

# PAIN IN AMERICA: EXPLORING CHALLENGES TO RELIEF

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## HEARING OF THE COMMITTEE ON HEALTH, EDUCATION, LABOR, AND PENSIONS UNITED STATES SENATE ONE HUNDRED TWELFTH CONGRESS SECOND SESSION

ON  
EXAMINING PAIN IN AMERICA, FOCUSING ON EXPLORING CHALLENGES  
TO RELIEF

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FEBRUARY 14, 2012

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## **PAIN IN AMERICA: EXPLORING CHALLENGES TO RELIEF**

**TUESDAY, FEBRUARY 14, 2012**

U.S. SENATE,  
COMMITTEE ON HEALTH, EDUCATION, LABOR, AND PENSIONS,  
*Washington, DC.*

The committee met, pursuant to notice, at 2:31 p.m. in Room SD-430, Dirksen Senate Office Building, Hon. Tom Harkin, chairman of the committee, presiding.

Present: Senators Harkin, Sanders, Hagan, and Whitehouse.

### **OPENING STATEMENT OF SENATOR HARKIN**

The CHAIRMAN. The Senate Committee on Health, Education, Labor, and Pensions will come to order.

Chronic pain is a significant public health challenge that has yet to receive adequate attention given the tremendous impact it has on people all across our Nation. It is estimated that approximately 116 million adults in America—more than the number of adults affected by heart disease, cancer, and diabetes combined—suffer from some form of chronic pain.

These often debilitating conditions have a tremendous impact on many daily activities making it difficult for many individuals with chronic pain to even meet their own basic needs. Chronic pain profoundly affects quality of life. It remains one of the most challenging conditions to assess and effectively treat. Let me repeat that: it remains one of the most challenging conditions to assess and effectively treat even though it is one of the top reasons for doctor visits.

Because of the pervasive impact of chronic pain, we have convened this important hearing today to explore the current state of research, care, and education with respect to chronic pain. To examine barriers associated with treatment and to discuss opportunities for further research in prevention strategies.

As the Chair, not only of this committee, but of the Appropriations Subcommittee on Labor, Health and Human Services, Education and Related Agencies, I have long encouraged a more ambitious emphasis on pain research at the National Institutes of Health.

In 2003, NIH took a huge step forward in this area by creating the NIH Pain Consortium. Leaders at NIH recognized that despite the fact that every institute and center addresses some aspect of chronic pain, none had the sole responsibility for this critically important issue, nor were the various institutes coordinating their

pain research. This lack of coordination limited the attention given to pain research and despite advances made by the NIH Pain Consortium, more still needs to be done at NIH and across the Federal Government to address the unanswered questions surrounding diagnosis, treatment, and prevention of chronic pain.

Today's hearing will largely focus, not exclusively, but largely focus, on the recently released report by the Institute of Medicine titled, "Relieving Pain in America: A Blueprint for Transforming Prevention, Care, Education, and Research." This crucial report examines the issue of chronic pain in America, identifies some barriers to more effective pain research and treatment, and suggests a plan for addressing these barriers.

The report advocates for enlightening health care providers, patients, and the public on the substantial burdens of living with chronic pain, and it highlights areas for improvement in pain research, care, and education. We need to do a better job of educating in medical schools and in our residencies about the different forms of pain and how they should be treated; the so-called physiological pain that everyone recognizes right away from a sprained ankle, a burn, a broken arm, or cancer where we know the physiological source of that pain.

But then, how about the physiological pain for which we do not know the source—irritable bowel syndromes, spastic colons, fibromyalgia, back pain, and so many others—where there does not seem to be any underlying physical trauma, but we do not know the source. How do we educate our doctors to understand this and to make, as I say, the right type of assessment and diagnosis?

I look forward to the testimony of our expert witnesses who approach the issue of chronic pain from a variety of perspectives, all with the goal of addressing this critical, but often neglected, public health issue, and this is a public health issue not only in what it costs this country in terms of dollars, but also in terms of lost productivity and loss of quality of life.

I thank you all for being here today and I look forward, certainly, to your testimonies.

We will have two panels. On our first panel, we will hear from Dr. Lawrence Tabak, the Principal Deputy Directory of the National Institutes of Health, our No. 2 person at NIH. Dr. Tabak also served as the Director of the National Institute of Dental and Craniofacial Research, and co-leads the NIH Pain Consortium.

Dr. Tabak, welcome. Thank you for your service at the NIH. Your statement will be made a part of the record in its entirety, and if you could sum it up in several minutes or so, I would appreciate it. Thank you very much.

I also ask to leave the record open for any opening statements by Senator Enzi or other Senators who may be coming here later.

Dr. Tabak, welcome and please proceed.

**STATEMENT OF LAWRENCE A. TABAK, D.D.S., Ph.D., PRINCIPAL DEPUTY DIRECTOR, NATIONAL INSTITUTES OF HEALTH, WASHINGTON, DC**

Mr. TABAK. Mr. Chairman, thank you and thank you for the opportunity to testify about pain, one of the most important public health problems facing our Nation.

I will highlight what the NIH is doing in partnership with other Federal agencies to advance pain research and treatment, and I also hope to convey some of the promising opportunities that science offers to overcome the challenges of preventing and treating chronic pain.

Pain can provide useful information, warning our bodies of potential damage. However, chronic pain can be debilitating in terms of many long term diseases like arthritis, diabetes, or cancer. This pain is not only a current public health challenge, but an increasing problem for the future.

Perhaps the most important modern insight about pain is that chronic pain, however it begins, can also become a disease in and of itself. This recognition of chronic pain as a disease has important implications for how we study pain, treat pain, and structure our health care system to provide care to patients suffering from pain.

Congress took steps toward advancing research, education, and care for people with pain through specific provisions in the Affordable Care Act. The Act directed the Secretary of the Department of Health and Human Services to establish the Interagency Pain Research Coordinating Committee, the IPRCC. IPRCC responsibilities include summarizing advances in pain care, identifying gaps and duplications of effort across the Federal research portfolio, and recommending how to disseminate information about pain care. The IPRCC will hold its first meeting on February 27.

The Secretary also engaged the Institute of Medicine, the IOM, to convene a conference on pain to increase recognition of pain as a public health problem, survey the adequacy of pain care, identify barriers to care, and recommend how to reduce these barriers. The IOM report noted that progress will require a better understanding of the biology of pain, improvements in the therapy development process, and removal of barriers to optimal care in the health care system at large.

NIH activities drive improved scientific understanding, complement private sector therapy development, and inform the societal and care delivery issues that ultimately fall within other agencies' missions.

The NIH Pain Consortium coordinates pain activities across the NIH institutes and centers with individual components of NIH, taking the lead on specific programs as appropriate to their mission.

For example, the NIH Blueprint for Neuroscience Research is soliciting interdisciplinary research to learn how changes in neurosignaling and circuitry underlie chronic pain. Recent NIH initiatives also address the education of pain care professionals and researchers, which was another key issue highlighted by the IOM report.

To complement and encourage investigator-initiated research on pain, NIH has undertaken many specific initiatives. These include one entitled, "Mechanisms, Models, Measurement, and Management in Pain Research," which the IOM commended for its comprehensiveness. Other funding opportunities target specific conditions including, recently, ocular pain migraine, temporomandibular joint disorders, vulvodynia, and nerve damage from cancer therapy to name but a few.

The National Center for Complementary and Alternative Medicine recently funded two centers on chronic low-back pain and is spearheading a trans-NIH agency effort under the aegis of the Pain Consortium to develop diagnostic criteria for back pain.

The National Institute of Diabetes and Digestive and Kidney Diseases' Multidisciplinary Approach to the Study of Chronic Pelvic Pain Research Network is another example that embraces the systemic or whole body approach.

In conclusion, as a scientist, I am encouraged by the opportunities for progress that research presents. As a clinician who has experience treating patients in pain, I embrace the important shift toward treating chronic pain as a complex multifaceted syndrome of its own, and I know we must all work together to enable the development and delivery of new and more effective treatments. To take full advantage of what medical science can provide now and in the future, the IOM report called for transformation of how we, as a Nation, understand and approach pain management and prevention.

Next month, at the first IPRCC meeting, the committee will begin its work toward developing a framework to execute the transformation within the research community.

Thank you, and I would be happy to answer any questions.

[The prepared statement of Mr. Tabak follows:]

PREPARED STATEMENT OF LAWRENCE A. TABAK, D.D.S., PH.D.

#### INTRODUCTION

Thank you for the opportunity to testify about one of the most important public health problems facing our country. Today I will highlight what the National Institutes of Health (NIH) is doing in partnership with other Federal agencies to implement the Affordable Care Act provisions for advancing pain research and treatment. I also hope to convey our excitement about progress in the science of pain and the promising opportunities that science offers to overcome the challenges of preventing and treating chronic pain.

Pain can provide useful information that warns of potential damage to our bodies. Just how essential normal pain sensation is to a healthy life is evident from the problems faced by people who have rare conditions that leave them without any pain sensation, including repeated, severe injuries that go unnoticed. Acute pain is pain that has a sudden onset, lasts a short time, and can usually be linked to a specific injury or illness. Chronic pain lasts for several months or more. It can arise, for example, as a persistent pain after an original injury heals, as a debilitating symptom of long-term diseases, like arthritis, diabetes, or cancer, or in many cases from unknown causes, as in irritable bowel syndrome, fibromyalgia, vulvodynia, chronic headaches, and temporomandibular disorders. Chronic pain can also be a debilitating symptom of long-term diseases, like arthritis, diabetes, or cancer. Paradoxically, the very success of medicine in improving survival from cancer, heart disease, HIV/AIDS, stroke, traumatic brain injury, and many other diseases has increased the number of people confronted by chronic pain because more people are living with conditions that can lead to chronic pain. So too has the overall aging of the population, which results in more individuals suffering from painful conditions such as arthritis. Thus, pain is not only a current public health challenge, but an increasing problem for the future.

Although chronic pain can accompany many diseases, perhaps the most important modern insight about chronic pain is that chronic pain, however it begins, can also become a disease in and of itself. Changes in the brain and elsewhere in the nervous system can cause pain to persist long after it has any adaptive value. This recognition of chronic pain as a disease, together with an increased understanding of the maladaptive physiological and psychological changes that underlie the persistence of pain, has important implications for how we study pain, treat pain, and structure our health care systems to provide care to patients suffering from pain.



## IMPLEMENTATION OF THE AFFORDABLE CARE ACT'S PAIN RESEARCH PROVISIONS

Congress took a step toward advancing pain research, education, and care for people with chronic pain via specific provisions in the Affordable Care Act. The law directed the Secretary of HHS to establish the Interagency Pain Research Coordinating Committee (IPRCC) to coordinate efforts within HHS and across Federal agencies that support and conduct pain research. When the Act was signed into law, the Secretary, through NIH, established the IPRCC and solicited nominations for membership on the committee through an open, transparent process. NIH received nominations for almost 100 individuals. After reviewing the impressive group of candidates, the Secretary selected the final roster of committee members, heeding the guidance from the Act on the expertise and personal experience that should be represented, and the input from the public received through the nomination process. The IPRCC roster was announced on February 13, 2012, and the IPRCC will meet for the first time at the NIH on March 27, 2012. Dr. Story Landis, director of the National Institute of Neurological Disorders and Stroke (NINDS), is the interim chair. The duties of the IPRCC include summarizing advances in pain care research supported by Federal agencies, identifying critical gaps in basic and clinical research, ensuring there is no unnecessary duplication of efforts, recommending how to expand public-private research partnerships, and advising how to improve dissemination of information about pain care. NIH is working with other IPRCC member agencies to gather and analyze the agencies' scientific advances, research portfolios, public private partnerships, and education and dissemination activities for review and discussion at the committee's first meeting in March.

The Affordable Care Act also called for the Secretary to engage the Institute of Medicine (IOM) to convene a "Conference on Pain." The stated goals are to increase the recognition of pain as a public health problem; survey the adequacy of pain assessment, diagnosis, treatment, and management; identify barriers to care; and recommend how to reduce these barriers and improve pain care research, education, and clinical care, including public private partnerships. The Secretary, acting through the NIH, contracted with the IOM, which assembled an outstanding committee, chaired by Dr. Philip Pizzo, dean of the School of Medicine at Stanford University, and vice-chaired by Dr. Noreen Clark, director of the Center for Managing Chronic Disease at the University of Michigan, to conduct this independent assessment. Rather than a single conference to cover all topics, the committee held four focused meetings, from November 2010 through March 2011, providing extensive opportunities for public testimony. The patients, patient advocates, health care providers, and others who shared their experiences of living with pain, the state of treatment, and barriers to care provided vital information that significantly influenced the final report. Following consideration of public and expert testimony, analysis of the information provided by the NIH and other Federal agencies, closed deliberations, and the expert review that is the IOM's forte, the IOM issued the report "Relieving Pain in America: A Blueprint for Transforming Prevention, Care, Education, and Research"<sup>1</sup> in June 2011, meeting the deadline set by the Affordable Care Act.

The IOM report contains a wealth of information and recommendations for the long-term scientific, medical, and societal response to the public health problem of chronic pain. The report's independent assessment of the public health and economic burden of pain was itself an important result. The study showed that the burden of chronic pain is enormous and care is far from adequate. As cited in the report, chronic pain affects at least 116 million Americans, costing up to \$635 billion in medical treatment and lost productivity, and producing incalculable suffering for people of every age. The report also identified specific recommendations for the NIH, and the NIH is responding quickly to these recommendations. As one example, the IOM report recommended that the NIH designate a specific NIH institute to lead pain research efforts, and the NIH director has officially given the NINDS this role. The IOM report also recommended that NIH enhance the activities of the trans-NIH Pain Consortium<sup>2</sup> and increase administrative support toward that end. In response, NINDS will establish an office to support all activities of the Pain Consortium and IPRCC. Dr. Landis is also chairing an executive committee of the trans-NIH Pain Consortium, made up of five institute and center directors, that is working to enhance Consortium activities to move pain research forward.

The IOM report called for a coordinated, national effort of public and private organizations to create a cultural transformation in how the Nation understands and ap-

<sup>1</sup><http://iom.edu/Reports/2011/Relieving-Pain-in-America-A-Blueprint-for-Transforming-Prevention-Care-Education-Research.aspx>.

<sup>2</sup><http://painconsortium.nih.gov/>.

proaches pain management and prevention. To achieve this goal, the IOM recommended that the HHS Secretary work across and beyond government, bringing together a wide range of Federal agencies, private-sector, and state-level entities to create a “comprehensive population health-level strategy for pain prevention, treatment, management, and research.” We at NIH strongly support the report’s emphasis on greater interdisciplinary coordination at both the policy and research level. In order to address the research component of this recommendation, the first IPRCC meeting will include an analysis of the data on Federal agencies’ pain portfolios, and the committee will work with HHS leadership toward developing a framework to execute this strategy. Coordination and efficient use of resources are always more important, both within HHS and across other Federal agencies, such as the Department of Veterans Affairs and the Department of Defense, which are represented on the IPRCC.

#### SCIENTIFIC OPPORTUNITIES AND NIH RESEARCH

As the IOM report noted, progress toward alleviating chronic pain requires a better understanding of the biology of pain; improvements in the therapy development process; a greater focus on interdisciplinary approaches for research and the treatment, management, and prevention of pain; and removal of barriers to optimal care in the health care system at large. Congress assigned the IPRCC the task of assessing the landscape of activities across the Federal Government, identifying gaps or duplication, and recommending a future path. As the IPRCC’s work moves forward, I would like to highlight some of NIH’s activities in this area.

