot imagine what anybody else would have gone through as a caretaker other than what I have. I mean, it is really difficult, although probably my husband does not think so, and we have a lot of support. He goes to the respite care twice a week, which is wonderful, and because of Gail, we know a lot about it, or Gail Marion. It is a hard life.

Reverend WELCH. Do I have a little time?

Senator SCOTT. Yes, sir, you have some time, absolutely. About three minutes.

Reverend WELCH. My secret was I got detected early and I got care early, and I am still in care, and that is a critical thing. I go

for therapy every week, pretty much, and so I have always got someone to talk to. I do not get stuck in a rut.

If this is about getting more money allocated for Alzheimer's research, I am a hundred percent for it. I just do not know what to do about it.

As I say, I got good treatment. I have still got good doctors. I go for therapy, psychotherapy, and maybe that is my message. When a family gets diagnosed with Alzheimer's, make sure the person that got the diagnosis goes for therapy after they get on their feet, which I am doing now, and make sure the family goes, the entire family, because you have got a professional to talk to, and you do not start drinking too much, or you do not get depressed, or you do not get angry, why did God do this to me, and so and so over here. It is living free.

Mrs. WELCH. I do have one more comment.

Senator SCOTT. Yes, ma'am.

Mrs. WELCH. It totally left me now. I am sorry. I do not know what it was.

Reverend WELCH. This is the State of our lives.

Senator SCOTT. All right. Well, at this point, we will start asking some questions, and we will have an opportunity to engage the panelists on some of the topics that we think are important for us moving forward.

Mr. Roper, thank you for your investment and your work on collaboration. What are some of the barriers in attracting and encouraging investment in medical research from the private sector? You will note that both myself and

Senator Collins serves on the Committee on Aging as well as HELP, which is Health, Education, Labor, and Pensions, so we are going to spend a lot of time—we are in a unique position to try to take the information that we gain from you all and apply it, frankly, and one of the questions we have is the public-private partnerships, so how do we get more invested from the private sector, from your perspective?

Mr. ROPER. Senator, when we talk about startups, and startups usually are the people who take the research and they try to apply it to a medical need, and that takes investment, and we talk about the term “de-risking” an investment. That means that you will draw more money to invest in a technology if you can reduce the risks, and one of the big risks is regulatory risk. How long is it going to take to get regulatory approval? How straight is that path? How quickly will we know whether this meets the criteria?

NIH is great and important for researchers, but for private industry, the FDA is the bottleneck and the point of regulatory risk for a lot of investment. That is a key function.

Senator SCOTT. Dr. Helpert, would you like to add anything on the issue of private partnerships as it relates to the 501(c)(3) process and looking for ways to use the crowdfunding mechanism to attract more resources?

Dr. HELPERN. Well, as far as if you are asking what are the challenges and how could we move faster, I would agree, the regulatory burden is unbearable. It—the regulatory burden, in general, in my office, where I have my own laboratory which I have three or four post-docs, a couple of graduate students, and several technicians,

probably a total—other faculty totals maybe 15 to 20 people—I spend probably 60 percent of my time in processes of writing and answering regulatory issues with regard to grants and IRBs, other formal organizations that I have to respond to and report to just to keep the lab running. That is how serious it is, so I think, if I had to name one thing, it is the regulatory burden.

Senator SCOTT. Thank you very much.

Mrs. Welch, currently, over 250,000 people in the United States serve as caregivers for loved ones, much like yourself. When you estimate the value of that caregiving in dollars, not just in love and affection but in real dollars, it exceeds \$4 billion of uncompensated care, which is a tremendous amount of an investment on behalf of family members. In addition to that, that represents about 300 million hours providing unpaid care to Alzheimer's patients in 2014.

My question to you and perhaps the Reverend as well is are you aware of any innovations in the area of the biomedical industry that could improve the quality of the care that is being delivered and/or ease the burden, and if not specifically in the biomedical, the bioengineering space, do you have any recommendations on ways to provide greater support to caregivers around our country.

Mrs. WELCH. I remember what I was going to say now. To answer your question, no, I do not, but what I was going to say was there is very little support for the caregiver and also for the patient. When somebody gets Alzheimer's, it is almost like there is just nobody there, and even your best friends—we do have two who are still in contact with us on a regular basis, but the reality is that—and even your children, and I love my children, but two of them flew the coop way out to California a long time ago and they are not that interested. We have one daughter who lives in Anderson and who is a social worker, so she is very supportive, but there is very little support.

Senator SCOTT. Okay. Well, I have about 30 seconds left on my questions before we get to the next round. Reverend, I know that you volunteer at a respite care, a faith-based organization that provides some respite care. Would you comment on how helpful that organization and/or similar organizations would be to providing some type of relief for caregivers, either Mrs. or Reverend Welch?

Reverend WELCH. Well, I volunteer and I am a patient—

Senator SCOTT. Yes, sir.

Reverend WELCH. I have Alzheimer's, and Gail Marion back here is in charge of our program—

Senator SCOTT. Yes, sir.

Reverend WELCH. She would have some things she could enlighten you on, but the power of a group for people that are struggling with Alzheimer's and memory loss is very powerful. We get together two times a week, and a lot of it is just socialization. There is not a big program. You know, we talk. We have a good time. Sometimes, we have a program, but it is the relationships, because when you get Alzheimer's, you look around, all of a sudden, your friends are gone, your job is gone. It is amazing.

Mrs. WELCH. And your car is gone.

Reverend WELCH. Your car is gone. Your freedom is gone. Once they take your car.

Senator SCOTT. Those keys are important.

Reverend WELCH. You are a prisoner.

Senator SCOTT. Keys are very important. My grandfather has encouraged me to know that.

Reverend WELCH. I apologize for being dramatic about it, but—

Senator SCOTT. Yes, sir.

Reverend WELCH. Once the car is gone, it is bad, and the worst thing about it, now that I am on a rant here—

Senator SCOTT. Well, before you get on your rant, sir, we certainly know that, as I want to be a pastor one day, perhaps in my future, we get three closings, but my time is up. We are going to come back to you for your second closing in just a few minutes.

Reverend WELCH. You need to ask for more time.

Senator SCOTT. Yes, sir.

Reverend WELCH. You deserve it. You deserve it.

Senator SCOTT. God bless you, sir. We will take that up with the Chairwoman when we get back to D.C., but right now, Senator Collins, it is your time.

The CHAIRMAN. Thank you very much, Senator Scott.

Doctor Helpern, one of the problems that people have is getting diagnosed accurately and early enough with Alzheimer's—and I can see that the Reverend Welch is nodding in agreement to this—because there is not a simple way right now. I know in the case of my family members, it has been cognitive tests that were given to determine whether or not they had Alzheimer's. Could you update us on the potential for imaging to help us bring about earlier and more accurate diagnosis of Alzheimer's. Can imaging show us the plaques, the tangles in the brain? Can imaging show that areas of the brain may have shrunk? Could you tell us about the promise of imaging helping us get to earlier diagnosis, and equally important, more accurate diagnosis?

Reverend WELCH. Well, the problem is enormous.

Dr. HELPERN. Thank you. I feel like this is kind of a planted question for me.

The CHAIRMAN. It was not, though, but it is of huge interest to me and so many others.

Dr. HELPERN. Well, yes, there are tremendous advances being made in imaging technology. You know, the brain is one of the hardest organs to study. We cannot take it out, look at it, probe it, poke it, and then put it back in. We have to do everything hands off, so non-invasive technologies like MRI are very important for us to continue to develop for these kind of purposes.

Everyone knows that there has been PET imaging developed, positron emission tomography, for imaging plaques in the brain, but my own personal view here is that our attention on the deposition of plaques in the brain has just been too lopsided. There is more to Alzheimer's disease than amyloid plaque, and I think it has been a mistake in our part to focus so much attention on amyloid plaque, and in fact, it is one of the reasons why drug companies are now backing off from the development of different drugs, because approaching imaging plaque and looking for plaque early on has not paid off. The clinical trials in removing plaque have not been successful.

Developing ways to image plaque earlier and earlier is not the direction that I would go and that many people are going. What we

are doing is looking at changes in the brain that occur prior to any kind of clinical symptomology whatsoever. The concept would be inspecting a building before it crumbles. If you went inside a building, an apartment complex that was about to crumble, you might be able to detect cracks in the bearing walls and you might be able to detect cracks in the ceiling because things are imminent. Things are changing rapidly.

That same analogy, we want to apply to imaging, so we want to use MRI to look for things that are going wrong in the brain prior to any kind of clinical symptomology. In my particular area of expertise, we are looking at "miling" the wiring in the brain. There is a school of thought out there that Alzheimer's disease can be thought of almost like a bandwidth problem. In other words, it is a computer analogy that it cannot process the information that we have in the same speed that we used to, and, therefore, that is where the memory problems come from.

It is not necessarily one, you know, my idea versus this idea, but we need to open our eyes to different approaches to looking at this disease much earlier than when the clinical symptoms already start, and MRI is one of those technologies that could be advanced most rapidly.

The CHAIRMAN. Thank you.

I know from talking to scientists across the country that it is something that the focus on the amyloid plaques is misplaced, or that that is one factor, but that I believe there is a protein that may transmit, called tau, may be playing a bigger role. It may be all of the above. It may be neither, and it is one reason that we need to increase the investment in research so we can explore these alternatives.

Dr. HELPERN. Right. I wanted to mention a couple of facts. First of all, if we image people for plaque, 25 percent of the people, of normal controls, normal people, elderly people walking around that have no plaque that we can detect, a significant number of those subjects then go on and get Alzheimer's disease, so 25 percent of the people that we could image, we do not even detect, even if we had a method to detect plaque.

Just because there is plaque in the brain does not mean you have Alzheimer's disease. There are other reasons why plaque develops in the brain. It is no question that plaque is an integral part of the disease process, but there are other things that we could be looking at, and there is, speaking honestly, at the level of NIH and other organizations, kind of a good ol' boy on the bus system. If you are not looking at plaque, you do not get included in the communications, so when we propose alternative ideas, they are kind of pooh-poohed away because it is not mainstream, and we have to stop that, and particularly in this disease, and start looking outside the box, if you will.

The CHAIRMAN. Very interesting.

Just one quick question for Mrs. Welch, who is one of the 40 million family caregivers that we have in our country. I know from personal experience watching in my family what compassion and endurance that takes.

I am curious whether you would have known about this faith-based group that is providing some respite care for you and help

for your husband had you not had a daughter who was involved in treating people with Alzheimer's disease, because what I find in Maine, particularly in rural Maine, is there is such an absence of help for family caregivers, which is one reason I have introduced my bill, and there is not respite care, or if it exists, people do not know how to access it. Would you have known how to access this care but for your daughter?

Mrs. WELCH. Well, yes, I would have, because I have known Gail Marion for many years, and so it was interesting. Just a little aside, I called her and I said, I do not know how I am going to get Jerry there. Would it be okay if he was a volunteer? You do not know this.

Senator SCOTT. New information.

Mrs. WELCH. She said, what a wonderful idea, and so then one day, Jerry came out to me. He was agreeable, and then one day we were walking out of the respite care and he said, "I do not know if I am a patient or I am a volunteer," and I said, well, you are both.

The CHAIRMAN. Thank you. Thank you.

Mr. DUNCAN. Will the Chairwoman yield?

The CHAIRMAN. Yes.

Mr. DUNCAN. From my own personal experience, I give a plug out to the National Alzheimer's Association in that we did not utilize them soon enough. They had resources for giving my mom, who was a primary caregiver, a break, but we were too late contacting them, and I would urge anyone that experiences Alzheimer's to reach out early enough, because there are resources there that I believe, from my understanding, that could assist in that area of your question, and so I certainly appreciate the resources that they offered to my mom, but we just did not take advantage of them, and I think that is probably the case of so many families, that they do not reach out early enough and they do not take advantage of the resources that may be available, and I yield back. Thank you so much.

The CHAIRMAN. Thank you. The Alzheimer's Association does do a wonderful job, as do the Area Agencies on Aging in trying to connect people, but I still think there is also, in states like ours where people are so family oriented and self-reliant, there sometimes is a natural tendency not to reach out and try to handle it yourself, and I think that is really hard.

Thank you, Madam Chairman.

Senator SCOTT. Yes, ma'am.

Probably and perhaps my last five minutes of questions, and Senator, if you have any further questions, as well. As I think about the conversation that we are having and the importance of early detection, early diagnosis, your daughter seeing the signs early on, this question is for the entire panel, anyone who wants to take a stab at it.

Someone else mentioned the ability to have a blood test that shows a predisposition to it. Can we perhaps reemphasize the importance of early detection and perhaps name a few of the ways that we can do so. You were fortunate enough to have a daughter who was involved in caring for Alzheimer's patients. Perhaps it is the imaging, maybe it is the blood test, but I would love just to

have a synopsis on a few ways for early detection. Then I have one final question for Dr. LaBerge.

Yes, ma'am.

Mrs. WELCH. I do not know——

Dr. HELPERN. You know, early detection is difficult. We are designing experiments right now for early detection in imaging. The problem is, we want to go out and take a cohort of, say, a hundred to a couple of hundred normal elderly subjects and we do not know who are going to get Alzheimer's disease, develop a test that we can do, and then we have to watch them for a period of time to see who is going to develop Alzheimer's disease in order to correlate the test, the early diagnostic test. We cannot go out and study Alzheimer's disease and develop a test for early diagnosis. It is too late, so that is the quandary of developing early detection methods. It is a very labor-intensive process of studying large numbers of normal subjects and watching them progress with age.