In fiscal year 2011, NIH supported \$386 million in research focused on chronic pain. This total does not include all of the extensive related research on diseases, such as cancer, arthritis, diabetes, and stroke that often cause chronic pain. The details of individual pain-focused grants are publicly available on the NIH RePORTER Web site.<sup>3</sup> NIH activities drive improved scientific understanding, complement private sector therapy development, and inform the work of other agencies on care delivery and other issues. Investigator-initiated research that engages the insight and ingenuity of researchers throughout the United States and across disciplines is the core of NIH success generally, and is responsible for much of the recent progress in the science of pain cited in the IOM report. Pain research plays to that strength because so many different aspects of science hold promise for pain. Genetics, brain imaging, engineering, molecular biology, ion channels, neural plasticity, behavioral sciences, and many other areas of expertise are being brought to bear on the problems of chronic pain. NIH investigator-initiated research programs support the full spectrum of research from basic understanding of mechanisms of pain, through translation of discoveries to therapeutics, and on to clinical testing of candidate treatments and prevention strategies.

To complement and encourage investigator-initiated research on pain, NIH undertakes many specific initiatives. The NIH Pain Consortium coordinates pain activities across the NIH, with individual components of the NIH taking the lead on efforts appropriate to their missions. The IOM report noted the comprehensiveness of research topics in the broad NIH funding opportunity announcement (FOA) for research on “Mechanisms, Models, Measurement, and Management” in pain research. The Consortium designed this FOA to stimulate a wide range of basic, translational, and clinical research on pain, from the micro perspective of molecular sciences to the macro perspective of behavioral and social sciences. Other recent FOAs have focused on specific conditions, such as ocular pain, migraine, vulvodynia, interstitial cystitis/painful bladder, nerve damage from cancer therapy, orofacial pain, and HIV/AIDS. The NIH’s National Center for Complementary and Alternative Medicine (NCCAM) is strongly engaged in pain activities because people who suffer from chronic pain are frequent users of complementary therapies. NCCAM recently funded two centers to study neural processing of chronic low-back pain using neuroimaging and to understand how mind-body interventions affect these processes. NCCAM is spearheading a trans-NIH effort under the aegis of the Pain Consortium to engage with the research community on the development of diagnostic criteria for studies of chronic low-back pain, a critical step to performing rigorous clinical trials and ultimately improving care. The National Institute of Diabetes and Digestive and Kidney Diseases (NIDDK) is leading another major effort, the Multidisciplinary Approach to the Study of Chronic Pelvic Pain (MAPP) Research Network,<sup>4</sup> which includes researchers with clinical, epidemiological, and basic research expertise, all working collaboratively. The Network embraces a systemic—or whole-

<sup>3</sup> <http://projectreporter.nih.gov/reporter.cfm>.

<sup>4</sup> <http://www.mappnetwork.org/>.

body—approach in the study of interstitial cystitis/painful bladder syndrome (IC/PBS) and chronic prostatitis/chronic pelvic pain syndrome (CP/CPPS).

On a trans-NIH scale, the NIH Blueprint for Neuroscience Research<sup>5</sup> is currently conducting a Grand Challenge on pain. The goal of the Grand Challenge is to establish collaborative research between pain scientists and non-pain neuroscientists from other fields, such as learning and memory, to learn how changes in neural signaling and circuitry underlie chronic pain.

The need for education of pain care professionals and researchers is also a key issue highlighted by the IOM report. To address this issue, the NIH Pain Consortium is encouraging medical, dental, nursing and pharmacy schools to respond to a new funding opportunity to develop Centers of Excellence in Pain Education (CoEPEs).<sup>6</sup> The National Institute on Drug Abuse (NIDA) is leading the CoEPEs program, which will develop pain management curriculum resources for health care professionals that will advance the assessment, diagnosis, and safe treatment of pain, while minimizing the abuse of opioid pain relievers.

NIH also conducts scientific workshops on pain, which serve several purposes, from catalyzing research collaboration to promoting enhanced interaction with patient advocacy groups. Over the last year, for example, workshops have focused on specific conditions including vulvodynia, chronic fatigue syndrome, chronic sickle cell pain, and temporomandibular joint disorder (TMJD or TMD), and on cross-cutting topics, such as sex differences in pain and overlapping chronic pain conditions. These workshops have led to the growing appreciation of common underlying mechanisms in many poorly understood chronic pain conditions that disproportionately affect women and served as the basis for NIH establishing a new trans-NIH working group on overlapping chronic pain conditions in the fall of 2011.

#### SCIENTIFIC PROGRESS AND A VISION FOR THE FUTURE

Chronic pain is highly prevalent, and the treatment options for people suffering from pain are too often inadequate. However, it is important not to lose sight of scientific progress and the promise for the future. Consider a vision that contrasts sharply with the current state of pain understanding and care that the IOM described. Picture a new reality where physicians and patients will have a broad array of options for preventing and treating chronic pain, tailored to each person's unique pain experience and responsiveness to treatments. Better understanding of why acute pain becomes chronic will enable physicians to prevent many cases of chronic pain, or even to reverse the changes in the brain and nervous system that cause pain to persist. With advances in knowledge, when chronic pain does occur, interventions will reduce the pain, but limit side effects, through tools such as precisely targeted drugs, gene therapy, biologics, brain stimulation devices, and behavioral strategies. Biomarkers and non-invasive imaging methods will better diagnose pain and enable physicians and patients to optimize treatments. Together these advances will provide *personalized* and *targeted* therapies for each patient.

What is particularly exciting to me is that—thanks to research advances in many areas of science—we are well on our way to this new reality. Insights from the study of neural plasticity are leading to new understanding of how chronic pain develops, with hints already of how to prevent chronic pain in some cases or even to reverse these persistent “memories” of pain when they occur. Scientists are beginning to define a range of biological, psycho-social, and genetic factors that shape individual differences in pain perception and response to therapies, and contribute to the considerable differences between the sexes in their risk for developing chronic pain conditions. For example, the first large-scale, prospective clinical study for a chronic pain condition is examining the role of these risk factors in onset of temporomandibular joint disease (TMJD), a common and debilitating pain condition that predominately affects women.<sup>7</sup> The exploration of genes involved in developing and maintaining chronic pain and those that can help to relieve pain has also led to many important discoveries. An industry funded human clinical trial using gene therapy to relieve cancer pain was recently completed, advancing from the NIH-funded preclinical studies of the research team.<sup>8</sup> In another gene study, a gene variant discovered by NIH researchers protects some people from chronic pain after back surgery and may help to determine best therapeutic strategies for patients.<sup>9</sup>

<sup>5</sup><http://neuroscienceblueprint.nih.gov/>.

<sup>6</sup><http://www.altarum.org/project-highlights-pain-education>.

<sup>7</sup>Supplement to J. Pain, 2001 Nov; 12 (11): T1–T108; <http://www.jpain.org/issues?issuekey=S1526-5900%2811%29X0013-5>.

<sup>8</sup>Fink DL, et al. *Ann Neurol*. 2011 Aug;70(2):207–12.

<sup>9</sup>Tegeder I, et al. *Nat Med*. 2006 Nov;12(11):1269–77.

Brain imaging has also provided insights into why some people experience pain differently and how chronic pain changes brain structure and function. Remarkably, there are tantalizing indications that people may learn to reduce their pain when real time brain imaging provides them immediate feedback on activity in pain-related areas of their own brains.<sup>10</sup> Neuroanatomical techniques, combined with direct examination of patients, have allowed NIH-funded researchers to decipher the neural basis for the troublesome extreme light sensitivity in migraine, one of the most common chronic pain conditions.<sup>11</sup> As research on pain at the cellular and molecular level advances, several teams of scientists have identified specific molecules as potential targets for drugs that could block pain with fewer side effects. For example, the resolvins are small molecules biosynthesized from omega-3 fatty acids that are showing promise in rodent models in treating inflammatory pain without the side effects of other typically used analgesics.<sup>12</sup> In addition, well-controlled, methodologically sound, NIH-funded studies have examined the effectiveness of alternative therapies, such as tai chi for fibromyalgia<sup>13</sup> or massage therapy for lower back pain,<sup>14</sup> providing much-needed evidence that these therapies might be useful for certain patients.

#### CONCLUSION

Chronic pain is a debilitating problem with enormous individual and societal costs. Through the newly formed IPRCC and the implementation of recommendations in the IOM report, NIH is enhancing collaborations with other agencies and the private sector to move pain research forward. NIH looks forward to continuing to work with the committee on this issue as the IPRCC activities progress. Although the scientific and societal challenges for improving care for chronic pain should not be minimized, we are excited about what the future holds. There are extraordinary opportunities for progress.

Thank you and I would be happy to answer any questions.

The CHAIRMAN. Dr. Tabak, thank you very, very much. And thank you again for your leadership on this issue. I just have a few questions. I want to delve into the Department's strategy with respect to coordination of pain management.

Can you elaborate on when we can expect the Department to provide us with a full report on what steps the Federal agencies are taking to implement the IOM report recommendations? And is the comprehensive strategy recommended by the IOM being completed?

Mr. TABAK. First step in this process, of course, was the establishment of the Interagency Pain Research Coordinating Committee. The Secretary established this in July 2010 and selected the final roster of 19 members; this includes 7 Federal members, 6 academic members, and 6 public members. This committee will hold its first meeting on March 27 on the NIH campus. Dr. Story Landis, Director of NINDS, will act as the interim chair.

The NIH is currently working with other IPRCC member agencies to gather and analyze the agency's pain-related scientific advances, their scientific portfolios to get an overview of their public-private partnerships, and their individual efforts toward education and dissemination. So that these may be reviewed and discussed at the committee's first meeting in March.

The CHAIRMAN. OK. I am also interested in the promotion of prevention and wellness. You talked about the prevention of pain. As you know, a large segment of the Affordable Care Act is prevention and wellness.

<sup>10</sup> deCharms RC, et al. *Proc Natl Acad Sci USA*. 2005 Dec 20;102(51):18626–31.

<sup>11</sup> Nosedá R, et al. *Nat Neurosci*. 2010 Feb;13(2):239–45.

<sup>12</sup> Xu ZZ, et al. *Nat Med*. 2010 May;16(5):592–7.

<sup>13</sup> Wang C, et al. *N Engl J Med*. 2010 Aug 19;363(8):743–54.

<sup>14</sup> Cherkin DC, et al. *Ann Intern Med*. 2011 Jul 5;155(1):1–9.

What about the role of prevention? I mean, it seems like we have an issue of chronic pain, but how do you prevent it? Are there prevention strategies?

Mr. TABAK. Obviously, this is a multifaceted problem and so the first portion, of course, is to delineate those people who are most at-risk to develop chronic pain. There are a number of ongoing studies which seek to identify so-called risk factors that individuals may have, which make them particularly susceptible to pain. This can take the form of studies of their genetic backgrounds.

For example, in the Orofacial Pain: Perspective Evaluation and Risk Assessment, which is termed OPPERA and you perhaps will hear more about that in the second panel. Individuals have been studied in a prospective manner and a number of genes of interest have been identified with those that associate with pain. These give you clues as to who might be particularly susceptible.

Another gene variant has been discovered which seems to be protective for people from chronic back pain after back surgery. This gives you insights as to who may be more or less susceptible to these painful conditions.

Another option is to begin to dissect the molecular pathways which underlie chronic pain and in so doing, identify new and novel targets that would allow you to intervene to either reduce or, indeed, eliminate the progression from an acute situation to a more chronic one.

For example, scientists have identified several specific molecules from the omega-3 fatty acids which are termed "resolvents," and what these are able to do is they are able to reduce pain associated with inflammation which, as you know, is now generally treated with opioids, or cyclooxygenase or COX inhibitors.

So finally, there are a series of studies that are ongoing using real time brain imaging, which allow us to understand how one is able to control one's reaction and sensation to painful stimuli, and in so doing this, once again, we may be able to come up with biomarkers that will allow us to identify the subset of people who are most at-risk.

The CHAIRMAN. Very good. Dr. Tabak, thank you again, very much. I will leave the record open for any questions that Senator Enzi and others might have. Thank you very much, Dr. Tabak.

Mr. TABAK. Thank you.

The CHAIRMAN. We will call our second panel.

Dr. Philip Pizzo, I hope I correctly pronounced that, who is the Chair of the IOM report that I just referenced here. Dr. Pizzo is joining us from Stanford University, where he is a professor in the Pediatrics and Microbiology and Immunology Department. Dr. Pizzo will focus on the IOM report and recommendations for future areas of research.

Next, we have Dr. William Maixner, will you please come up to the witness table, please; and the same with Miss Veasley and also Dr. Sarno. So, Dr. Maixner, Miss Veasley, and then Dr. Sarno down here on the end.

We welcome Dr. William Maixner. Dr. Maixner is the director of the Center for Neurosensory Disorders at the University of North Carolina at Chapel Hill. Dr. Maixner comes to us today with significant experience in the area of pain management research. He

has experience working at NIH and has developed an orofacial pain management program at Chapel Hill.

Christin Veasley, the executive director of the National Vulvodynia Association will share with us her personal story with chronic pain. Recently, she was appointed to serve on the Inter-agency Pain Research Coordinating Committee at NIH. The Committee was created to coordinate pain research activities across the Federal Government.

Next we have Dr. John Sarno, a Professor of Rehabilitation Medicine at New York University Medical Center and practitioner at Rusk Institute of Rehabilitation Medicine. Dr. Sarno, the author of four books on pain, will share his work with respect to treating chronic pain.

I thank all of you for coming here. Your statements will be made a part of the record in their entirety, and I ask you if you could sum up your statement in 5 or 7 minutes. There is probably a little light down there. I do not get too nervous if it goes over, unless it goes over a long time. But if you are summing up in 5 to 8 minutes, that is fine with me. As I said, your statements will all be made a part of the record in their entirety.

Dr. Pizzo, again, welcome and please proceed.

Dr. PIZZO. Thank you very much, Mr. Chairman.

The CHAIRMAN. Punch the button.

**STATEMENT OF PHILIP A. PIZZO, M.D., DEAN OF THE SCHOOL OF MEDICINE, STANFORD UNIVERSITY SCHOOL OF MEDICINE, STANFORD, CA**

Dr. PIZZO. Thank you very much, Mr. Chairman. It is an honor to be here with you today, and I appreciate very much your interest in this important topic.

Today, I would like to share with you the results of our Institute of Medicine committee that I co-chaired with Noreen Clark from the University of Michigan.

The important findings from our committee, alluded to earlier, as follows: the number of Americans suffering from chronic pain number 116 million, which is actually an underestimate because this does not take into account children, individuals in chronic custodial facilities, people in the military, and others. This is a huge problem in terms of magnitude of numbers, but it is equally shadowed by the financial impact of pain in this country as well.

Currently, we spend between \$560 to \$635 billion a year on pain. That is more than we spend as a nation on cancer, heart disease, and diabetes together. It costs us \$100 billion from our State and Federal budgets to cover the cost of pain care. The reality is that those expenditures are not alleviating pain in America as we know it today.

Our committee was certainly mindful of the fact that there is much to be done in developing cost-effective methodologies as we go forward, but the magnitude is simply astounding.

We recognized that we had five charges from the Affordable Care Act through HHS, and to the NIH in our work. The first was to delineate the public health patterns of care, the magnet of pain, the magnitude of the challenges and problems as they stand today.

The second was to review the impediments and barriers to accessing care for individuals with pain.

To better delineate the demographic groups and special populations who are impacted by pain.

To identify the scientific tools and technologies that are at our disposal today and that might be used for both research, care, education, and treatment.

And to discuss better ways of developing new approaches to researching pain through public and private partnerships.

We were fortunate to have an outstanding committee of 19 individuals representing virtually all professional disciplines from science and medicine, to law and ethics, nursing and clinical practitioners. We worked over a 7-month period to produce the report that stands before you.

In doing so, we reviewed the literature, we held a number of public workshops and meetings, we reviewed testimony from over 2,000 individuals. We commissioned an econometric report to help us assess the impact of pain. We concluded that relieving acute and chronic pain is a significantly overlooked problem in the United States.

We were guided by a series of overarching principles as we began our work. The first is, pain management is a moral imperative. The second is that chronic pain can be a disease in its own right. That there is a need for a more comprehensive approach using interdisciplinary methods to treat and diagnose pain, and to better utilize preventative strategies. We recognized the importance of collaboration between physicians, and patients, and other providers in the education, management, and prevention of pain.

We were not specifically charged to look at the important issue of opioids and their use in pain. We opined on the issue and recognized that there are multiple sides to the important issue, and that this is a topic that should be further studied, but we mainly focused on pain from a public health perspective. In doing so, we also recognized the individual impact of pain, and I would like to read you just 4 testimonials from the over 2,000 that we received.

First, from an advocate,

“Treating a pain patient can be like fixing a car with four flat tires. You cannot just inflate one tire and expect a good result. You must inflate all four.”

From a physician with chronic pain,

“Pain management and physical rehabilitation was never addressed in my medical school curriculum, nor in my family practice residency. My disability could have been avoided or lessened with timely treatment, and I could still be the provider instead of the patient.”

From a clinical pharmacy specialist,

“We cannot successfully treat the complexity of pain without treating the whole patient. Insurance companies will pay for useless, expensive procedures and surgeries, but won’t pay for the simple cognitive behavioral therapy and physical rehab therapy.”

From a patient with chronic pain,

“I’ve a master’s degree in clinical social work. I have a well-documented illness that explains the cause of my pain. But when my pain flares up and I go to the E.R., I’ll put on the hospital gown, I’ll lose my social status and my identity. I’ll become a blank slate for doctors to project their own biases and prejudices on to.”

These are just four of thousands of testimonials that led us to conclude that alleviating pain in America must result in a cultural transformation in how pain is perceived, how physicians and other providers care for pain, and how we develop our social contract with each other to advance clinical care, education, and research.

We concluded 16 recommendations and in doing so, we focused on the public health issues; pain care and management; education of patients, communities, and providers; and research. To help our committees with this activity, we prioritized for the 16 recommendations as ones that we felt should be completed and implemented by the end of 2012. We brought our report forth in June 2011 with that hopeful expectation, and I would like to share with you the highlights of those four recommendations.

The first is that the Secretary of HHS should create a comprehensive population-level strategy for pain prevention, treatment, management, and research. And that this should be coordinated across public and private sectors, include an agenda for developing research, improve pain assessment and management programs, improve ongoing efforts to enhance public awareness of pain. This should include the multiple Federal and private agencies.

Second, we recommended that the Secretary of HHS with other Federal, State, and private sector entities should develop strategies for reducing the barriers of the care of pain, focusing in particular on populations disproportionately affected by and undertreated for pain.

Third, we recommended that health care providers, insurance, and others should work collaboratively between pain specialists and primary care clinicians including referral to pain specialists when appropriate. There are about 4,000 pain specialists in the United States, not nearly enough to cover all those with pain. Therefore, we look to enhanced education and training of primary care physicians to work collaboratively in new care models to better direct and delineate for those suffering from pain.

And finally as an immediate recommendation, we recommended that the Director of NIH should designate a lead institute at the NIH that is responsible for moving the pain research agenda forward along with increased support for, and scope for, the pain consortium. This should involve pain advocacy and awareness, and organizations, and should foster public and private partnerships.

There were 12 other recommendations as well, and we felt that these recommendations serve the goal of creating a comprehensive population-level strategy for pain prevention, management, and research.

The scope of the problems in pain management is truly daunting, and the limitations in knowledge and education of pain health care professionals are glaring. The medical community must actively engage in the necessary cultural transformation to reduce pain suf-



fering of Americans, and work collaboratively to do so with the public and private sectors.

Thank you very much for listening to me.

[The prepared statement of Dr. Pizzo follows:]

PREPARED STATEMENT OF PHILIP A. PIZZO, M.D.

#### SUMMARY

I would like to share with you some of the conclusions and recommendations from the Institute of Medicine Report on *Relieving Pain in America: A Blueprint for Transforming Prevention, Care, Education and Research*. The Patient Protection and Affordable Care Act of 2010 required that the Department of Health and Human Services (HHS), through the National Institutes of Health (NIH), charge the Institute of Medicine (IOM) to conduct this study. I served as the chair of a 19-member committee that initiated its work in November 2010 and delivered the final report to the Congress and NIH in June 2011.

We found that the magnitude of pain in the United States is astounding. More than 116 million Americans have pain that persists for weeks to years. That this number does not include children, individuals in nursing homes or chronic care facilities, prisons or the military, makes the impact even more significant. The total cost of pain is \$560–\$635 billion per year. This is higher than the costs of cancer, cardiovascular diseases and diabetes together. This includes nearly \$100 billion annually from Federal and State budgets. The committee fully recognizes the magnitude of these expenditures and appreciates that more effective and efficient approach to pain management and preventions must consider cost as well as effectiveness.

The committee was charged to review and quantify the public health significance of pain, identify barriers to pain care, determine special populations impacted by pain, identify the tools and technologies to treat pain and enhance pain research along with public-private partnerships in support of pain research, care and education.

In preparing its report the committee reviewed the literature, held public meetings and workshops, received testimony and comments from more than 2,000 Americans, and commissioned a review on the economic burden of care. We concluded that relieving acute and chronic pain and the resultant suffering will require a cultural transformation in how pain is perceived and judged both by people with pain and by the health care providers who help care for them. The overarching goal of this transformation should be gaining a better understanding of pain of all types and improving efforts to prevent, assess and treat pain. The committee's report offers a blueprint for achieving this transformation that includes 16 recommendations that address the public health challenges, pain care and management, the education of patients, communities and providers and research needs and opportunities. To help establish priorities, the IOM Committee recommended that 4 of its 16 recommendations be implemented by the end of 2012 and that the remaining 12 recommendations be completed before the end of 2015 and then be maintained on an ongoing basis. The recommendations are as follows:

#### *Immediate—Complete by the end of 2012*

1. The Secretary of HHS should create a comprehensive population-level strategy for pain prevention, treatment, management and research.

2. The Secretary of HHS along with other Federal, State and private sector entities should develop strategies for reducing barriers to the care of pain—focusing in particular on populations disproportionately affected by and undertreated for pain.

3. Pain specialty professional organizations should support collaboration between pain specialists and primary care clinicians, including referral to pain specialists when appropriate.

4. The Director of the NIH should designate a lead institute at the NIH that is responsible for moving pain research forward, along with an increase in the support for and scope of the Pain Consortium. This should involve pain advocacy and awareness organizations and should foster public-private partnerships.

Twelve other recommendations focus on public health, clinical care, education and research issues that should be completed by 2015. Taken together, these recommendations serve the goal of creating a comprehensive, population-level strategy for pain prevention, management and research. The scope of the problems in pain management is daunting, and the limitations in the knowledge and education of health care professional are glaring. The medical community must actively engage

in the necessary cultural transformation to reduce the pain and suffering of Americans. Importantly the cultural and social transformation needed to alleviate pain in America will require the collaboration of the healthcare provider community with patients and their families who are suffering from pain, including their communities, professional societies and advocacy organizations as well as State and Federal Governments. New public-private partnerships and a broad concerted effort that addresses pain as a public health initiative as well as an individual's source of suffering will be necessary if we are to make progress in alleviating pain. We must all be part of the dialog and the solution.

1. I am Dr. Philip A Pizzo, dean of the Stanford University School of Medicine as well as professor of Pediatrics and of Immunology and Microbiology. I am a pediatric oncologist and a pediatric infectious disease specialist. Before joining Stanford in 2001, I was the physician in chief of the Children's Hospital Boston and chair of Pediatrics at Harvard Medical School. Prior to that I spent 23 years at the National Cancer Institute as a senior investigator, chief of pediatrics, and scientific director. I have been an elected member of the Institute of Medicine since 1997 and was also elected to the IOM Council in 2006. I chaired the Institute of Medicine's Committee on Relieving Pain in America: A Blueprint for Transforming Prevention, Care, Education and Research.

2. Today I would like to share with you some of the conclusions and recommendations from our IOM Committee. First, the magnitude of pain in the United States is astounding.

- a. More than 116 million Americans have pain that persists for weeks to years. That this number does not include children, individuals in nursing homes or chronic care facilities, prisons or the military, makes the impact even more significant.
- b. The total cost of pain are \$560–\$635 billion per year.
  - i. This is higher than the costs of cancer, cardiovascular diseases and diabetes together.
  - ii. Includes nearly \$100 billion annually from Federal and State budgets.
- c. The treatments covered by these expenditures doesn't fully alleviate American's pain.
- d. The committee fully recognizes the magnitude of these expenditures and appreciates that more effective and efficient approach to pain management and preventions must consider cost as well as effectiveness.

3. The 2010 Patient Protection and Affordable Care Act required HHS to enlist the Institute of Medicine to examine pain as a public health problem.

- a. Acting through the NIH, the IOM Committee on Pain that I chaired along with Dr. Noreen Clark, Myron Wegman Distinguished University professor and director of the Center for Managing Chronic Disease at the University of Michigan, as co-chair, was charged to address the current state of the science regarding pain research, care and education and to specifically:
  - i. Review and quantify the public health significance of pain, including the adequacy of assessment, diagnosis, treatment and management of acute and chronic pain in the United States.
  - ii. Identify barriers to appropriate pain care and strategies to review them.
  - iii. Identify demographic groups and special populations and what needs to be done to address their needs.
  - iv. Identify what scientific tools and technologies are available, what strategies can enhance the training of pain researchers, and what interdisciplinary research is necessary in the short, and long-term to advance research and improve diagnosis, care and management.
  - v. Discuss opportunities for public-private partnerships in support of pain research, care and education.
- b. Our committee included 19 members with a wide range of expertise in the broad biopsychosocial aspects of pain—including the ethical, legal, clinical and public health perspectives, along with traditional and complementary medicine began its work in late November 2010. We completed our work over a 7-month period, thanks to the incredible support from the IOM and especially Adrienne Smith Butler, and submitted our report to Congress and the NIH in June 2011.
  - i. Reviewed the literature.
  - ii. Held public meetings and workshops.
  - iii. Received testimony and comments from more than 2,000 Americans.

- iv. Commissioned a review on pain's economic burden.
  - v. We concluded that relieving acute and chronic pain is a significant overlooked problem in the United States.
4. Our committee first established a number of underlying principles to help guide our work. Among them is that:
- a. Pain management is a moral imperative;
  - b. Chronic pain can be a disease in itself;
  - c. There is value in comprehensive treatment that includes interdisciplinary approaches, with a wider use of existing knowledge and a focus on prevention;
  - d. We recognized the conundrum of opioids and that this requires balance and additional review but were specifically directed that this topic was not part of the charge of our committee; and
  - e. We recognized the importance of collaboration of patients and clinicians—in education, management and prevention and that there is a value to a public health approach—to education and management.
5. While we recognize that our focus was on the public health implications of pain, we understood that it is the individual human impact of chronic pain that underscores why this is such an important issue for our families, patients, communities and nation. I offer just a couple of comments from the more than 2,000 that we received:
- a. *From an advocate*: Treating a pain patient can be like fixing a car with four flat tires. You cannot just inflate one tire and expect a good result. You must work on all four.
  - b. *From a physician with chronic pain*: Pain management and physical rehabilitation was never addressed in my medical school curriculum nor in my family practice residency. My disability could have been avoided or lessened with timely treatment, and I could still be the provider instead of the patient.
  - c. *From a clinical pharmacy specialist*: We cannot successfully treat the complexity of pain without treating the whole patient. Insurance companies will pay for useless, expensive procedures and surgeries but won't pay for simple cognitive-behavioral therapy and physical rehab therapy.
  - d. *From a patient with chronic pain*: I have a master's degree in clinical social work. I have a well-documented illness that explains the cause of my pain. But when my pain flares up and I go to the ER, I'll put on the hospital gown and lose my social status and my identity. I'll become a blank slate for the doctors to project their own biases and prejudices.
6. An overarching conclusion from our report on Alleviating Pain in America is that to reduce the impact of pain and the resultant suffering will require of cultural transformation in how pain is perceived and judged both by people with pain and by the health care providers who help care for them. The overarching goal of this transformation should be gaining a better understanding of pain of all types and improving efforts to prevent, assess and treat pain. The committee's report offers a blueprint for achieving this transformation that included 16 recommendations that addressed:
- a. Public health challenges;
  - b. Pain care and management;
  - c. Education of patients, communities and providers; and
  - d. Research.
7. To help establish priorities, the IOM Committee recommended that 4 of its 16 recommendations be implemented by the end of 2012 and that the remaining 12 recommendations be completed before the end of 2015 and then be maintained on an ongoing basis. These are as follows:
- a. Immediate—Complete by the end of 2012
    - i. The Secretary of HHS should create a comprehensive population-level strategy for pain prevention, treatment, management and research to:
      - 1. Coordinate efforts across public and private sector;
      - 2. Include agenda for developing research;
      - 3. Improve pain assessment and management programs; and
      - 4. Improve ongoing efforts to enhance public awareness of pain.
 This should involve multiple Federal, State and private sector entities—including the NIH, FDA, CDC, AHRQ, HRSA, CMS, DOD, VA, professional societies and others.
    - ii. The Secretary of HHS along with other Federal, State and private sector entities should develop strategies for reducing barriers to the care of

pain—focusing in particular on populations disproportionately affected by and undertreated for pain.

- iii. Through CMS, the VA, DOD, health care providers, insurers and others—support collaboration between pain specialists and primary care clinicians, including referral to pain specialists when appropriate.

- 1. Given the prevalence of chronic pain, it is not realistic or desirable to relegate pain management to pain specialists alone. There are fewer than 4,000 such specialists in the United States with limited geographic coverage. Ideally primary care physicians would coordinate pain management, but such a change cannot be achieved without significant improvements in education and training. Moreover payment systems must be restructured to allow primary care physicians to spend more time with patients with chronic pain and deliver care more effectively. Given the increasing demands on primary care physicians, it would be unfair to add expectations without providing opportunities for education and payment for counseling patients. Similar issues and constraints apply to nurses, psychologists, physical and occupational therapists, pharmacists, and practitioners of complementary and alternative medicine.

- iv. The Director of the NIH should designate a lead institute at the National Institutes of Health that is responsible for moving pain research forward, along with an increase in the support for and scope of the Pain Consortium. This should involve pain advocacy and awareness organizations and should foster public private partnerships.

- b. Near-term and enduring—complete by 2015 and maintain

- i. Public Health

- 1. Improve the collection and reporting of data on pain.

- ii. Care

- 1. Promote and enable self-management of pain.

- 2. Provide educational opportunities in pain assessment and treatment in primary care.

- 3. Revise reimbursement policies to foster coordinate and evidence-based pain care.

- 4. Provide consistent and complete pain assessments.

- iii. Education

- 1. Expand and redesign education programs to transform the understanding of pain.

- 2. Improve curriculum and education for health care professionals.

- 3. Increase the number of health professionals with advanced expertise in pain care.

- iv. Research

- 1. Improves the process for developing new agents for pain control.

- 2. Increase support for interdisciplinary research in pain.

- 3. Increase the conduct of longitudinal research in pain.

- 4. Increase the training of pain researchers.

8. These recommendations serve the goal of creating a comprehensive, population-level strategy for pain prevention, management and research. The scope of the problems in pain management is daunting, and the limitations in the knowledge and education of health care professionals are glaring. The medical community must actively engage in the necessary cultural transformation to reduce the pain and suffering of Americans. Importantly the cultural and social transformation needed to alleviate pain in America will require the collaboration of the healthcare provider community with patients and their families who are suffering from pain, including their communities, professional societies and advocacy organizations as well as State and Federal Government. New public-private partnerships and a broad concerted level that addresses pain as a public health initiative as well as an individual source of suffering will be necessary if we are to make progress in alleviating pain. We must all be part of the dialog and the solution.

The CHAIRMAN. Thank you, Dr. Pizzo. Did I pronounce that right?

Dr. PIZZO. Yes, you did. Thank you.

The CHAIRMAN. All right, Dr. Pizzo.

Dr. Maixner, welcome. Please proceed.

**STATEMENT OF WILLIAM MAIXNER, D.D.S., Ph.D., DIRECTOR,  
CENTER FOR NEUROSENSORY DISORDERS, UNIVERSITY OF  
NORTH CAROLINA AT CHAPEL HILL, CHAPEL HILL, NC**

Mr. MAIXNER. Thank you, Mr. Chairman.