There are biomarkers in the blood, in the CSF. We can detect them in the brain. Mostly, it is beta amyloid that people are trying to detect. There are new techniques for imaging tau, something called tau in the brain, but we have to look, as I said—I am repeating myself—we have to look beyond the amyloid markers, because there are other markers that we can investigate, but too much of our resources, I believe, has been going into one area. Thank you.

Senator SCOTT. Dr. LaBerge——

Dr. LABERGE. Yes, sir.

Senator SCOTT [continuing]. a question on health care collaboration. It seems like your program, the medical translational technology program, has been successful and has really brought together many shareholders in the area of bioengineering and research. You also mentioned the fact that, I believe the number that you mentioned was \$176 billion on diabetes. Is there a significant correlation between Alzheimer's and the acceleration of other diseases, and if so, will the collaborative work that you are seeing happen in South Carolina help to reduce those costs?

Dr. LABERGE. The cost of health care has always been a big burden for everybody, and when we do reform of health care, it is always associated with cost, so when bioengineers or engineers work in team with Dr. Helpern, who is a basic scientist working in the brain diseases, or when we work with industry, our work here is focused on translation.

I mentioned quickly that it is important to have Federal dollars invested in the research, but if this technology that Dr. Helpern is developing is not going to end up in the hands of clinicians, it is not going to do much, so it is not dollars that are really well invested, so the collaboration is very important.

What we are doing in Greenville, and this is not just a Greenville project, this is a South Carolina project—the State has invested a lot of money in there—is making sure that, as scientists, as engineers, we are working with clinicians, with health caregivers, so that they can actually tell us what the problems are. A lot of research money has been invested without really knowing that it could benefit patients.

I would say, nowadays, there is definitely a definite argument in order to secure funding, so once you have the funding, you need to

be able to funnel it through the system so that it will end up with a product, a technology, an assay that you will be able to detect, or pre-Alzheimer's stages.

What we have done in this State is like we talked a bit about the SmartState program that the State has established. The SmartState Senior, or the SeniorSMART program that Dr. Dye is part of is aimed at doing something like that. It has just been really recently that—or, actually, it is because of you, and I really got invested in Alzheimer's and aging by preparing for this hearing, discovering what our group is doing and how we can help our colleagues to develop their technology.

Even though now I cannot tell you that what we are doing is going to help Alzheimer's, what it is going to do is making sure that those patients are more mobile. If we know that exercise also helps delay Alzheimer's onset, if we can put someone who has arthritis and a knee replacement get more active sooner, maybe the onset of the disease will take more time. I do not know if the Reverend has done exercise when he was younger, but if he had arthritis, he was not able to do it.

The same thing with congestive heart failure. I mean, heart disease is hypertension. Diabetes leads to that. If we do not have enough technology, medical devices, even replacing tissues—you know, organ printing is not really a dream anymore. That exists. You can actually replace tissues and put patients more back on their feet sooner, healthier, happier. They will have less depression and then they will basically overcome their brain disease, as well.

As you can see, this is an integrated approach, really taking aging and health as a matter of everybody, because we all suffer from that from our own families. Ourselves, too, we are all aging, you know. Aging is from birth to whenever we depart. It is really a project—let us call that a project that I think your Committee has an impact in different aspects of what the United States is all about. This is education. This is health. This is regulatory with FDA, and this is definitely NIH, and we forgot NSF. A lot of the basic work needs to be done at NSF.

That with interagency projects that now for funding or taking a little bit more empowerment, I think you really need to make sure that it also involves patient advocacy on this so that we really understand what their needs are and we can provide for them. I will say it would be a good use of taxpayers' dollars.

Senator SCOTT. Thank you very much.

The CHAIRMAN. Doctor LaBerge, I want to thank you for the work that you are doing on diabetes. Another hat that I wear in the Senate is I founded the Senate Diabetes Caucus back in 1998 and we have been able to work together to triple research funding. That is the kind of work we need to do on Alzheimer's, and there are some interesting connections where there is some experimentation going on with inhaling insulin and Alzheimer's has been called the diabetes of the brain by some, so I am very interested in the work that you are doing.

Let me do just one final question for Mr. Roper, and that is the average age of a first-time NIH grant recipient today is 42. That is up from 36 in 1980. Dr. Francis Collins, who regrettably is not a relative, although I wish he were, the head of NIH, has told us

in Congress that he is worried that we are losing an entire generation of younger scientists who are seeking opportunity outside of our country to do their research. Do you have any suggestions for us on how we can make sure that we keep that talent here in the United States?

Mr. ROPER. Well, the House-passed version does have an Innovation Fund of \$10 billion—\$8.5 billion that was really geared toward encouraging and funding young scientists, and I think that those efforts are the right direction to—you have to put some money to attract them, and it has to have some sense that this is not a two-year thing and then it is gone that you are constantly being jerked around by government budgetary processes that leave you uncertain about where your life work is going to be continued or not, but the Innovation Fund, I think, is a great start.

The CHAIRMAN. Thank you.

I have often thought we should have multi-year funding in this area so people would not have that uncertainty about whether the grant is going to be renewed. Doctor.

PANEL MEMBER. If I could add, and because I am in the area where I am training these young scientists, one of the things that we could do differently at NIH—a couple of ideas, and they are not just mine—would be to provide more training grants, so these are called K awards, and they pay the salary of the individual, of the young faculty person. Most of the problems that we have with regard to the research in universities is coming up with supporting the salary of a faculty member early on in their career. These are not large, very large grants, but having more availability or directing more of those funds toward the K awards, K23, et cetera, where they can pay for their salary for the first five years—or not all of their salary, it is a good portion of their salary—so that they can develop their program and build it would be great.

The other area is to—and this is a 30,000-foot observation—is to stop focusing so much on specific projects that I have to define every little single detail in order to get reviewed. The NIH ought to be funding more senior people as investigators. We know you are doing good science. Here is some money to support your laboratory for five years. At the end of five years, we will review what your progress has been in the field, and if it is good, we will give you another five years of funding.

Every time we turn around and we want to try something, like finding an early marker, we have to stop, collect preliminary data, write a grant, submit it, get it reviewed, but from the initial idea to the funding, it is a three-year cycle every time we come up with a new idea.

The CHAIRMAN. Thank you very much.

I want to thank all of our witnesses today. You added enormously to our understanding, and thank you, Senator Scott, for inviting me here.

Senator SCOTT. Absolutely.

Thank you, as well, to all the witnesses for your participation today. We certainly appreciate the investment of your time and your energy and your expertise.