Let me just start by thanking the Chairman for indulging these testimonies. It is truly an honor for me. I was born in Ottumwa, IA, southeast Iowa, and so to be testifying before an Iowa Senator is truly an honor for me, but more so for representing the pain research community and the patients who suffer from a hidden epidemic. Let me start my formal statement.

It is truly a tribute to our political system that the voices of many, as well as a few, can be heard and acted upon. Today, I would like to further detail several of the points made in the IOM report, "Relieving Pain in America," which provides clear and unequivocal evidence that more than 100 million of our fellow citizens are experiencing a silent, hidden, and poorly treated epidemic. An epidemic that is as real as the polio epidemic that visibly shackled hundreds of thousands of Americans, and caused individuals and families to suffer greatly. No less real is the suffering of millions of Americans who frequently suffer silently without the outward signs of an iron lung.

Similar to the polio epidemic, a transformative national effort is needed to crush the epidemic of chronic pain worldwide. I submit that we now possess the tools and the knowledge to conquer this epidemic and to bring relief to millions worldwide. The real question is whether the fortitude and will to mount a focused campaign that results in adequate treatments and cures for common conditions exist within the United States today.

During the remainder of my time, I would like to highlight some of the salient points from the IOM report, and also address some of the barriers that exist in the area of research, education, and patient care.

We have already heard two testimonies related to the magnitude of this problem, impacting over 100 million Americans as we sit here today, with horrendous cost to society, over \$600 billion annually paid by our society for these conditions.

New to this committee and to the understanding of the public, I think, is that chronic pain is truly a disease. It is more than a symptom. It is a disease in its own right. We understand the biology to a large extent, and many of the genetic and biological principles that lead to this very devastating set of conditions.

I firmly believe that we now have adequate knowledge with the biology, the psychology, and the social fabric that underlies chronic pain conditions, as well as the genetic factors that we are at the verge of being able to make substantial progress on this massive public health issue.

There are, however, several fundamental barriers that preclude a national transformative effort that I would like to highlight, and recommend as outlined in the IOM report, but also offer some of my own perspectives on solutions as well.

With respect to barriers to research, in my view, one of the major barriers represents the substantial mismatch between the allocation of NIH funding for pain research, though one can quibble about that level. It ranges from 0.4 percent to 1.3 percent. Yet, we

know that the consumption of health care dollars is enormous. If we look at Medicare costs alone, 14 percent of the Medicare budget is used to treat chronic pain. Yet again, only about 0.8 percent of our NIH resources are used for the study of chronic pain.

If we look beyond Medicare, if we look at the consumption of direct and indirect costs associated with treating common conditions, including chronic pain, we find that almost 30 percent of direct and indirect costs are associated with the payment for the treatment of chronic pain conditions.

In my view, there needs to be additional resources either provided to NIH targeted toward chronic pain and pain initiatives, or a proportionate allocation of NIH appropriations that are used to further address pain-related conditions. There are other substantial issues that are outlined in the IOM report related to research, but to me that is one of the primary fundamental research barriers that currently is impeding progress.

In the area of education, it has already been alluded to that curriculum as a fundamental problem. I served at UNC School of Dentistry as Associate Dean for Academic Affairs for 6 years, and had an opportunity to look at the curriculum content that we have devoted to pain management and pain mechanisms. I am proud to say that at UNC, we have 20-some hours of didactic offerings and practical offerings which, in my view, is still very insufficient. Compared to medical curriculum where the average student receives nine sessions related to pain management and pain mechanisms. Woefully inadequate, in my view, to provide competent individuals who are able to diagnose, assess, and treat patients with chronic pain conditions.

I recommend major curriculum reform that is associated with discussions with accrediting agencies, and perhaps discussions with the Department of Education that will help mandate further change in curriculum. I am not one to easily recommend mandates, but I can tell you this is a daunting task trying to work in more clock hours for a specific discipline.

Manpower issues, the lack of education has direct impact on the sparse manpower that we have with respect to individuals who are competently trained to deliver management and diagnoses of chronic pain conditions. I think expansion of our GME programs that will permit sponsored fellowships and residencies in health care related to chronic pain management would be extremely helpful.

Barriers to patient care, they are substantial. As we heard earlier, reimbursements for primary care physicians who are on the frontline, reimbursement is very poor for these conditions. I think mechanisms need to be placed for primary care physicians for reimbursements, but also mechanisms to improve their continuing education opportunities, incentives given to our general physicians to promote continuing education as it relates to pain management.

The need, in my view, for both patient barriers and primary care barriers is the need for advanced pain management centers. There have been words made to the effect that we need such centers. I think it is now time that advanced pain management centers become a reality. These can represent the most important portals of entry to the health care system, portals of referral from primary

care physicians, portals of entry for patients who suffer from debilitating chronic pain conditions.

As we all know, most chronic pain conditions in patients require doctor shopping, going from one doctor to another for diagnosis and treatment. We desperately need coordinated pain centers that have both education, patient care, and research missions behind their walls. This will be one of the most important aspects of action that will help break through barriers that both patients and clinicians face.

I have other aspects and recommendations to my written testimony, but I would just like to conclude by saying that addressing and breaking through these barriers will not only improve the human condition, but will fuel new economic opportunities and job creation that will endure well into the 21st century. The tools and pathways needed to conquer the hidden epidemic of chronic pain are now before us.

We Americans have an established and proud history of curing debilitating public health epidemics and improving the human condition. A national initiative similar to what we addressed with the polio epidemic is needed. It is within our reach and we will relieve suffering of millions of Americans by so accomplishing this initiative.

All that is required is to hear and to act upon the voices of those who suffer from this epidemic.

Thank you, Chairman.

[The prepared statement of Mr. Maixner follows:]

#### PREPARED STATEMENT OF WILLIAM MAIXNER, D.D.S., PH.D

##### SUMMARY

##### CHRONIC PAIN IN AMERICA—A SILENT EPIDEMIC

- Impacts 116 million Americans, approximately \$600B in annual costs with greater costs than cancer, heart disease, and diabetes combined.
- Chronic pain is a disease of the nervous system that has a biological basis and a pathophysiology that pain scientists are having great success in unraveling. This bodes well for new research initiatives that will result in novel treatments and cures for this epidemic.
- We currently have adequate knowledge of many of the biological events that contribute to the perception of acute and chronic pain, but a coordinated effort that permits the translation of current knowledge into clinical practice is lacking.
- Barriers to developing effective treatments and cures:
  - Research:
    - Major mismatch between NIH annual funding (approximately 0.8 percent of NIH budget) and annual direct and indirect costs of chronic pain (14 percent of annual Medicare costs for treatment of pain-related conditions; approximately 30 percent of direct and indirect costs associated with the treatment of all common diseases (cardiovascular, pulmonary, cancer, endocrine, digestive diseases)).
    - The review process (i.e., study sections) for pain-related grant applications needs to be modified to incorporate reviewers with competency in pain mechanisms and pain management. Grant applications associated with pain should be distributed to multiple study sections and should be reviewed by expert reviewers in the field of pain.
    - A need to develop new methods to diagnose and treat chronic pain patients based on the concept of “personalized” medicine. This will require both large scale clinical studies and basic science studies that further delineate pain mechanisms and putative therapeutic targets.
    - A need to expand and integrate funding opportunities across public and private sectors.

- Education:
  - Curriculum: Clock hours are very few and not well-integrated resulting in inadequate knowledge and skills-based competencies regarding the evaluation and treatment of acute and chronic pain conditions. There is a major need for curriculum reform—mandated via accrediting agencies or by the Department of Education.
  - Manpower: A limited number of trained health care providers, basic and clinical scientists with background and interest in pain mechanisms and pain management. There is a major need to expand educational opportunities for the training of health care providers at all professional levels. A need to focused training grants and GME-sponsored residents/fellows across all areas of health care.
- Patient Care:
  - Primary Care:
    - Reimbursements are poor.
    - Referral process to advance pain managements units is eclectic at best with no clear “portal” for referral and management. There is a strong need to incentivize the development of pain patient portals that enable rapid referral and multidisciplinary management for chronic pain patients.
  - Advanced Pain Management Centers of Excellence:
    - Reimbursements for non-procedure-based care are poor and bundled reimbursements for multidisciplinary approaches should be considered and rewarded.
    - Should provide a portal of entry that is not departmentally (silo) based and is integrated across the health care system.
    - Partner with public-private networks to conduct comparative effectiveness assessments of current and new treatments.
  - Patients:
    - Portals of entry into the health care system are not clear resulting in “doctor shopping” with the hope of identifying a clinical facility that understands, validates, and can manage chronic pain. The establishment of bona fide Pain Management Centers of Excellence is required.

Addressing and breaking through these barriers will not only improve the human condition but will fuel new economic opportunities and job creation that endure well into the 21st century.

The tools and pathways to resolving this silent epidemic are now before us. We Americans have an established history of curing debilitating public health epidemics to improve the human condition. A national initiative similar to the way that we addressed the polio epidemic is needed and within our reach to relieve the suffering of millions of Americans.

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#### PAIN IN AMERICA—THE HIDDEN EPIDEMIC

Senators, colleagues and guests, let me start by noting my sincere appreciation for the opportunity to testify before this distinguished body. It is a tribute to our political system that the voices of many, as well as the few, can be heard and acted upon. Today, I would like to further detail several of the points made in the IOM report *Relieving Pain in America*, which provides clear and unequivocal evidence that more than 100 million of our fellow citizens are experiencing a silent, hidden, and poorly treated epidemic. An epidemic that is as real as the polio epidemic that visibly shackled hundreds of thousands of Americans and caused individuals and their families much suffering. No less real is the suffering of millions of Americans who frequently suffer silently without the outward signs of an iron lung. Similar to the polio epidemic, a transformative national effort is needed to crush the epidemic of chronic pain worldwide. I submit that we now possess the tools and knowledge to conquer this epidemic and to bring relief to many millions worldwide. The real question is whether we have the fortitude and will to mount a focused campaign that results in adequate treatments and cures for common chronic pain conditions.

During the next few minutes I would like to provide you with an overview of what I consider to be the salient points of the IOM report and then address issues related to barriers to research, education, and patient care that collectively impair a transformative initiative that will defeat this hidden epidemic.



While the IOM report *Relieving Pain in America* draws several evidence-based findings, I would like to highlight a few key findings:

1. The epidemic of chronic pain impacts over 100 million Americans.
2. The direct medical costs and indirect annual costs associated with chronic pain is approximately \$600B, which is greater than the societal annual cost for cancer, heart disease, and diabetes combined.
3. Chronic pain is more than a symptom that causes patients to seek treatment. It is a disease of the nervous system that has a biological basis and a pathophysiology. Today, well-trained and dedicated pain scientists are making great progress in unraveling the biological, psychological, and genetic mysteries of chronic pain. This bodes well for new research initiatives that can lead to novel treatments and cures for this epidemic.
4. While we have adequate knowledge of many of the bio-psychosocial and genetic factors that contribute to the perception of acute and chronic pain, a coordinated national public and private effort is required to successfully translate current knowledge into clinical practice.

While we are making progress in unraveling the epidemic of chronic pain, future progress in delivering relief to millions faces many hardened and daunting barriers that require a transformation in the way we think about chronic pain and the delivery of health care to the millions who suffer from this epidemic. I would like to highlight some of the barriers that are impeding this transformative effort and offer potential solutions that will enable the transformative step to occur.

- Research:

1. There is a major mismatch between NIH annual funding (approximately 0.8 percent of NIH budget) and annual direct and indirect costs of chronic pain (14 percent of annual Medicare costs for treatment of pain-related conditions; approximately 30 percent of direct and indirect costs associated with the treatment of all common diseases (cardiovascular, pulmonary, cancer, endocrine, digestive diseases)).

*Recommendation:* A greater share of Federal funding for pain research is needed and can be provided by additional targeted funding to the NIH or a portion of allocated NIH appropriations should be devoted to pain research.

2. The review process (i.e., study sections) for pain-related grant applications needs to be modified to incorporate reviewers with competency in pain mechanisms and pain management.

*Recommendation:* Grant applications associated with pain should be distributed to multiple study sections and should be reviewed by expert reviewers in the field of pain.

3. There is a substantial need to develop new methods for diagnosing and treating chronic pain patients based on the concept of “personalized” medicine.

*Recommendation:* The funding of clinical studies and basic science studies that further delineate pain mechanisms and putative therapeutic targets with a focus on identifying key clinical characteristics (phenotypes, biomarkers, molecular profiles) that permit diagnoses based on patient heterogeneity and result in personalized or tailored pain therapies.

4. In order to accomplish a transformative national research initiative coordinated public-private initiatives are required.

*Recommendation:* That the newly formed Interagency Pain Committee be charged with developing, integrating and monitoring public-private funding opportunities.

- Education:

1. Curriculum: Clock hours are very few and not well-integrated resulting in inadequate knowledge and skills-based competencies with respect to the ability of health care providers to evaluate and treat acute and chronic pain conditions.

*Recommendation:* Mandated curriculum reform—mandated via accrediting agencies and/or by the Department of Education.

2. Manpower: A limited number of trained health care providers, basic and clinical scientists with background and interest in pain mechanisms and pain management. There is a major need to expand educational opportunities for the training of health care providers at all professional levels.

*Recommendation:* Provide resources for training grants and GME-sponsored residents/fellows training across all areas of health care.

- Patient Care:

1. Primary Care:

- Reimbursements are poor and when coupled with inadequate education in the area of pain diagnosis and treatment results in inadequate patient care.  
*Recommendation:* Increase reimbursement for services provided in the primary care setting and provide incentives to complete CME offerings in pain management.

- Referral process to advance pain managements units is eclectic at best with no clear “portal” for referral and management.

*Recommendation:* There is a strong need to create incentives/funding that leads to the development of referral portals to Advance Pain Management Centers, which will enable rapid referral and results in the multidisciplinary management of chronic pain patients.

2. Advanced Pain Management Centers of Excellence:

- Reimbursements for non-procedure-based care is poor.

*Recommendation:* Create bundled reimbursements for multidisciplinary approaches.

- Should provide a portal of entry that is not departmentally (silo) based and is integrated across the health care system.

*Recommendation:* Provide funding to support the initial infrastructure development of several Advance Pain Centers of Excellence which integrate across the health care delivery system. These centers should have mission statements related to patient care, research, and education.

- These centers should be on the forefront of conducting comparative effectiveness studies.

*Recommendation:* Federally funded Advanced Pain Centers should partner with public-private networks and other regional Advanced Pain Centers to conduct comparative effectiveness assessments of current and new treatments.

3. Patients:

- Portals of entry into the health care system are not clear resulting in “doctor shopping” with the hope and luck of identifying a clinical facility that understands, validates, and can manage chronic pain.

*Recommendation:* The establishment of bona fide Advanced Pain Centers of Excellence which are “branded” and have public visibility.

Addressing and breaking through these barriers will not only improve the human condition but will fuel new economic opportunities and job creation that will endure well into the 21st century. The tools and pathways needed to conquer the hidden epidemic of chronic pain are now before us. We Americans have an established and proud history of curing debilitating public health epidemics to improve the Human Condition. A national initiative similar to the way that we addressed the polio epidemic is needed and within our reach and will relieve the suffering of millions of Americans. All that is required is to hear and to act upon the voices of those who suffer from this epidemic.

The CHAIRMAN. Thank you, very much, Dr. Maixner. I had briefly introduced Miss Veasley when she came to the panel, but I would yield to Senator Whitehouse for further elaboration on our next witness.

Senator Whitehouse.

Senator WHITEHOUSE. Thank you, Chairman. If you do not mind, I would also like to make a brief comment.

The CHAIRMAN. Yes, sir.

#### STATEMENT OF SENATOR WHITEHOUSE

Senator WHITEHOUSE. First of all, thank you for holding a hearing on this important topic. The costs that come with chronic pain are enormous, and they are not just health care costs measured in dollars. They are also human costs measured in quality of life.

As Rhode Island's attorney general, I brought together a group of health care stakeholders to look into problems we were facing in making pain management a routine part of patient care. Our work centered on simple things like making pain a fifth vital sign, recorded by the medical establishment. If my memory serves, Memorial Hospital was the first to take that step, and other Rhode Island hospitals have since followed.

Promoting awareness and education about pain management, particularly for patients nearing the end of life both across providers and patients, has to be a fundamental part of any strategy to improving pain care. We worked with Dr. Joan Teno of Brown University who had done a study showing that the majority of families who are with a dying loved one reported that their loved one had died in pain. Of the families who reported that their loved one had died in pain, a majority of the families described that family member's pain as severe or excruciating.

It is a really important issue and it gives me great pleasure to introduce Christin Veasley, who is a dedicated advocate and the executive director of the National Vulvodynia Association. She plays a critical role in raising awareness and understanding about vulvodynia and pain disorders that disproportionately affect women, and she also happens to be a resident of North Kingstown, RI.

Christin received her bachelor of science from the University of Wisconsin. Before coming to the National Vulvodynia Association, she worked in the Department of Neurology at the Johns Hopkins University School of Medicine investigating the neurophysiological mechanisms of pelvic pain and inflammation.

I am pleased to announce that Chris was recently appointed to the NIH's new Interagency Pain Research Coordinating Committee. Her personal and professional experience will be a great asset to the committee whose mission is to identify gaps in basic and clinical research on the symptoms, causes, and treatment of pain.

Chris, congratulations on that achievement and that important assignment. We look forward to hearing your testimony today and I will close, again, with my gratitude to the Chairman for allowing me to recognize a native Rhode Islander who we are very proud of.

The CHAIRMAN. Thank you, Senator Whitehouse, and thank you for your opening comments too.

Miss Veasley, as I said, your statement will be made a part of the record in its entirety. Please proceed as you so desire.

**STATEMENT OF CHRISTIN VEASLEY, EXECUTIVE DIRECTOR,  
NATIONAL VULVODYNIA ASSOCIATION, NORTH KINGSTOWN,  
RI**

Ms. VEASLEY. Thank you, Senator Whitehouse, Chairman Harkin.

As director of the NVA, an organization that serves a long-neglected and stigmatized group of women with chronic vulvar or genital pain, and as a pain sufferer myself, it is truly a privilege that I do not take lightly to be before you today to share just some of what millions of Americans are experiencing in their daily battle against chronic pain.

We are very grateful for the committee's work calling on the IOM to study what the IOM committee concluded is a national crisis that we have a moral imperative to address. The IOM report and today's hearing have given us renewed hope. Hope that our country is listening to us, cares about our plight, and is ready to enact long overdue change to help us regain some quality of life and our ability to contribute to society.

I survived a near-fatal accident when I was 15-years-old and also found a resolution to the debilitating vulvar pain I experienced in my twenties. I have had residual back and neck pain for 20 years and since 2008, I have developed jaw and facial pain, as well as migraine headache. My story echoes the experiences of millions. I am just one of many.

The reality is that my choice in being here today, while it is a privilege, means that for the rest of this week and maybe next, that I will be somewhat incapacitated, and many in our country really do not have this choice anymore.

From the moment I open my eyes every morning, the first thing I feel is pain and it stays with me throughout the day. As the number of hours I devote to managing appointments, pain symptoms, and medication side effects, which right now average about 25 hours a week for me, my normal daily activities have become more and more difficult, and the most meaningful pieces of me and my life feel like they slowly fade away.

Due to inadequate research efforts, doctors do not have the training or scientific information they need to effectively manage pain. As patients, we are left completely disillusioned, forced to navigate the health care system on our own, and implement a trial and error process that can easily take months to years to find a treatment to lessen the pain that we experience.

In the last 4 years alone, I have been to specialists in four different States. I have tried 15 different treatments, and I still live with moderate to severe daily pain that impacts every part of my life. I have easily spent \$10,000 on out-of-pocket expenses alone in the last 2 years. I am privileged to have an understanding employer and good health insurance, which many in our country do not have.

Pain exhausts, depletes, dehumanizes, and drains you in every single capacity: physically, emotionally, spiritually, and financially. It is only by God's grace and with the support of my family that I function as well as I do.

And because pain's very purpose is to warn you that something is wrong with your body, it is completely impossible to ignore. Your mind is cloudy. Your attention is scattered, and it feels like you live with a veil over your face, blurred and unfocused. Work goes undone. Productivity and efficiency feel like things of the past. I only selectively engage in activities that I once enjoyed with my family because of the increased pain and disability that follow. Life does not stop; it just simply goes on in our absence.

Chronic pain is an invisible disability. You would not be able to tell by looking at me today that I have any kind of problem. You look fine on the outside, but many feel like dying on the inside. When you suffer from pain in an area of your body that is still not candidly discussed by our country like women with vulvodynia do,

the suffering they feel is further compounded with embarrassment, stigma, and isolation.

As the IOM report highlights, all of what I have just described disparately impacts women. Further, mounting research shows that once you develop one pain syndrome, you are more likely to develop pain in other areas of your body. This is the reason why the NVA joined forces with the Endometriosis Association, the CFIDS Association of America, and the TMJ Association to form the Chronic Pain Research Alliance, the first collaborative advocacy effort to advance a smarter and more cost-effective approach to research on neglected pain conditions that frequently co-occur and disproportionately impact women. In addition to vulvodynia, there are TMJ, chronic fatigue, endometriosis, fibromyalgia, interstitial cystitis, irritable bowel, and headache.

Our 2010 report drew many of the same conclusions as the IOM's. Women have more frequent, more severe, and longer lasting pain than men, but are treated less aggressively. Their reports are routinely dismissed as psychogenic or hysterical, and therefore not real frequently leading to mental health diagnoses. Our failure to deal with just these conditions adds a wasteful \$80 billion a year to our growing health care bill, and despite this impressive toll, the NIH's research investment average just \$1.36 per affected woman in 2010.

The end result, as we have already heard, is that the afflicted are routinely misdiagnosed, shuffled from office to office, inappropriately treated, and left without hope. It takes months to years and multiple consults to obtain an accurate diagnosis, and when one is given, evidence-based treatments are limited, forcing the afflicted to experiment with multiple treatments with unknown benefit and risk.

Because of this disparity and the historical neglect of these conditions, it is essential for future pain initiatives to include a long overdue and appropriate inclusion of these conditions. We applaud the HELP Committee, the IOM, and the NIH for your initial steps to address this national crisis. We strongly support the IOM's main recommendation that by the end of 2012, HHS should create a comprehensive population-level strategy for pain.

Additionally, all of the recommendations stem back to one thing, and that is research. We need an increased, smarter, and more cost-effective Federal research approach by placing greater priority on collaborative research across the conditions, as well as across NIH institutes and Federal agencies. It is only through research that we will better understand the mechanisms of pain, delineate effective treatments, and that the medical community will have the scientifically proven information they need to make appropriate diagnostic and treatment recommendations. Then, and only then, will the haphazard treatment of pain, as well as the costly and wasteful health care spending come to an end giving the millions of American pain sufferers and their families the one thing that we desperately want returned to us and that is our lives.

Thank you.

[The prepared statement of Ms. Veasley follows:]

## PREPARED STATEMENT OF CHRISTIN VEASLEY

## SUMMARY

The Institute of Medicine (IOM) report and today's hearing give us renewed hope that our country is listening to us, cares about our plight, and is ready to enact overdue change to help us regain our quality of life and ability to contribute to society.

I survived a near-fatal car accident in my teens and found a resolution to the debilitating vulvar pain I experienced in my twenties; however, back and neck pain have been an unwanted companion for 21 years and since 2008, I've developed jaw and facial pain, as well as migraine headaches. Normal daily living has progressively become more difficult. I spend 25 hours a week managing pain, appointments and medication side effects. Due to a woefully inadequate research effort, doctors don't have the scientific information they need to adequately diagnose and treat pain. As patients, we are left completely disillusioned, forced to navigate the health care system on our own and implement a trial-and-error process to find treatment(s) to lessen the pain. In the last 4 years, I've been to specialists in four states, have tried 15 treatments and still suffer with moderate to severe daily pain. In the last 2 years, I've easily spent over \$10,000 in out-of-pocket expenses alone. Pain exhausts, depletes and drains you in *every* capacity—physically, emotionally, spiritually and financially. It is only by God's grace, and with the support of my family, that I function as well as I do. Because pain's very purpose is to warn you that something is wrong, it is impossible to ignore. My mind is cloudy and my attention is scattered, like living with a veil over my face—blurred and unfocused. Work goes undone, I feel unproductive and I only selectively engage in activities that I once enjoyed with my family because of the increased pain/disability that follows. Life doesn't stop—it simply goes on in my absence. In social settings, I pretend to the best of my ability to be OK because people don't understand. Chronic pain is an invisible disability, and the associated suffering is further compounded with embarrassment, isolation and stigma.

Further, a growing body of scientific evidence shows that once you develop one pain syndrome, you are more likely to develop pain in other areas of your body. Also, as the IOM report highlights, all of what I've just described disparately affects women. This is the reason why the NVA joined forces with the Endometriosis Association, CFIDS Association of America and The TMJ Association to form the Chronic Pain Research Alliance (CPRA)—the first collaborative advocacy effort dedicated to alleviating the suffering caused by neglected pain conditions that frequently co-occur and disproportionately affect women including: vulvodynia, temporomandibular disorders, chronic fatigue syndrome, endometriosis, fibromyalgia, interstitial cystitis, irritable bowel syndrome and chronic headache. Our groundbreaking 2010 report drew many of the same conclusions as those reached by the IOM. (Please see the attached report\* and patient comments.) The report's key findings include:

(1) Women report pain that is more frequent and more severe, and of longer duration than men, but are treated less aggressively. Health care providers are more likely to dismiss women's pain reports as "emotional, psychogenic, hysterical or oversensitive" and therefore "not real," leading to more frequent mental health diagnoses.

(2) Our failure to effectively deal with these disorders adds \$80 billion annually to our country's growing health care bill, and much of this could be saved through an expanded research effort and improvements in diagnosis and treatment.

(3) Despite their impressive personal and economic toll, NIH's research investment in these conditions is severely shortchanged, averaging just \$1.36 per affected woman in 2010. What little research that has been conducted has lacked sufficient coordination, interdisciplinary collaboration and direction.

(4) The end result is that sufferers are routinely misdiagnosed, shuffled from office to office, inappropriately treated and left without hope, needlessly suffering. It takes months to years, and multiple consults, to obtain an accurate diagnosis. When a diagnosis is given, evidenced-based treatments are limited, forcing the afflicted to experiment with a myriad of therapies with unknown risks/benefits until they find a treatment(s) to relieve some of the pain.

We applaud Congress, NIH and the IOM for their initial steps to address this national crisis. Going forward, it is essential that:

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\*The report referred to may be found at [www.EndWomensPain.org/WIP2011ReportFINAL\(1\).pdf](http://www.EndWomensPain.org/WIP2011ReportFINAL(1).pdf).

(1) HHS-funded research on these conditions is significantly increased, and taxpayer investments be made more efficient and effective by placing greater priority on collaborative interdisciplinary research across the conditions, as well as across HHS agencies and NIH Institutes and Offices;

(2) HHS agencies aggressively expand, in a multidisciplinary fashion, the cadre of scientists who study chronic pain; and

(3) HHS launch an aggressive awareness campaign that includes the most current scientific information on the diagnosis, treatment and prevention of these disorders, to educate health care professionals, patients and the American public.

It is only through an expanded, smarter and more cost-effective Federal research effort that: (i) we will better understand the causes and mechanisms of chronic pain, as well as delineate effective treatments; (ii) the medical community will learn how to recognize and adequately manage pain; and (iii) medical professionals will have the scientifically proven information they need to make appropriate diagnostic and treatment recommendations. Then, and only then, will the haphazard treatment of chronic pain, as well as costly and wasteful health care spending come to an end, giving the millions of American pain sufferers the one thing they desperately want returned to them—their lives.

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Chairman Harkin, Ranking Member Enzi, members of the committee, thank you for the opportunity to speak with you about how chronic pain affects the lives of millions in our country.

We extend our sincere gratitude to the committee for passing a bipartisan amendment that called upon the prestigious Institute of Medicine (IOM) to study this public health crisis and develop recommendations on how to improve pain research, medical care and education. I *cannot* overstate its importance. The IOM report and today's hearing give us renewed hope—hope that our country is listening to us, cares about our plight, and is ready to enact long-overdue change to help us regain our quality of life and ability to contribute to society.

My name is Christin Veasley. I am the executive director of the National Vulvodynia Association (NVA), a non-profit organization dedicated to improving the lives of the 1 in 4 American women, and countless adolescents who, throughout their lifetime, suffer with chronic vulvar (genital) pain. In addition to serving as an organizational representative, I am also a chronic pain sufferer myself. I survived a near-fatal car accident in my teens and found a resolution to the debilitating vulvar pain I experienced in my twenties; however, back and neck pain have been an unwanted companion for 21 years, and since 2008, I've developed jaw and facial pain, as well as migraine headaches.

My story echoes the experiences of millions in our country who bravely fight pain every day of their lives. From the moment I open my eyes each morning, the first thing I feel is pain. Just to get out of bed can be an insurmountable challenge. Normal daily living has become more and more difficult and it is a struggle to just get through the day. As the number of hours devoted to medical appointments, managing pain symptoms and coping with unpleasant side effects of medications increase, which for me currently averages 25 hours per week, the most meaningful parts of life can slowly fade away if you're not diligent. Pain exhausts, depletes and drains you in *every* capacity—physically, emotionally, spiritually and financially. It feels like my life and spirit are being sucked dry, and I have to fight to remain an active participant in my own life. It is only by God's grace and the support of my family that I function as well as I do.

Because the very purpose of pain is to warn you that something is wrong with your body, it is impossible to ignore it. I am constantly distracted. No matter how hard I try to focus, my mind is cloudy and my attention is scattered, like living with a veil over my face—blurred and unfocused. Work goes undone. Productivity and efficiency are things of the past. I only selectively engage in activities that I once enjoyed with my husband and daughters because of the increased pain and disability that follow. Life doesn't stop—it simply goes on in my absence. In social settings, I do my best to pretend that I'm OK, because no matter how well-intentioned others may be, they simply can't understand. Having previously experienced pain in the vulva for 7 years—a part of the body that is not openly discussed in our society—I can testify that the suffering is further compounded by embarrassment, stigma and isolation. While it may be socially acceptable to tell another that you have a headache, women are not comfortable disclosing their inability to sit due to vulvar pain. Chronic pain is an invisible disability. Sadness, isolation, frustration, anger, anxiety, and a host of other unwanted emotions and feelings can dominate you and easily change who you are.

It's logical to ask, "why not see a different doctor or get better treatment?" The answer was recently summarized by a leading pain physician in the journal *Lancet*:

"Overall, currently available treatments provide modest improvements in pain and minimum improvements in physical and emotional functioning. The quality of evidence is mediocre and has *not* improved substantially during the last decade."—(Turk DC, et al., *Lancet* 2011;377:2226–35.)

Because of this, doctors don't have the scientific information they need to make appropriate diagnostic and treatment recommendations. They look at me, shrug their shoulders and really don't have any idea whether a certain medication or treatment is going to work. As patients, we are left completely disillusioned, forced to navigate the health care system on our own and implement a trial-and-error process to find a treatment(s) to lessen the pain. In the last 4 years alone, I've been to specialists in four different States, have tried 15 different treatments and still suffer with moderate to severe daily pain. In the last 2 years, I've easily spent over \$10,000 in out-of-pocket expenses alone. While I am fortunate to have an understanding employer and good health insurance, many in our country are not.