I would say, without objection, members will have five days to submit additional material for the record and written questions for

witnesses to the Chair. I would ask each of you to respond as promptly as possible to any written questions from members that we forward to you.

This hearing is adjourned.

[Whereupon, at 11:40 a.m., the Committee was adjourned.]

APPENDIX

Prepared Witness Statements

**Testimony for
The Senate Special Committee on Aging
South Carolina Field Hearing
Aging in South Carolina:
Biomedical Research in the Palmetto State**

September 2, 2015
Strom Thurmond Institute
Clemson, SC

**By
Wayne Roper
President
South Carolina Biotechnology Industry Organization (SCBIO)**

Madam Chairman and members of the committee: We welcome you to South Carolina and appreciate the chance to discuss some of the country's most extensive aging research right here in South Carolina. This is taking place through private industry, entrepreneurs, research at our three research universities and collaborating organizations.

We mention only in passing promising research at The University of South Carolina, and the Medical University of South Carolina in Charleston along with other organizations. Martine LaBerge, chair of the Clemson Department of Bioengineering and member of the SCBIO board will certainly cover the Clemson landscape.

Our focus at the South Carolina Biotechnology Industry Organization is private industry. SCBIO represents those entrepreneurs, researchers and executives who are moving therapies to market to relieving suffering and improving lives. Research can be impressive, but it changes nothing until it gets to patients -- and that is the focus of SCBIO. We are a non-profit business association dedicated to growing life science businesses and the full ecosystem for innovation in therapies and cures.

Toward that end, I point to the most important streamlining in more than a decade of the government-regulated process to get therapies to patients. The House-passed 21st Century Cures, or H.R. 6, is a major legislative milestone with its impressive bipartisan margin of 344 to 77.

We know that the Senate HELP Committee -- of which Sen. Scott is a member -- is working on its own legislation but we strongly urge H.R. 6 as a model for how it modernizes clinical trials, brings patients at the center of treatment decisions, improves coordination between regulating agencies and importantly, increases funding to the National Institutes of Health and Food and Drug Administration -- \$1.5 billion a year in baseline funding and an \$8.75 billion innovation fund for NIH, and \$550 million more for the FDA. NIH is the critical launching point for what is becoming an explosion of discovery in biomedical science and digital health. The

FDA for years has seen its mission expand and funding contract but is critical to increasing the safe, but efficient throughput of therapies and cures.

Getting discovery to patients requires a long process and lots of money. SCBIO members are launching new companies, moving therapies to market across the spectrum of age-relevant disease.

They include CreatiVasc, a company recognized by the FDA as one of three in the country with breakthrough technology to create a new arterial port system for kidney dialysis patients.

In diabetes, Perle Bioscience of Charleston, is moving to clinical trial a combination therapy that hopes to eliminate the need for insulin shots in certain patients with Type I diabetes.

And Neuro-Quest, an Israel-based technology with North American headquarters here with a promising, technology for an affordable early diagnostic blood test for Alzheimer's Disease, before symptoms become clinically apparent. As you know, that is the key to developing effective intervention.

In stroke, we have young startup companies looking at neuro-stimulation across the brain to forestall or even reverse some of the devastating impact of stroke effects. And increasingly we are seeing an explosion of Health IT companies developing smart phone apps for compliance monitoring and real time information.

Some of this comes out of MUSC's Dr. Robert Adams, who chairs the SmartState Center of Excellence in Stroke treatment, and recently helped launch the \$5 million Center for Biomedical Research Excellence in Stroke therapies. He is responsible for implemented the REACH MUSC Network, which has provided around-the-clock, Internet-based stroke consultation at over 20 sites. It has doubled the percentage of South Carolinians within a 60-minute drive of a stroke treatment center to 76%. And now they are able to quickly fly certain stroke patients to MUSC to have remove the arterial blockage and stop the stroke. With this is a \$4 million American Heart Association grant targeted to research the disparities in stroke recovery among African Americans.

All you have to do is look at the aging research in South Carolina and know how important NIH funding is and what a significant effort is being made on all facets of aging.

At the University of South Carolina, more than \$35 million from the NIH, CDC and other agencies support more than 11 centers and specific projects on aging.

These specific centers and projects include:

- **The SmartHOME Center of Economic Excellence:** Led by SmartState Endowed Chair, Dr. Sue Levkoff, SmartHOME brings together expertise from many disciplines to innovate solutions to improve the quality of life for older adults and their caregivers and families. SmartHOME leverages advances in health information technology, robotics, and computer science with behavioral health interventions and monitoring systems to enable older adults to stay in their own homes and maintain their independence.
- **The NIH Complementary Alternative Medicine (CAM) Center at the USC School of Medicine:** This research center, headed by Drs. Prakash Nagarkatti and Mitzi Nagarkatti, studies the mechanisms by which various plant-derived products can be used to prevent and treat inflammatory and autoimmune diseases, many of which disproportionately affect aging populations. In one current study, the CAM Center team is investigating the use of resveratrol, an anti-aging compound derived from grape skin, to relieve neuroinflammation, which plays a role in Alzheimer's and other neurodegenerative diseases.
- **The NIH COBRE Center for Dietary Supplements and Inflammation (CDSI):** Co-directed by Drs. Prakash and Mitzi Nagarkatti, this center performs research on dietary supplements to see how they regulate inflammation. This center is currently studying dietary supplement applications for cancer, obesity, hypertension, diabetes, Alzheimer's, atherosclerosis and several other autoimmune diseases that regularly impact older adults.
- **The Assistive Robotics and Technology Lab (ARTLab):** Headed by Dr. Jenay Beer, the ARTLab works to develop and improve assistive technologies, including robotics and smart home devices, to improve the quality of life for older adults and their caregivers. Current projects focus on leveraging smart technologies for retirement community employees, preventing and detecting falls and enhancing telepresence devices and applications to meet the needs of older adults.
- **The NIH Center for Colon Cancer Research (CCCR):** Headed by Dr. Frank Berger, the CCCR engages in cutting-edge research aimed at making the breakthrough discoveries that will lead to improved methods for prevention, diagnosis, and treatment of colorectal cancer, the risk for which increases with age. The CCCR also has a robust outreach program that provides awareness, education and screening programs throughout South Carolina.

- **The Office for the Study on Aging:** Located in the Arnold School of Public Health, this research group educates caregivers of patients with dementia and manages the SC Alzheimer's Disease Registry, which is the largest registry of its kind in the country, making it a very unique research resource for study of the disease.
- **The PREMIERS Stroke Study:** This year, Dr. Souvik Sen, USC School of Medicine Neurology Department Chair and SmartState endowed chair for stroke research, is launching a brand new study on stroke prevention through the treatment of gum disease. Few people realize that gum disease can elevate a person's stroke risk nearly three-fold. This study will leverage telemedicine to reach aging individuals in rural communities with stroke care, a strategy that has been shown to reduce stroke-related death and disability rates, which are high in South Carolina.
- **The Neurology Residency Training Program at the USC School of Medicine:** This newly developed program will train neurologists in South Carolina with a goal of alleviating the anticipated need for more neurologists as the South Carolina population grows older in the coming years.
- **The Center for Effectiveness Research in Orthopaedics:** This center, led by Dr. John Brooks, the SmartState Endowed Chair of Rehabilitation and Reconstruction Sciences, is assessing the relative effectiveness of alternative approaches to treat musculoskeletal problems in the elderly. His team is also studying the benefits and risks of higher rates of intensive drug treatment for complex elderly stroke patients.
- **The Prevention Research Center (PRC):** The PRC was established in 1993 as part of the Prevention Research Centers Program of the Centers for Disease Control and Prevention (CDC). Today, PRC researcher Dr. Daniela Friedman is working to establish the SC Healthy Brain Research Network Collaborating Center to advance research into cognitive health and healthy aging issues around Alzheimer's disease and related dementias. Recently, Dr. Sara Wilcox led the effort to create the Healthy Aging Research Network to better understand the determinants of healthy aging in older adult populations, identify ways to promote healthy aging and to assist in the translation of such research into sustainable community-based programs throughout the nation.
- **The Cancer Prevention and Control Program (CPCP):** Led by Dr. James Hébert, the CPCP was founded in 2003 to investigate and begin to alleviate the stark health disparities present in South Carolina, especially those resulting in higher cancer incidence and mortality rates in the African-American community in our state. Virtually all of the University of South Carolina's epidemiologic cancer research is conducted here at the Cancer Prevention and Control Program, and much of our work focuses on modifiable risk factors, such as diet and exercise.

At the Medical University of South Carolina, The Center on Aging is one of the oldest at the university and has 68 affiliated faculty members from all 6 colleges. Funding for age-related research at MUSC has increased 10-fold in the last 15 years to approximately \$33 million

One thing that does mark aging research in South Carolina is collaboration among our three research universities with the annual Aging Research Day. Members of the South Carolina Aging Research Network (SCARN) support this interdisciplinary research conference. It draws around 150 participants from all disciplines, including engineering, nutrition research, basic science, social work, and clinical research. This year it explored stress and aging and next year it will be sensory systems and aging.

At the University of South Carolina, more than \$35 million from the NIH, CDC and other extramural funding agencies support research into issues around aging through

South Carolina's collaborative prowess is evident in Health Sciences South Carolina, one of the nation's first statewide clinical data warehouse systems with participants that include seven of the state's largest health systems, and the research universities to facilitate health research and create new tools for better health outcomes. HSSC is partnering with North Carolina in a \$15 million study funded by Duke Endowment on using data-driven innovations to improve health outcomes in our states' high rates of diabetes, stroke, obesity, heart disease, and health disparities.

See Appendix for further listings

APPENDIX**More South Carolina based Research on Aging and Improving quality of life:
SmartState® Centers (Aging and Quality of Life related)**

- Brain Imaging
Dr. Joseph Helpern: helpern@musc.edu Office: 843.876.2480
- Clinical Effectiveness and Patient Safety
Dr. John Schaefer: schaefer@musc.edu Office: 843.792.8873
- Healthcare Quality
Dr. Helga Rippen: RIPPEN@mailbox.sc.edu Office: 803.576.5902
- Health Facilities Design and Testing
Anjali Joseph, Ph.D., EDAC: anjali@clermson.edu Office: 864-656-2273
- Medication Safety and Efficacy
Dr. Charles Bennett: 803.777.2289
- Molecular Proteomics for Cardiovascular Disease and Prevention
Michael R. Zile: zilem@musc.edu Office: 843.876.4761
- Neuroscience
Gary Aston-Jones: astong@musc.edu Office: 843-792-6092
- Regenerative Medicine
Agneta Simionescu, PhD.: agneta@g.clemson.edu Office: 864.656.3729
- Rehabilitation and Reconstruction Sciences
John Brooks, PhD: JBrooks2@mailbox.sc.edu Office: 803.777.9224
- Renal Disease Biomarkers
Michael Janech: janechmg@musc.edu Office: 843.792.4123
- SeniorSMART®: (SMARTBrain,® SMARTWheels,® SMARTHome®)
Dr. Sue Levkoff: slevkoff@mailbox.sc.edu Office: 803.777.4521
- Stroke
Dr. Robert J. Adams: adamsrj@musc.edu Office: 843.792.3020
- Technology Center to Advance Healthful Lifestyles
Dr. Frank Treiber: treiberf@musc.edu Office: 843.792.8852
- Vision Science
Argentini Anderson, PhD: aanderson@che.sc.gov Office: 803.737.2276

**South Carolina based Research on Aging and Improving quality of life:
Additional Centers, Networks, Institutes & Offices:**

- MUSC Center on Aging
 - Cheryl Dye, PhD: tcheryl@clemsun.edu Office: 803.432.3843
- SCARN: South Carolina Aging Research Network:
 - Lotta Granholm, Ph.D., DDS: granholm@musc.edu Office: 803-432-3843
- South Carolina Institute of Medicine and Public Health (IMPH):
 - Joseph L. (Lee) Pearson, MS, DrPH: lee@imph.org Office: 803-576-5852
- University of South Carolina Center for Gerontology
 - Dr. Rita J. Chou: rjchou@sc.edu Office: 803.777.9265
- Office for the Study Of Aging at the University of South Carolina
 - Brenda L. Hyleman, LISW-AP & CP: hyleman@mailbox.sc.edu Office: 803) 777-0260
- Healthy Aging Research Network Collaborating Center
 - Sara Wilcox, PhD: swilcox@sc.edu Office: 803.777.8141
- University of South Carolina Prevention Research Center (part of the CDC's Healthy Brain Research Network)
 - Sara Wilcox, PhD: uscprc@mailbox.sc.edu Office: 803.777.4253
- Institute for Engaged Aging
 - Cheryl Dye, PhD: tcheryl@clemsun.edu Office: 864.656.4442
- Center for Success in Aging (Greenville Health System):
<http://www.ghs.org/healthcareservices/medicine/geriatrics/Centerforsuccessinaging>

Additional SC Research on Aging and Quality of Life

- South Carolina College of Pharmacy: Aging Research Day and Annual Geriatrics Symposium:
<http://sccp.learningexpressce.com/index.cfm?fa=view&eventID=2089>
- South Carolina Aging Research Conference (Coastal Carolina):
<https://www.coastal.edu/caar/internPaper3.pdf>
- 11th Annual Aging Research Day:
<http://webcache.googleusercontent.com/search?q=cache:PKOg7aF-MIOJ:www.clemson.edu/centers-institutes/aging/documents/Aging-Research-Day-2015-agenda.docx+&cd=8&hl=en&ct=clnk&gl=us>
- SC Lieutenant Governor's Office on Aging:
 - <http://aging.sc.gov/staff/Pages/default.aspx>
 - <http://www.aarp.org/content/dam/aarp/livable-communities/plan/planning/south-carolina-state-plan-on-aging-2013-2017-aarp.pdf>