*"After years of misdiagnoses (in my twenties), four miscarriages, four surgeries and, finally, a total abdominal hysterectomy at the age of 25, I am living proof of how poorly women's health needs are addressed. I suffered excruciating pain. This horrible disease ate through my body and eventually devoured my dreams. It is my hope and prayer that no other young woman on the brink of her life endure the pain, humiliation and disappointments that I experienced."*—**Shelli, an endometriosis patient**

A growing body of scientific evidence backs my experience and that of millions of pain sufferers, i.e., once you suffer from one chronic pain disorder, you are more likely to develop additional pain conditions in other parts of your body. *Additionally, as highlighted in the IOM report, all of what I've just described disparately affects women with chronic pain.*

This is the reason why the NVA joined forces with the Endometriosis Association, Chronic Fatigue and Immune Deficiency Syndrome Association of America and The TMJ Association, to form the Chronic Pain Research Alliance (CPRA)—the first collaborative scientific advocacy effort in our country dedicated to alleviating the significant human suffering caused by prevalent, neglected and poorly understood pain conditions that frequently co-occur and disproportionately affect women. These disorders include vulvodynia, temporomandibular disorders, chronic fatigue syndrome, endometriosis, fibromyalgia, interstitial cystitis, irritable bowel syndrome and chronic headache.

In 2010, the CPRA launched the Campaign to End Chronic Pain in Women and released the ground-breaking report, *Chronic Pain in Women: Neglect, Dismissal and Discrimination: Analysis and Policy Recommendations*, which for the first time in history documents the human and financial toll that these conditions impose on women, their families and the U.S. economy. (Please see the attached report and additional patient comments.)

The report's key findings include:

(1) Women report pain that is more frequent, more severe and of longer duration than men, but are nonetheless treated for pain less aggressively. Women's pain reports are often taken less seriously by health care professionals than men's. Medical professionals are more likely to dismiss women's pain reports as "emotional, psychogenic, hysterical or oversensitive" and therefore "not real," leading to more frequent mental health diagnoses.

(2) Our failure to effectively deal with these pain disorders adds as much as \$80 billion a year in direct and indirect costs to America's annual health care bill, much of which could be saved through an expanded Federal research effort and improvements in diagnosis and treatment.

(3) Despite their impressive personal and economic costs, research funding through the National Institutes of Health (NIH) is severely shortchanged, averaging just \$1.36 per affected woman in 2010. This is less than a tenth of 1 percent of the annual estimated cost of these conditions. Also, what little research that has been conducted has lacked sufficient coordination, interdisciplinary collaboration and direction. As a result, the disorders' underlying causes are unknown, diagnostic protocols are lacking and there are very few, if any, scientifically proven treatments. Health care professionals are therefore left without adequate knowledge to appropriately diagnose and treat chronic pain sufferers.

*"Consider that lost productivity due to diabetes cost \$58 billion in 2007 [and in 2008], NIH spent just over \$1 billion on diabetes research and invested 1.7 cents for every productivity dollar lost. In comparison, last year the NIH spent*



*only \$4 million in CFS research—an investment of less than one one-hundredth of a penny for every productivity dollar lost.”—Jennie Spotila, chronic fatigue syndrome patient*

(4) The end result is that Americans suffering with these pain conditions are routinely misdiagnosed, shuffled from office to office, inappropriately treated and left without answers or hope, needlessly suffering. It typically takes several months to years, and multiple consultations, to obtain an accurate diagnosis. When a diagnosis is given, evidence-based treatment options are severely limited. Sufferers are forced to experiment with a myriad of therapies, most with unknown risks and benefits, until they find a treatment(s) to relieve some of their painful symptoms.

*“The reason they gave me when they refused to treat me at the emergency room was, ‘We can’t treat you for pain because we would be treating a symptom rather than the cause of a problem.’ My response to them was, ‘After 12 years of surgeries and treatment and over \$200,000 in medical expenses, no one has fixed the problem, and in fact, it has gotten worse.’”—TMJ patient*

We applaud Congress, the National Institutes of Health and the Institute of Medicine for their initial steps to address the alarming public health crisis. Going forward, it is essential that:

(1) HHS-funded research on these conditions is significantly increased, and taxpayer investments be made more efficient and effective by placing greater priority on collaborative interdisciplinary research across the conditions, as well as across HHS agencies and NIH Institutes and Offices.

(2) HHS agencies aggressively expand, in a multidisciplinary fashion, the cadre of scientists dedicated to studying chronic pain.

(3) HHS launch an aggressive multiyear awareness campaign, which includes the most current scientific information on the diagnosis, treatment and prevention of these disorders, to educate health care professionals, patients and the American public.

It is only through an expanded, smarter and more cost-effective Federal research effort that: (i) we will better understand the causes and mechanisms of chronic pain, as well as delineate which treatments are effective and do not harm; (ii) the medical community at large will learn how to recognize and adequately manage pain; and (iii) medical professionals will have scientifically proven information they need to make appropriate diagnostic and treatment recommendations. **Then, and only then, will the haphazard treatment of chronic pain, as well as costly and wasteful health care spending come to an end, giving the millions of American pain sufferers like Madalyn the one thing they desperately want returned to them—their lives.**

*“My doctors just threw up their hands, not knowing what to do with me. I went to four doctors and each one said something different. I can’t believe I have to go through this, and the expense is unbelievable. I am in so much pain and I just want my life back.”—Madalyn, age 19 (suffers from chronic fatigue syndrome, fibromyalgia and TMJ)*

#### ATTACHMENT—CHRONIC PAIN RESEARCH ALLIANCE—QUOTES/STORIES FROM PATIENTS AND FAMILY MEMBERS

*“After examining me and doing an ultrasound, my doctors said the only problem I had was in my head. . . .”—Rosemarie, endometriosis patient*

*“Is it too much to ask that we, the patients, no longer be bound to a system where no one professional takes responsibility for the patient—a system of unbelievable referrals with unscientific, unproven treatments (and hope) sold to the patient by each referring physician? In many cases, patients end up worse and more and more destitute, yet they grasp for hope with each referral. Is it too much to ask that we get the protection we deserve under the Hippocratic Oath to do no harm and the laws of the United States?”—Terrie Cowley, TMJ patient and President of The TMJ Association*

*“I am a 26-year-old female with fibromyalgia and a mixed connective tissue disorder (MCTD) closely related to systemic lupus erythematosus, and I experience widespread muscle and neuropathic pain that oftentimes becomes so debilitating that it impairs basic functioning such as standing and walking. After several attempts at managing my pain through different narcotic pain relievers that had failed, my rheumatologist referred me to the medical center’s pain clinic to have a pain medicine specialist take over the pain management aspect of my case. Among his reasons for referring me to a pain medicine specialist, the rheumatologist claimed, was that he was already overwhelmed with managing my disease to keep*

the MCTD from chronically flaring up and keeping track of the prescription medications relating to those goals. He explained that adding and monitoring narcotics further complicated his workload and required additional time to monitor interactions as well as his vulnerable Drug Enforcement Administration number.”—Fibromyalgia patient

“It’s a relief to finally have names for my conditions after suffering most of my life with a myriad of symptoms.”—Susan, vulvodynia, interstitial cystitis, and fibromyalgia patient

“My doctors just threw up their hands, not knowing what to do with me. I went to four doctors and each one said something different. I can’t believe I have to go through this, and the expense is unbelievable. I am in so much pain and want my life back.”—Madalyn, TMJ, chronic fatigue syndrome and fibromyalgia patient

A compilation of e-mails received by the TMJ Association:

“I have a 46 year old son that is suffering from severe TMJ. He has been under treatment for 15 years for it and everything they have tried, including several TMJ surgeries, have failed. He has now lost his job, (Fire Investigator), has no benefits, is filing bankruptcy and was so desperate with the pain. He lives in Austin, TX. I am willing to sell my home and apply the money to help him. My husband and I are 73 & 74 so our lives are not as important as his is. He has 2 children still living at home. Since my husband spent 28 years in the army, I think we can get help with housing with them, for us. Please, please, is there any help for him?”—David’s mother (April 2008)

“Our son died as a result of all the suffering he had. David became addicted to his prescription drugs and had gone to a short term rehab but needed more help. He stayed with us for 2 years and finally went to the hospital to detox, stayed 3 days and then agreed to go into Teen Challenge. His heart had become weakened over the years of prescription medications and he put a Fentanyl patch on and then to get more relief, he put the other patch in his mouth. It was too much for his heart. He was a brilliant man, adored his 3 children and wanted so much to get well. He died September 29, 2010 at the age of 48 sitting in a chair in our backyard and my husband found him very shortly after he died. David left behind a wife, 26 and 19 year old daughter, and a 21 year old son. It is so hard to see what the family can suffer through all this . . . but these young ones of ours have paid the price for the pain and addiction. Our hearts go out to anyone suffering this dreadful disease. You are doing such a great work and we will keep you in our prayers for February 14th Senate Hearing.”—David’s mother (January 2012)

“The hardest thing was to approach my condition rationally, because I needed doctors to take me seriously. What I really wanted to do was to scream or cry out of frustration and utter desperation.”—Vulvodynia patient

“My periods were getting worse, but I was used to having debilitating pain so I did not think that it was necessarily unusual. Eventually, out of sheer desperation, I went to a local clinic . . . and [the doctor there] found a pelvic mass of approximately 6–7 cm . . . that needed surgical removal. I was in a state of shock. How did it get that way? I had seen doctors on a regular basis for the last year. While I awaited surgery, I had another period where I started hemorrhaging and drifted in and out of consciousness on the floor of a washroom at work. Finally the surgery took place and the doctor told me I had endometriosis.”—Endometriosis patient

“I did get my insurance to pay for most of this by not calling it TMJ (they don’t like those letters). My doctor called it jaw joint surgery and a bone spur. The surgery cost over \$30,000 and I paid \$100 co-pay.”—TMJ patient

“The reason they gave me when they refused to treat me at the emergency room was, “We can’t treat you for pain because we would be treating a symptom rather than the cause of a problem.” My response to them was, “After 12 years of surgeries and treatment and over \$200,000 in medical expenses, no one has fixed the problem, and in fact, it has gotten worse.” The hospital then refused any treatment, even though my blood pressure/temperature was high, and then labeled me a “drug-seeker” on my hospital records. Now, I am petrified every time I have to ask for pain medications.”—TMJ patient

“Consider that lost productivity due to diabetes cost \$58 billion in 2007. Last year [2008], NIH spent just over \$1 billion on diabetes research. In other words, NIH invested 1.7 cents for every productivity dollar lost. If NIH allocated research funds to CFS as it has to diabetes, then a 1.7 cent investment per dollar lost would translate into \$1.3 billion dollars in annual research. Apparently, NIH believes that CFS does not merit such investment. Last year the NIH spent only \$4 million in CFS research—an investment of less than one one-hundredth of a penny for every productivity dollar lost.”—Jennie M. Spotila, chronic fatigue syndrome patient

"My daughter has had endo for over 4 years. Our insurance dropped us because the RN at the company said my daughter (a teen) could have a hysterectomy and not run up all these bills!"—Jeannie

"I have constant headaches, neck pain, ear and jaw pain. I can't get rid of it. Comes and goes like a roller coaster. Not a happy way to live."—Michael, TMJ patient

"Endometriosis runs in my family. I suffered years of infertility and had three surgeries. Now my daughter who is 22 has all the symptoms. She's talking to a doctor that wants to burn the lesions off—that's what was done to mine. Have we made no progress at all in reducing scar tissue?"—Susan

"I am a post-hysterectomy survivor of endometriosis. We found out about my daughter's endo when she was 11. She had painful symptoms before her first period and we went to numerous doctors who told us everything from "Amanda or a family member is making up these symptoms to get attention and/or drugs" to "Amanda just needs to understand that cramps are a way of life for women." Her first surgery was at age 12 and even the doctor who performed the surgery was shocked at the extensiveness of her endo. Now two-and-a-half years later, Lupron, drugs, and more surgery, we are making a last effort to save her reproductive ability."—Kari

"I suffer from TMJ have horrible pain in my jaw from constantly clenching it. I've had all new caps put on my bottom teeth and have had 4 teeth pulled due to them breaking as a result of the strain. At times my jaw will lock and it hurts to open my mouth. I wear a night guard that provides some relief at night. This whole process has become extremely expensive and my insurance isn't picking up most of it . . . ."—Jacqueline, TMJ patient.

"I suspect there is a lot of suicide in women and girls with endo. I attempted suicide several times as a teen because the pain was that intense. I was planning on trying again in my mid-20's when I discovered the Association. I suspect I may have been successful that time. The Endometriosis Association literally saved my life."—Terri

"My 18 year old is suffering terribly with endo, so much so that she has been unable to attend school for the past 1½ years and it has cost her participating in graduation this week. She thankfully is a strong willed young woman and my husband and I are her supporters 100 percent of the way. We are at a loss on treatment however. She has had two laser treatments with minimal lasting results. My husband is a family physician and he particularly feels helpless."—J.

"I have suffered with intermittent headaches, jaw pain, loss of sleep, poor quality sleep for almost 10 years due to jaw clenching/TMJ. I have had two different bite guards, my teeth adjusted for proper bite, seen two different general dentists and two subspecialist dentists. It is obvious to me that there is little consensus between different practitioners and that more research into the treatment of this disorder is needed."—Tara, TMJ patient

"After years of misdiagnoses (in my twenties), four miscarriages, four surgeries and, finally, a total abdominal hysterectomy at the age of 25, I am living proof of how poorly women's health needs are addressed. I suffered excruciating pain and continual bleeding for months. Handed a Rx for Valium or some other medication to "calm" me because doctors felt my symptoms were emotionally induced. This horrible disease ate through my body and eventually devoured my dreams. Years later I find myself with rheumatoid pains, diagnosis of fibromyalgia, Hodgkin's lymphoma and breast cancer. It is my hope and prayer that no other young woman on the brink of her life endure the pain, humiliation and disappointments that I experienced."—Shelli

"I feel as if I am at the end of my rope. I have lost my job and may end up losing my home. I have been able to work since December 2010 & ended up getting fired in January 2011 because my FMLA didn't get approved. I also suffer from allergies and my ENT & I originally thought that was the cause of my ear pain. However, once the redness in my ear tubes went away we discovered I also had TMJ Disorders."—Laura, TMJ patient

"Endometriosis bites to the very soul of our lives—everyday! I have grieved the loss of friends, the loss of employment and purposefulness. It's unbelievable to realize how the basic concept of many is that endo is only a pain thing! Oh, goodness, how can I ever explain that endo is so very much more? It's fatigue, it's allergies to all kinds of chemicals/cleansers/perfumes (any kind of public place is a menagerie of smells to be allergic to!), it's erosion of the can-do attitude, it's a hounding, cureless "poison" in my body that affects every facet of one's life!"—Janeen

"I am 19 years old. I had to graduate from a homeschool program because I was just not physically able to go to school every day. I have not been able to work and every day I hear about that from my parents. I am not able to live up to who they want me to be. It's hard for me because I had always made them proud (i.e., sports,

school, community service) but now I can't. They think that I am lazy, when really I want to work. I would do anything to feel well enough to be able to go to a job every day. I don't know what I can do to make them understand what I am going through. I have become severely depressed, developed an eating disorder and feel that every day to get up is a challenge."—Zoe

"I am 24 and I was diagnosed with vulvodynia when I was 18. I experienced symptoms when I first had intercourse at the age of 17 and was in excruciating pain. All I could do was curl up on the couch the next day. At first, I thought that the pain was normal, that it was supposed to hurt the first time. But the pain wasn't getting better so I went to the doctor, actually four [doctors], and they all told me different versions of the same thing: I was just "tight" or "small" inside; that I just need to relax, that I should just have more sex, etc. One even suggested that I have a glass of wine (remember I was 17 at the time).

I finally found a knowledgeable provider who told me that I had vulvodynia. For the past 5 years I have been on different treatments including physical therapy, bio-feedback and several drug regimens. I've also had a vestibulectomy surgery and then a follow up surgery and I am [still] in chronic pain.