- Aging in South Carolina, A Snapshot:
https://secf.memberclicks.net/assets/site/EngAGEmment/agingfactsheet-sc_08-22-12.pdf
- The Duke Endowment, Aging in Place in the Carolinas:
<http://dukeendowment.org/sites/default/files//evalutaion-reports/Aging%20in%20Place%20White%20Paper%202013%20v2.pdf>
- Study on SC's Senior Citizens:
<http://www.ipspr.sc.edu/publication/Older%20SC.pdf>
- South Carolina Senior Citizens' Handbook: A Guide to Laws and Programs Affecting Senior Citizens:
http://www.schar.org/Portals/0/Senior_Citizens_handbook.pdf?ver=2014-11-13-143005-503



TESTIMONY

U.S. Senate Special Committee on Aging
 Aging in South Carolina: Biomedical Research in the Palmetto State
 September 2, 2015

**Clemson University Translational Aging Research and Engineering:
 Interdisciplinary Research and Innovation Programs in Bioengineering,
 Regenerative Medicine, and Population Health**

Martine LaBerge, PhD., FBSE, AIMBE Fellow
 Professor and Chair of Bioengineering

Executive Director, Clemson University Biomedical Engineering Innovation Campus (CUBEInC)
 Clemson University, Clemson, South Carolina

Senator Scott, Senator Collins, and distinguished guests, it is a privilege and honor to speak before you this morning. My name is Martine LaBerge, and I am a faculty member at Clemson University with an adjunct appointment in orthopaedic surgery at the Medical University of South Carolina. I also serve as Chair of the Department of Bioengineering at Clemson and as Executive Director of the Clemson University Biomedical Engineering Innovation Campus, known as CUBEInC. I sincerely thank you for the opportunity to provide testimony this morning about the impact of the exciting biomedical technology and health research led by Clemson University to ensure that older Americans can fulfill a longer, healthier and independent life.

As South Carolina's land-grant institution, Clemson University has tackled the socioeconomic burden of aging through an integrated, interdisciplinary approach. The result is significant, with impactful biomedical technology and health research, economic development, and education programs. We have taken as an opportunity that South Carolina is an ultimate retirement destination. In the Upstate, more than 21% of Oconee County residents are older than 65 years while 23% of residents of both Beaufort and Georgetown counties on our coast are considered elderly. As such, South Carolina is an ideal location to conduct research focused on the ability to age in place through use of innovative-care models and technology for managing chronic conditions and/or age-related disabilities as well as caregiver education and support. Our state is also an ideal platform for gerontology and geriatrics research and engineering; we are fully aware that the outcome of our work will impact our fellow citizens and our economy.

Clemson presents an extensive portfolio of research programs, initiatives, and partnerships developed to foster aging-related health research and innovations and workforce development. Our **Clemson University School of Health Research (CUSHR)**, led by Dr. Windsor Sherrill, is a multidisciplinary unit of Clemson that facilitates medical research and scholarship in partnership with health care systems in the state. In partnerships with the Medical University of South Carolina (MUSC), the Greenville Health System (GHS), and the Greenwood Genetic Center, Clemson brings a wealth of research expertise, and the health care systems offer the clinical opportunities students and researchers need to put their ideas into action. Healthcare

practitioners and Clemson researchers work together to improve outcomes and to keep the patient as a focus. The result is breakthroughs in health care delivery, access, and affordability that make a difference in the doctor's office, the operating room, and beyond. For example, a true breakthrough at the forefront of our research agenda is regenerative medicine and precision medicine. With aging, diseased and failed organs and tissues must be replaced. Who would not dream of replacing an aging and diseased liver, heart, pancreas, or brain tissue with a new one? Considered utopian not too long ago, fabrication of organs is no longer a dream, it is a reality that Clemson helped pioneer with its bioprinting technology. Others may claim the concept, but 3D printing for producing a cellular construct was introduced by Clemson University researchers in 2003 and patented by Clemson in 2006. This technology has been licensed to Organovo. Through our Hansjörg Wyss Endowed Chair in Regenerative Medicine, our tissue engineering and regeneration research programs, our internationally renowned researchers, and our clinical partnerships, we can address the technological, clinical and ethical challenges associated with regenerative medicine and precision medicine to meet individual patient needs. The **Clemson-MUSC Bioengineering Program** was formally established in 2003 and is pivotal for regenerative medicine. The Program's mission is to bridge engineering and physical sciences with the life sciences disciplines to better understand fundamental biological and disease processes. The program is located on the MUSC campus in Charleston, where Clemson Bioengineering faculty and their research personnel maintain full-time laboratories and office space. This joint program provides a clinical setting that offers tremendous opportunities for both faculty and students to innovate and develop new technologies for precision medicine. Research must be accelerated and rapidly translated so that our nation's aging citizenry can be assured that their diseased and aging tissues can be replaced.

And in parallel, our quest for longer lasting and improved medical devices remains a priority. The affordability and availability of these medical devices and technology are known to be of great interest to the **Senate Special Committee on Aging**. Clemson is also at the forefront of medical device and technology research. In fact, our **Department of Bioengineering** is recognized worldwide as the birthplace of the field of biomaterials, the building blocks of medical devices. For more than 50 years, our bioengineering researchers have developed numerous technologies that have improved artificial joints, bone-implant fixation, bone-fracture fixation, and heart valve replacements, among others. We continue to develop patient-focused and outcome-driven bioengineering research projects to meet clinical needs. Our teams include students and healthcare practitioners and, where possible, patients.

For example, more than 600,000 knee replacements are performed annually in the United States. With an aging population staying in the workforce longer and obesity on the rise, demand for total knee replacement surgery is expected to exceed 3 million by the year 2030 according to a study published in the August 2013 issue of *Journal of Bone and Joint Surgery*. The Engage Knee System, a knee replacement that can be selectively locked in extension by patients with weakened knees and instability developed by Dr. John Desjardins and former PhD Bioengineering student Dr. Eric Lucas, is an example of innovation developed to meet special needs of the aging population. This research is part of a future in which patients adjust prostheses to fit activities at work and play. The pioneering work on elastin degradation in

tissues as a phenomenon of aging by Dr. Naren Vyavahare and his team has led to licensed technology aimed at preventing elastin degeneration to reduce signs of aging. Every year, more than 300,000 patients undergo replacement surgery after structural failure of their heart valves. When an aging patient suffers from severe heart-valve disease, the structure must be replaced by an implant. Dr. Vyavahare and his research group develop new technology aimed at increasing the functional lifetime of the device.

Approximately 25% of Americans over age 60 have diabetes; it affects functional status and risk of institutionalization for older patients. According to the American Diabetes Association, the total estimated cost of diagnosed diabetes in 2012 was \$245 billion, including \$176 billion in direct medical costs. Direct cost is largely attributed to glucose monitoring. Clemson bioengineering students, Kayla Gainey, Tyler Ovington, and Alex Devon developed a new, inexpensive type of test strip made of commonly available materials using bioprinting as a platform to develop the technology. Diabetics can be provided with low-cost testing equipment they need to manage their blood sugar. This technology was licensed to Accessible Diagnostics, with doctoral student Kayla Gainey serving as its chief technology officer.

The examples cited above are a few among many bioengineering success stories where university, state, and federal funding led to discoveries that have been translated to patient care. Clemson University in collaboration with the Medical University of South Carolina and the University of South Carolina have established the **South Carolina Medical Translational Technology program (SCMedTransTech)**. The three universities have partnered with six hospitals in South Carolina, AnMed Health System, Bon Secours St. Francis Health System, Greenville Health System, MUSC Health, Oconee Medical Center, and Palmetto Health System, to support research aimed at developing clinically relevant technology and its rapid translation. SC MedTransTech focuses on the clinical potential of translational research and comprises a critical mass of researchers and innovators throughout the State of South Carolina who use a team approach where engineers, scientists, students, and clinicians work together to develop technology to address clinical needs. Through this unique partnership between universities, hospitals and Stryker, a leading medical device manufacturer, technology licensing and commercialization are optimized. Our goal is to continue developing in-state start-up companies based on our technologies by stimulating an entrepreneurial culture within the state's biomedical engineering inventors. This culture is practiced and exemplified at CUBEInC.

The Clemson University Biomedical Engineering Innovation Campus (CUBEInC), located on the Patewood campus of Greenville Health System in Greenville, SC, is aimed at educating and nurturing investigators and leaders who can develop, implement, and market innovative scientific and technological knowledge related to aging and related disabilities. CUBEInC integrates education, research and economic development in medical technology and attracts clinical and industrial participation with multi-investigator research laboratories. It provides the environment essential to faculty and students to conduct research to improve patient care delivery and disease diagnosis in collaboration with healthcare practitioners. Research conducted through this strategic initiative enhances patient-oriented outcomes while stimulating economic growth in the Upstate. Targeted research areas include orthopaedic

engineering, cardiovascular science and engineering, tissue engineering, bioimaging, advanced surgical technologies, and regenerative medicine, among others. CUBEInC is supported by a robust clinical trial program at Greenville Hospital System (GHS) and its Institutional Review Board resources for the use of humans in research. With the financial support of the South Carolina Life Sciences Act, industry partners, and Greenville Health System, CUBEInC plays a key role in the growth of South Carolina's biotech industry, finding new ways of diagnosing and treating illness associated with aging. At CUBEInC, we also educate a graduate engineering workforce at the forefront of medical device recycling and reprocessing through a unique certificate integrated in the GreenMD program led by Dr. Melinda Harman. Reprocessing of medical devices helps healthcare providers enhance patient care by controlling supply costs and maintaining safety and quality control. Studies have shown that up to 50% of healthcare cost related to medical devices, including their disposal as biohazardous waste, can be saved through well-executed reprocessing programs. The pioneering research in regenerative medicine in the laboratory of Dr. Dan Simionescu at CUBEInC in collaboration with scientists at Clemson, the National Cardiovascular Center in Osaka, Japan, and the Cardiovascular Surgery Center in Cape Town, South Africa, has led to the development of tissue-engineered scaffolds from decellularized blood vessels. Scaffolds are treated with agents to control their *in vivo* biodegradability and enriched with specific growth factors to promote host cell infiltration, remodeling and revascularization. This technology offers a unique potential to create functional and viable tissue constructs for patients requiring organ replacement.

Through the School of Health Research, Clemson uses an integrated approach to tackle health research where bioengineers, public health scientists, construction scientists, architects, psychologists, sociologists, and industrial engineers, to name a few, work in teams to address aging and health disparities. The **Clemson University Institute for Engaged Aging (IEA)**, led by Dr. Cheryl Dye, provides the nexus for Clemson faculty conducting research to promote quality of life for older adults. Faculty Associates from all Clemson colleges collaborate on research teams to explore aging, from the cellular level to the built environment. Institute faculty are brought together with researchers at the Greenville Health System, University of South Carolina (USC), Palmetto Health System, and the Medical University of South Carolina (MUSC) through the South Carolina Aging Research Network (SCARN) and its annual Aging Research Day as well as through SeniorSMART™, the Smart State Center of Economic Excellence focused on promoting independent living of older adults. SeniorSMART™, a partnership between Clemson University, USC and MUSC, has objectives to **Support Mobility, Activity, Rehabilitation, and Technology** for older adults.

Clemson University researchers have developed and implemented projects using community volunteer **Health Coaches (HCs)** to mentor peers in self-management of chronic conditions and to have trained healthcare clinical staff in health coaching skills. These efforts have yielded improvements in the health of HC clients and in the knowledge and skills of healthcare providers. The projects respond to the challenge of health reform legislation mandated by section 3026 of the Affordable Care Act and also address the Triple Aim framework of access, population health, patient experience of care, quality, and cost efficiency.

Recently, Clemson University partnered with Self Regional Healthcare to develop the **Center for Human Genetics**, a core campus adjacent to the Greenwood Genetic Center in Greenwood, SC. Clemson researchers and companies are engaged in human diagnostics, cognitive development, central nervous system, autism, birth defects, cancer, and inflammatory diseases. The collaborative seeks discoveries in genetic diagnostics and epigenetic therapeutics. In collaboration with the Greenwood Genetic Center, Clemson scientists develop diagnostics and therapeutics that have the potential to provide immediate diagnosis of a variety of diseases.

Clemson University and GHS Roger C. Peace Rehabilitation Hospital have partnered to address the needs of South Carolina's population of aging drivers by developing objective training and assessment programs in addition to developing and evaluating new products and services. This unique collaboration, led by Dr. Johnell Brooks of the **Department of Automotive Engineering**, houses university laboratories within a major healthcare system for cutting-edge multidisciplinary research with strong industry relationships. The partnership strives to be the recognized national leader, enabling the aging population to drive as long as safely possible through research and innovation.