It has been very difficult growing up with this. It has affected so much in my life. Now, after years of living with this, and going through incredibly painful, ultimately unsuccessful, surgeries I sometimes feel as if I have come to terms with this condition. For the most part, I just accept that this part of my life is not going to change and that accepting it and moving on is what I am working on. But I have to say; sometimes it seems that it will be an impossible feat to find a partner who will happily be with me for the rest of his life, especially if I'm not able to have sexual intercourse because of my vulvodynia."—Tamara

"I am the concerned and exhausted mother of a beautiful teenage daughter who has been suffering for about 5 years with excruciating and sometimes unexplainable pain. I am tired, frustrated and feel like a failure because I cannot help my daughter. I am watching her change, struggling through pain, trying desperately to stay in school and beginning to feel as if there is no end to her misery. Plus, the fact that we have already put in enough money into this we could've bought her a new car and it still isn't over."—Dawn, Mother of a TMJ patient

"At age 19, I married the man who was and still is my best friend. I was a virgin until our wedding night and when my husband and I first tried to have sex, I cried from the pain. We thought that was just the way things were when sex was new, but in my gut, I had known for years that something was wrong. Confusion and depression followed. I never wanted to attempt sexual or even mildly intimate contact, and our relationship suffered because of it. At age 20, I was told my symptoms were psychological and that I simply needed to stretch my vagina.

After so many painful and misunderstood exams, and so many shed tears, at age 21, I was diagnosed with vulvodynia. My gynecologist could only offer me antidepressants in an attempt to numb the physical pain, but the side effects were too much for me and I soon stopped. It took 3 more years before I was finally able to see a doctor who could help and provide me with treatment options. I am now 24 and am on a treatment plan. Though there is still discomfort, the condition, for me, is largely in my control. Two weeks of treatment was all it took for me to improve, and I had waited in the dark for more than 10 years."—Angela

"I am a 16 year old with endo. I was diagnosed this May along with my mother. For years doctors have never taken the pain that my mother and I feel seriously. Sometimes family members even thought that it was hard to believe we were in as much pain as we said we were. One day my boyfriend was reading the newspaper and found an article about endo. He suggested that I might have it, so I brought it to the attention of my mother. My mother and I read it and it hit too close to home. A month later we saw a gynecologist who understood what we were going through. Just the fact that someone understood and didn't think we were crazy made us feel so much better. I was put on the pill, and most of the symptoms have been suppressed. As for my mother, she's still waiting for more options."—Emily

"Why do our girls have to suffer so?"—Mother of an endometriosis patient

"The other women, and men, that I have spoken to have gone through a series of doctor appointments and tests, and felt like they were walking through a maze without any light in sight."—Kathleen Matarazzo Specia

"You're almost relieved when your blood work or tests show something because you're like finally this doctor with their fancy degrees is going to believe me, that there is something wrong with me."—Therese McAllister

"There is a belief there that when a woman has temporomandibular joint disorder, that it is all because of their stress and their age."—Therese McAllister

"I had a surgeon that looked at me and said, 'Well all women have endometriosis, and you just need to shake yourself off and get back to work.'"—Therese McAllister

"We know from a lot of research that providers are less likely to make an accurate and speedy diagnosis of female patients, based on what we call feminine style. The way that females, in this culture and this country especially, are trained to communicate at a very early age, are trained to be nicer, to use more qualifiers, to be more indirect, to be more relational—which means we spend more time getting to know someone."—Melinda Villagran, Ph.D., Associate Professor of Health Communication George Mason University

"I'm in too much pain to spend an hour and a half on hold with an insurance company, and the insurance companies know that, and they take advantage of it."—Jennifer Feldman

"Twelve surgeries later, I now have bilateral joints. Instead of a house, I have a jaw."—Beth Bigge

"I think if this was something that men were suffering from, there would be a lot more money going into the research, and would be a lot more solutions out there for them to choose from."—Karen, Vulvodynia patient

The CHAIRMAN. Thank you, Miss Veasley.

Now, Dr. John Sarno. As I said, Dr. Sarno was the author of four books, the first being "Mind Over Back Pain" in 1984; the second, "Healing Back Pain," in 1991; the third is "The Mindbody Prescription," 1998; and the fourth book is, "The Divided Mind," which I have right here, in 2006.

Dr. Sarno, welcome to our committee. Please proceed.

**STATEMENT OF JOHN E. SARNO, M.D., PROFESSOR OF CLINICAL REHABILITATION MEDICINE, NEW YORK UNIVERSITY SCHOOL OF MEDICINE, NEW YORK, NY**

Dr. SARNO. Thank you, Senator Harkin. Thank you for inviting me.

Pain syndromes can be grouped into two categories: those resulting from injury—this is the way I see it—from injury, surgery, or associated with severe infection as seen in patients in an acute hospital setting, and those with pain in the back, neck, shoulders, and limbs of a psychophysical origin. The high incidence of the latter group has evolved into a public health problem of great magnitude over the past 40 years.

It has been estimated that 80 percent of the population have a history of one of these painful conditions, which has led to the performance of a great deal of unnecessary surgery, and the widespread use of pain medication.

It is troubling to realize that the pattern of pain and physical examination findings often do not correlate with the presumed reason for the pain.

For example, pain might be attributed to degenerative arthritic changes at the lower end of the spine, but the patient might have pain in places that have nothing to do with the bones in that area, or someone might have a lumbar disc that was herniated to the left and have pain in the right leg. More importantly was the observation that 88 percent of the people with these pains had histories of such things as tension or migraine headache, heartburn, hiatus hernia, stomach ulcer, colitis, spastic colon, irritable bowel syndrome, hay fever, and asthma—that is quite a listing—eczema, and a variety of other disorders, all of which have been strongly suspected by physicians of being emotionally based. The pain syndrome here referred to as a tension myoneural syndrome, we believe to be fundamentally and mostly emotionally based.

Simple awareness of the diagnosis itself, we have found, can be therapeutic and eliminate the pain. For some patients, who accept

the concept of what is going on, it is necessary to work with a psychologist to get at the root of the problem. Although back pain may disappear spontaneously, in many patients it becomes a lifelong problem.

There is no logic to the traditional physical treatment. Instead, experience has shown, in my experience, that the only successful and permanent way to treat the problem is by teaching patients to understand what they have. A physician, because he recognizes both the physical and psychological dimensions of the condition must make the diagnosis. This cannot be made by a psychologist or a psychiatrist.

It goes without saying that pain syndrome must always be properly studied to rule out serious conditions such as cancer, tumors, bone disease, and many others.

The presence of persistent pain anywhere requires a comprehensive examination and tests. Although this disorder, the tension myoneural syndrome is the result of emotional phenomena, it is a physical disorder and must be studied as such. It is not, "in the patient's head."

There is a need to raise consciousness both inside and outside the field of medicine to help people or change people's perception of the cause of common pain syndrome, which represent a major public health problem.

Science requires, of course, that all new ideas be validated by experience and replication. It is essential that these ideas also be subjected to research study in the future.

Thank you.

[The prepared statement of Dr. Sarno follows:]

PREPARED STATEMENT OF JOHN E. SARNO, M.D.

#### SUMMARY

Pain syndromes can be grouped into two categories: Those resulting from injury, surgery, or associated with severe infection, as seen in patients in an acute hospital setting, and those with pain in the back, neck, shoulders and limbs of a psychophysical origin. The high incidence of the latter group has evolved into a public health problem of great magnitude over the past 40 years. It has been estimated that 80 percent of the population have a history of one of these painful conditions which has led to the performance of a great deal of unnecessary surgery and the widespread use of pain medication.

It is troubling to realize that the pattern of pain and physical examination findings often does not correlate with the presumed reason for the pain. For example, pain might be attributed to degenerative arthritic changes at the lower end of the spine but the patient might have pain in places that had nothing to do with the bones in that area. Or someone might have a lumbar disc that was herniated to the left and have pain in the right leg.

More importantly was my observation that 88 percent of the people seen had histories of such things as tension or migraine headache, heartburn, hiatus hernia, stomach ulcer, colitis, spastic colon, irritable bowel syndrome, hay fever, asthma, eczema and a variety of other disorders, all of which were strongly suspected by physicians of being emotionally based. This pain syndrome is referred to as the Tension Myoneural Syndrome (TMS).

When that theory was put to the test and patients were treated accordingly, there was an improvement in treatment results. In fact, it was then possible to predict with some accuracy which patients would do well and which would probably fail. Simple awareness of the diagnosis itself can be therapeutic and eliminate pain. On occasion it is necessary for the patient to work with a psychologist to get at the psychological root of the problem. Although back pain may disappear spontaneously, in many patients it becomes a lifelong problem.

There is no logic to the traditional physical treatment. Instead, experience has shown that the only successful and permanent way to treat the problem is by teaching patients to understand what they have. The notion of treating the "whole person" was not new to my thinking since I specialized in physical medicine and rehabilitation where this concept is fundamental.

A physician, because he recognizes both the physical and psychological dimensions of the condition, must make the diagnosis. It goes without saying that pain syndromes must always be properly studied to rule out serious disorders such as cancer, tumors, bone disease and many other conditions. The presence of persistent pain anywhere requires comprehensive examination and tests. Though TMS is the result of emotional phenomenon, it is a physical disorder and must be studied as such. It is not "in the patient's head."

There is a need to raise consciousness both inside and outside the field of medicine to help change people's perception of the cause of the common pain syndromes which represent a major public health problem. Science requires that all new ideas be validated by experience and replication. It is essential that these ideas be subjected to research study in the future.

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Pain syndromes can be broadly grouped into two categories: Those resulting from injury, surgery, or associated with severe infection, as seen in patients in an acute hospital setting, and those with pain in the back, neck, shoulders and limbs of a psychophysical origin. The high incidence of the latter group has evolved into a public health problem of great magnitude over the past 40 years. It has been estimated that 80 percent of the population have a history of one of these painful conditions which has led to the performance of a great deal of unnecessary surgery and the widespread use of pain medication.

Contemporary medicine does not recognize the psychological basis for a segment of these common pain syndromes. The biases that common pain must be the result of structural abnormalities of the spine, or chemical or mechanically induced deficiencies of muscle, coupled with the belief that emotions do not induce physiological change, have contributed to the exponential increase in the incidence of these now common pain disorders.

I first became aware of the high incidence of pain involving the back, neck, shoulders, buttocks, and limbs when I joined the staff of the Rusk Institute of Rehabilitation Medicine, as Director of Outpatient Services in 1965. Conventional medical training had taught me that these pains were primarily due to a variety of structural abnormalities of the spine most commonly arthritic and disc disorders, or to a vague group of muscle conditions attributed to poor posture, underexercise, overexertion and the like. Pain in the legs or arms was presumed due to compression (pinching of nerves). However, it was not at all clear how these abnormalities actually produced the pain.

The experience of treating these patients was frustrating and depressing; one could never predict the outcome. Further, it was troubling to realize that the pattern of pain and physical examination findings often did not correlate with the presumed reason for the pain. For example, pain might be attributed to degenerative arthritic changes at the lower end of the spine but the patient might have pain in places that had nothing to do with the bones in that area. Or someone might have a lumbar disc that was herniated to the left and have pain in the right leg.

Along with doubt about the accuracy of conventional diagnoses there came the realization that the primary tissues involved were nerve and muscle, specifically of the neck, shoulders, back and buttocks. Even more important was the observation that 88 percent of the people seen had histories of such things as tension or migraine headache, heartburn, hiatus hernia, stomach ulcer, colitis, spastic colon, irritable bowel syndrome, hay fever, asthma, eczema and a variety of other disorders, all of which were strongly suspected by physicians of being emotionally based. This pain syndrome is referred to as the Tension Myoneural Syndrome (TMS).

When that theory was put to the test and patients were treated accordingly, there was an improvement in treatment results. In fact, it was then possible to predict with some accuracy which patients would do well and which would probably fail. Simple awareness of the diagnosis can be therapeutic and eliminate pain. On occasion it is necessary for the patient to work with a psychologist to get at the psychological root of the problem. Although back pain may disappear spontaneously, in many patients it becomes a lifelong problem.

What are the emotions that stimulate the psychological reaction? They are legion. Everyday life pressures are obvious. Not so obvious, but of greater importance, are the self-imposed pressures of the need to be perfect and good, stimulated by the predominant culture of our time.

There is no logic to the traditional physical treatment. Instead, experience has shown that the only successful and permanent way to treat the problem is by teaching patients to understand what they have. The notion of treating the "whole person" was not new to my thinking since I was specialized in physical medicine and rehabilitation where this concept is fundamental.

Though the cause of this common pain disorder is emotional, the diagnosis must be made on physical rather than psychological grounds, in the tradition of clinical medicine. Psychologists may suspect that patients' symptoms are psychologically induced but, not trained in physical diagnosis, cannot say with certainty that they have TMS. A physician, because he recognizes both physical and psychological dimensions of the condition, must make the diagnosis. It goes without saying that pain syndromes must always be properly studied to rule out serious disorders such as cancer, tumors, bone disease and many other conditions. The presence of persistent pain anywhere requires comprehensive examination and tests. Though TMS is the result of emotional phenomenon, it is a physical disorder. It is not "in the patient's head."

Judging by the reactions of doctors in my immediate environment, most either ignore or reject the diagnosis. A few physicians in my own specialty say that they see the validity of the diagnosis but find it difficult to treat such patients. One hopes that the younger generation of physicians will be more open to this diagnosis.

There is a need to raise consciousness both inside and outside the field of medicine to help change people's perception of the cause of the common pain syndromes which represent a major public health problem. Science requires that all new ideas be validated by experience and replication. It is essential that these ideas be subjected to research study in the future.

The CHAIRMAN. Thank you, Dr. Sarno.

Now we will start a series of 5-minute rounds of questions, or I should say, a dialog with all of you.

Dr. Sarno, something you just said, I am going to skip around here a little bit. Where is it? Miss Veasley said something that I wanted to address.

Miss Veasley, in talking about a report, said that,

"Medical professionals are more likely to dismiss women's pain reports as emotional, psychogenic, hysterical, or oversensitive, and therefore not real, leading to more frequent mental health diagnosis."

So I ask you, is their pain real or is it just in her head?

Dr. SARNO. The pain is always real, but I think the problem is, it is not recognized sufficiently that emotional phenomena can actually bring on pain. If you would like a physiologic explanation, that is simple too. The simple reduction of blood flow, which can easily be accomplished by the brain to vital spinal nerves or any spinal nerve for that matter, but usually it is more in certain areas—the low back, for example, or the neck or shoulders—is easily done. I think that it is important to recognize that emotions can stimulate physiologic change.

Mr. MAIXNER. Mr. Chairman, may I also address that?

The CHAIRMAN. Dr. Maixner. Sure.

Mr. MAIXNER. Yes. I agree totally with what was just said. I think it is very important that we do not dissociate mind-body when we talk about chronic pain conditions, and put chronic pain conditions into strictly an in-their-head psychological component.

It is very clear from current research that there is an underlying neurobiology that is associated with affect, and mood, and emotionality. There is a neurochemistry. There is a very well-assessed neurobiology, and we know that many of the pain pathways that our patients have activated, activate these same pathways in the brain that are involved in affect and mood, and emotional response.



Chronic pain is really a mosaic. It is a mosaic of interactions between the affective domains of the brain and those areas of the brain involved in processing pain information. They are overlaid. It is really impossible for us to dissociate mind-body. In fact, when we talk about the emotional-psychological aspects of pain, we are really talking about an underlying neurobiology that leads to the overall gestalt of the sensation that our patients complain about.

The CHAIRMAN. Dr. Pizzo, I see you want to comment also. Yes.

Dr. PIZZO. Thank you. I certainly agree and appreciate that there is a broad array of contributing factors, as has been stated. I think it is also important for us to be very sensitive to the words we use and the way that they are received.

There is today a significant amount of perception felt by those suffering from chronic pain and, in fact, those called to serve on behalf of patients that there is a significant amount of, "emotional" contribution.

I think while there is no doubt that our emotions contribute to our physiology, I think that we have much work to do to look at our approach to pain, just as we do other neurological and psychiatric illnesses from a physiological perspective as well.