At Clemson University today, more than 150 researchers and scientists are conducting biomedical research that relates to aging. The examples above don't begin to reveal the wealth of knowledge they are making. But all have something in common: the quest for funding, which is especially difficult for translational research. Federal support for biomedical technology and aging research must keep up with inflation, and federal support for translational research and accelerated innovation must be given priority. NIH funding today is 25 percent less than the purchasing power of 10 years ago. As a result, the US government is spending \$25 on care for every dollar spent on finding a cure. And, this cost of care does not even take into consideration lost earning potential or the significant burden placed on families and care givers of elders.

In closing, I sincerely thank you for the opportunity to represent my colleagues and Clemson University and to share with you our success with a model based on collaboration and partnership, as well as our engagement in biomedical and health research to improve the quality of life of our seniors. Through our research, we are dedicated to transform economic development and the wealth of our state. South Carolina's assets, talent and leadership undoubtedly make it the ultimate aging-in-place destination. We look forward to working with you to fulfill the mission of the Special Committee on Aging.



Testimony of Joseph A. Helpert, Ph.D.
September 2, 2015

Medical University of South Carolina

Introduction

If I may, I would like to take a moment to provide a brief framework of the topic we are discussing here today. This may seem like an obvious statement, but the incidence of many diseases increases rapidly with aging. In fact, sixty five percent of all of the people who will die in the world today will die of age-related causes. In the United States, this percentage is closer to 90%. The problem is that aging is a co-factor in many diseases including cancer, heart disease, type 2 diabetes, hypertension and the most obvious one, Alzheimer's disease.

1) What research is being done in SC (MUSC)

Within this broad definition of "aging", MUSC has an equally broad portfolio of aging related research. Of course, NIH plays a significant role in supporting this research with grants ranging from traditional individual investigator R01 proposals to larger Center grants. However, our aging research is also support by the Alzheimer's Association, American Heart Association, American Cancer Society and the US Army as well as corporate support and various other foundations. Our total aging research portfolio of approximately \$33MM in direct costs is divided almost evenly between NIH (37%), corporate (31%) and other agencies (32%). These grants span all colleges within MUSC with the College of Medicine being the largest at 86% and the College of Nursing being our fastest growing.

2) What is the impact/importance of NIH funding for this research

In aging related research, MUSC's NIH portfolio provides approximately \$11.7MM in total direct costs. This NIH support is critical for our research mission for several reasons, but has been on the decline over the past few years due to pressures on the availability of NIH funds. Competition for NIH grant funding is fierce with the success rate for competitive grants being a significant challenge. The level of NIH funding also effects our ability to recruit top scientists to MUSC as NIH funding is used as a means of ranking a University.

One challenge for MUSC in securing additional NIH funding specifically in the area of Alzheimer's Disease and aging in general is the lack of an "Alzheimer's Disease Research Center" (ADRC). Such a center would make MUSC significantly more competitive in funding from the National Institute on Aging (NIA) as it would provide the necessary clinical focus for the recruitment and management of research subjects. NIH provides funding for ADRCs, however, we would need to first "seed" such a center at MUSC for several years before applying for such funding as a proven track record is critical for successful NIH funding.

3) How has this research positively impacted people's lives in SC

Research funding in the area of aging related diseases has a positive impact on the citizens of SC. Aside from providing a means for our citizens to participate in the latest advances in aging research, a focus on aging research can attract top clinicians and scientists to work at MUSC.

4) How can we promote/increasing private funding for continued research; how can we leverage public dollars

With the current pressures of securing research funding, particularly at the beginning of an individual's career, we have had to think creatively to develop alternative revenue streams for supporting research. In an attempt to address this challenge, approximately one year ago a colleague of mine and I established "Donors Cure Foundation". Donors Cure (a 501c3

charitable foundation licensed in nearly all 50 states) provides a mechanism to engage the public in supporting research through crowd funding. Donors Cure attempts to at least partially fill the gap in funding important medical research, particularly for 'pilot' projects and for early career scientists. Researchers use Donors Cure to explore new, creative ideas that they can eventually fund through a larger grant mechanism such as NIH.

Donors Cure teaches researchers to share what they do with non-scientists, an often overlooked, but important, skill. As a result, non-scientists get a glimpse into what research is really like and can be personally invested in finding a cure. In this way, we open the communication lines between researchers and the general public making donors partners – not just checkwriters. Currently, our supporting institutions include MUSC, Foundation for Research Development, Medical College of Wisconsin, State University of NY (upstate), Harvard-Massachusetts General Hospital, University of California (San Diego) and Washington University (St. Louis).

Joseph A. Helpem, Ph.D.
 Professor and Vice Chairman for Research
 Department of Radiology and Radiological Science
 Professor of Neurosciences
 Director, Center for Biomedical Imaging
 South Carolina SmartState® Endowed Chair in Brain Imaging
 The Levidow Family Distinguished Chair in Neurodegenerative Disease Research
 Director, MUSC Office of External Research Relations
 Medical University of South Carolina
 96 Jonathan Lucas Street, MSC 323
 Charleston, South Carolina 29425
 Tel: (843) 876-2460
 helpem@musc.edu

Written Statement from Jerry Welch

September 2, 2015

I was diagnosed in early March, 2007. On the phone with my daughter, she suggested I consult a neurologist as she had noticed that I asked the same question several times. Having worked with Alzheimer's patients, she was concerned about me.

The diagnosis was done with a series of tests on a computer by a psychologist. I was then given Aricept. Later, Nancy was talking Dr. Oliver who thought I was getting worse so he prescribed Namenda. He told Nancy not to give it to me until she was there.

While on a plane from Atlanta returning from California I picked up a discarded Atlanta Constitution in which there was an ad asking for persons diagnosed with Alzheimers to be in a study. The study was by Wythe Pharmaceuticals. During the study, blood tests and MAI'S were administered each time we went which was monthly. Interviews were also conducted on Nancy and myself. The drug was given by injection. Others in the study were given the drug by infusion and it was a different dosage. Obviously the purpose of the study was to arrest the progression of Alzheimer's or hopefully to reverse the process. I was on the study for almost five years but it was stopped three months before it was to end. Both of us thought it had helped but, of course, it could have been a placebo effect.

My life since the diagnosis has been one of losses. I lost my therapy career; I taught at AnMed in the Chaplaincy AND I lost my driver's license. As a result, I lost freedom of movement. I feel that the revoking of the driver license simply because one has Alzheimer's regardless of the level of impairment is horrendous! Another loss is socialization. I feel isolated whereas before I was a leader in Church and my professional organizations. Earlier in my life, I preached, taught and while in Seminary, worked my way through as a recreational therapist at a psychiatric hospital and then worked my way up as Acting Director of Activities.

I drove busloads of children in Louisville and drove a taxi in Louisville. As a young man home from college, I drove a large truck with military fire extinguishers from a suburb of Washington,DC to downtown Baltimore. Now I spend my days going to Respite Care two days and three days a week I have a driver who takes me and my dog on hikes.