This is a very complex interrelated array of events, and I think one of the things that our committee certainly heard, and that data ascribes, that one of the challenges that happens in medicine is that when we do not know an answer, we often ascribe it onto something else. Those assignments are often emotional and almost contributed back to the individual, as if that individual becomes the victim of their own suffering.

Therefore, the view of our committee was this really speaks to why there needs to be a cultural and social transformation in how we look at pain in its vast manifestations that affect individuals in very discrete and individual ways. To ground it in a better understanding of biology and illness, which is truly biopsychosocial, but which has much to be learned about its very manifestations and actions.

The CHAIRMAN. Yes, Ms. Veasley.

Ms. VEASLEY. Thank you. I certainly do not deny that my emotional health or anyone else that suffers with pain affects my ability to effectively cope with both the physical suffering and the effects of pain on my life. While I was hit by a car and nearly died, my pain has never been questioned by any medical provider, but this is not the experience of the average pain patient in our country.

And I would just put out there that there are many examples in medical history, for example, ulcers that were once attributable to stress and inability to emotionally cope, that we now know answers to. Their cause is bacteria, and just because we do not understand yet due to the inadequate research effort that we have had, the mechanisms and risks that result in chronic pain does not mean that it is made up in your mind and is not real. Thank you.

The CHAIRMAN. If I might respond, I think what Dr. Sarno was saying, and I have looked at this a lot, is not in someone's head. It is that certain psychological things that are happening in a person's unconscious can actually create things that cause real physical pain. As he said, the unconscious can sometimes, in order to

hide some other thing in your mind, could stem the flow of oxygen to a muscle or to a nerve. That tightens it up and you feel real pain. I do not think Dr. Sarno is in any way suggesting that this is anything in your head. It is just that certain emotional or certain unconscious underlying of people's minds sometimes create the pathways to real physical pain. If I might, am I correct in that?

Dr. SARNO. Yes. As I said, emotional phenomena can be responsible for physiologic pain and that is the important thing to bear in mind.

The CHAIRMAN. Dr. Pizzo, in looking over this "Relieving Pain in America," and looking at some of the different approaches that were taken, I do not see that being researched that much. Now, maybe I just do not understand it all that well, but I do not see that kind of an approach being researched. Is that so or not so?

Dr. PIZZO. The approach, meaning the emotional basis for pain?

The CHAIRMAN. Yes, not emotions being affected by pain.

Dr. PIZZO. Right, right.

The CHAIRMAN. But the emotions—and "emotions" is a word that I do not like—but the unconscious mind, something going on deep inside is causing certain physiological reactions in your body that are painful.

Dr. PIZZO. Yes. I think our view of the research needs around pain are actually quite broad and not defined by any boundary, and my comments earlier are not to pit one approach against the other, not to say that emotions are good or bad, or a physiologic pain, but more important than that is that it not manifest.

But rather, in our society today, there is a degree of stereotyping that does take place, advertently and inadvertently, and that has consequences, and it is not infrequent. Just as a matter of observation, that when something is not physiologically defined, it is often attributed to an emotional reaction. That is really what I was addressing and speaking to.

I think it is important and we heard very eloquently from Christin that when one manifests a degree of pain based upon an organ manifestation like cancer, there is often a rallying of our community to that individual because it defines suffering. See, I know this from my own life experience as a pediatric oncologist, someone who has cared for children with cancer and pain for many decades.

When someone comes in with a pain that is not fully defined or delineated as you described extremely eloquently, we make other assignments in terms of cause and etiology, and that is what creates the bias of both our providers, doctors, nurses, communities, our insurers, what they will pay for and not pay for, and these are profoundly important.

We are all too much a society today, a medical world today that is focused on doing something. Our insurance companies, in regards to pain, really are more focused on doing a procedure or giving medication, and less about, for example, cognitive or behavioral therapies or physical therapies which will work probably as well or better. I think we need a broad approach based on science.

I just want to also underscore your earlier question about research. We need a lot more research, and the research is not simply about what we think we know, but what we do not know. There

is an extraordinary need for much more fundamental, basic research in what causes pain, how it is manifested, and how we can go about treating it.

The therapies that we have today, although they work in many people, are quite limited and we need brand new insights to develop better approaches and innovations that will only come from very fundamental research as well.

The CHAIRMAN. Very well stated, thank you very much, Dr. Pizzo.

Senator Whitehouse.

Senator WHITEHOUSE. Thank you, Chairman. And thank you, again, for holding this hearing. I think it is very important and helpful.

I am going back now a couple of years to when we started working on this in Rhode Island. The thing that struck me was the extent to which, in various health care settings, the pain that a patient was experiencing was either deprecated or overlooked entirely, and that there was a systematic bias against recording it and reporting it. So even if you were able to convince the doctor on duty at a particular time that you were in great agony, when they went off-shift and somebody else came on, and they looked at your paper record, there was nothing to clue them because, at that point, pain was not treated as a vital sign and was not part of the equation. There was even some doubt about whether it was possible to do that given that there is some subjectivity involved, but clearly, that was something that we were able to get around.

My concern is how do we make sure that the hard records that exist in nursing homes, in hospitals, in various settings of patient care, particularly as we move into an electronic health record environment, have appropriate fields so that the patient's pain experience is being recorded, and can be treated seriously? Do you feel that we are there nationally at this point? I see a lot of heads nodding no.

Do you feel that a Federal standard requiring that certain steps be taken with respect to the day-to-day records, would that be a good idea? Is this something that we should be—I have been very active along with the Chairman and others on electronic health records, and meaningful use, and all that. Should we be focusing on this as a topic in that discussion as well? Let me start with Ms. Veasley. She gets the Rhode Island jump.

Ms. VEASLEY. Well, it is difficult because we do not have the answers for patients, but yet, we have millions of patients flooding doctors' offices every day needing help. And until we have that basic research, until we teach compassionate care, until providers understand that while we may not know all the mechanisms, just like many other diseases of the central nervous system, there are things that you can do to help patients.

To continue to ignore the pain that someone reports, I mean, as you previously mentioned, end of life care. I recently lost my mother-in-law to pancreatic cancer, which is excruciating. Never once was her pain questioned, but the ability to treat it was hampered by the fact that we do not have the answers yet or providers. They are left to kind of come to their own conclusions based upon their

clinical experience kind of treat pain as they see it. We really have to advance research and quickly.

Senator WHITEHOUSE. Dr. Pizzo.

Dr. PIZZO. Thank you very much for asking that question, which is enormously important.

We are moving as a nation much more toward a refined electronic medical system, and the U.S. Congress and the Affordable Care Act is helping with that, and we appreciate that.

Our committee did delineate, just as you suspected, that even though we have a lot of data, a lot of demographic data that is already in hand, there is much more that we need. It is one of the recommendations that we made to the Secretary of HHS and the related agencies to really facilitate a better collection of information that could help guide, much more deeply, the impact of pain on individuals. The metrics that we have are important, but relatively limited, and I agree with you that this would be enormously important going forward.

Senator WHITEHOUSE. Dr. Maixner.

Mr. MAIXNER. Yes. I agree and I think we have very, very good methodology available to us to rapidly assess both inpatient, outpatient levels of pain, and I think it could be easily implemented into electronic patient record.

I think the larger problem is how is that information acted upon by the health care system? When there is really a substantial pain, do we have well-trained individuals who can respond to that cry? Do we have individuals who can impact what we assess? The assessment tools are clearly there, but again, as I articulated in my testimony, we have very poor education with respect to pain and pain management, which greatly impacts the manpower that can respond to the epidemic that I discussed.

Senator WHITEHOUSE. I see that my time has expired. Chairman, thank you very much.

The CHAIRMAN. Just as a followup to Senator Whitehouse. Dr. Sarno, a new patient comes in to you, and they have pain. What do you do? How do you assess that person's pain? What process?

Dr. SARNO. As I said, he has to be thoroughly worked up, and studied, and all of the known pathological processes that could be involved. That is absolutely essential. When all of the important things have been ruled out, then I think it is possible to go into some detail with that individual about his life, what is going on, and so on.

Because I think that one, I want to say the same thing I said before, emotional phenomena can bring about physiologic change, and we have to keep that in mind. Obviously, we have to make sure that there is nothing else going on, so exhaustive studies are indicated before we would then begin to think about emotions and with pain.

The CHAIRMAN. Thank you very much.

Senator Hagan.

#### STATEMENT OF SENATOR HAGAN

Senator HAGAN. Thank you, Mr. Chairman, and thank you for holding this hearing.

I think it is extremely important because I do know that there are millions of people in our country today that are obviously suffering and in chronic pain. Dr. Maixner, and all of you, welcome, and I appreciate the expertise that we have here as well as personal experts.

Dr. Maixner, you seemed very optimistic in your testimony about the future for pain research and treatment. In your testimony, you state that, "Pain scientists are having great success in unraveling the pathophysiology and biological basis of pain."

Can you describe to me some of the ways that we, as policy-makers, can be helpful to ensure a successful path forward in this area of research and treatment?

Mr. MAIXNER. Yes, thank you, Senator, for the question. Thank you, Senator, for the question.

We are making great headway in the fundamental understanding of the biology, psychology, and genetics and molecular pathways that underlie common pain conditions. We have identified many of the risk factors that lead to conditions like PMD, fibromyalgia, and many of the so-called common, idiopathic pain conditions.

This is a parallel to what has happened in the cardiovascular community where risk factors such as lipids, cholesterol, stress, those factors have led to interventions, led to treatments, and prevention.

We are at that step now in the pain field where we have identified biological factors, genetic factors, psychological factors, not all, but many are now at our hand that we could begin to put them together into models to develop potentially new treatment strategies that relate to cognitive behavioral therapies, other types of behavioral therapies that can influence emotional response and distress. We have identified new targets for drug development. Novel targets for drug development that, I think, could be very helpful in the future.

We have the pieces, but we do not have initiatives that are large enough and well enough funded by both public and private entities that allow us to put these pieces together to study them prospectively, to evaluate the validity of our hypothetical constructs that we have with these risk factors.

What I think is truly needed are large scale, population-based studies that are housed out of these advanced pain centers of excellence that I have noted. These centers would have not only a patient care mission related to the portal by which physicians and patients come into treatment, but represent also research initiatives to actually document the validity of these risk factors, to document the effective therapies that we can now conceptualize from these theories that we have now put forward. To demonstrate the comparative effectiveness across many existing treatments and new treatments that we can advance.

We are at that point, where we can put forward large scale, proof of concept trials that could lead to new interventions, both behavioral interventions and therapeutic interventions.

Senator HAGAN. Thank you. Dr. Pizzo and Dr. Maixner, you discussed doctor shopping; I know Dr. Maixner has. Sometimes this is a barrier to properly treating patients with chronic pain.

On average, how many doctors does a patient suffering from chronic pain see before getting a proper diagnosis? If you have any estimates on the cost of the numbers of different doctors that a patient might go to? What does that cost the health care system? And is it because the patient does not get the response or they are still in pain that they feel they have to go to another doctor or are they also looking for more medication?

Dr. PIZZO. Yes. Senator, I think that is an important question. I wonder if I could just slightly broaden it, if you would be willing? Senator HAGAN. Please.

Dr. PIZZO. Clearly, what we know today, and as you have heard, is that we are spending as a nation between \$565 to \$630 billion a year on pain, and that over 116 million individuals are affected by it.

Many of those individuals do not have access to health care as we would like them to be able to. Even though we have some wonderful centers and need more, as Dr. Maixner has described, where really expert care can be given, as a Nation, we really need to think about a much more distributed model so that care is available to underserved communities who disproportionately are affected by pain.

African-American and Hispanic communities have a higher proportional degree of pain than other communities. Those suffering from some of the diseases that Christin Veasley and others have spoken about are disproportionately affected by their pain, and that means that we need a different care model. We need a different distribution of providers, both primary care physicians working together with specialists, nurses, pharmacists, and other on the frontlines, who might work in tandem with those centers, creating new partnerships between them. We need to pay for those services in a different way.

Right now, there is a disincentive that happens because of our current fee for service health care model, which does not allow enough time for physicians, or nurses, or others to spend with patients to listen to their stories, gather the information, and develop a portfolio or plan that is going to really be meaningful for them. That is another area that we need to do.

We need to think about how the payment system is restructured so that we are not just paying for expensive services, but paying for those that fit the patient.

The reality is that there are lots of therapies that are available today. Not one particular one is best for all patients, and not all are good for any one patient. We really need to look at the right match between them.

I would say that we certainly have innovations and interventions that are available today, but we have a great need for defining more. There is a great need for defining new, innovative therapies that we hardly know about today. We are just at the cusp of learning more about the nervous system and how it works, and I think there are great opportunities that lie ahead. I hope that these, coupled with better educational portfolio for physicians, nurses, and other providers on a distributed level working in tandem with specialists can create a new, public health approach to dealing with this very severe problem.

Senator HAGAN. How about the actual doctor shopping?

Dr. PIZZO. There is a fair amount of doctor shopping that goes on largely because no one individual is often satisfied with the results that they are having. On our committee, and Christin could speak to this, we have heard this many times. In fact, we have heard from some of our committee members who suffered from pain that if you do not get the results from one person, you should seek another because there may be another approach that will be beneficial to you. Do not give up. Empowerment of individuals is a really significant part of the equation.

On the other hand, many go from one doctor to another because Doctor A, B, C or Provider A, B, C never listened, never engaged, and never helped. That is something we need to see about as well.

Senator HAGAN. Miss Veasley.

Ms. VEASLEY. Yes, I could respond to actually both of your questions. Thank you.

In regards, we hear a lot about translational science and in any area, all the pain research in the world, or research on any given condition that takes place, if it does not trickle down to the patient for which it is supposed to serve, it is not helping.

I see a great opportunity for Federal initiatives to support ongoing educational and awareness initiatives aimed at both the medical community, the public, and patients to continually keep us all informed of the latest research that is coming out of UNC and other great institutions around the country. Right now, we do not have that. Even though some of these really great advances are taking place, it is not getting down to your average physician and your average patient.

In regards to doctor shopping, again, this goes right back to research. If we do not have basic research to inform clinicians of what the causes and effective treatments are for any pain condition, they are left to their own clinical conjecture to make decisions on what a patient's cause or treatment may be, and this even happens in the pain community.

We find physicians who just specialize in pharmacology, they just specialize in nerve blocks, or implanting devices in patients, even though a mound of research has shown that multidisciplinary care is how to treat pain. So you have many reasons why patients go from doctor to doctor.

One is that they are told that their problem is not real. "Your pain doesn't exist. You must be imagining this. I don't see any sign, or inflammation, or any problem that you may have." We do not understand the mechanisms.

I can tell you from personal experience and also from talking with thousands of patients that for as many doctors as you see, because we do not have this basic research, you are going to get that many diagnoses and that many different treatment recommendations. As I mentioned in my testimony, that leaves it up to a patient to fend for themselves and try to decide, "Out of all of these treatments which is going to help me?" That is completely impossible for anybody to do regardless of your level of education or socioeconomic status.

Senator HAGAN. Thank you. My time is up.

The CHAIRMAN. Senator Sanders.

## STATEMENT OF SENATOR SANDERS

Senator SANDERS. Thank you very much, Mr. Chairman, for holding this important hearing. And thank you all very much, panelists, for being here.

What I would like to begin with, Mr. Chairman, is ask unanimous consent to have testimony from Dr. Robert Shapiro, who is an expert on headache, be put into the record, if that is OK.

The CHAIRMAN. Yes.

Senator SANDERS. Is that OK?

The CHAIRMAN. Certainly.

[The information referred to may be found in Additional Material.]

Senator SANDERS. I was interested by—a couple of issues spring out to me. No. 1, the Institute of Medicine report found that a person with lower educational level, and presumably also lower income people, are more prone to suffer pain. As Chair of the subcommittee on primary health care we did, some months ago, a hearing on poverty as a death sentence. What we found is that if you are in the bottom 20 percentile, you are going to die 6½ years earlier than if you are in the top 20 percent.

I would imagine—so I would like to ask you, I guess what you are saying is that if you are poor, if you are uneducated, you are more likely to become ill. You are more likely to become ill. You are more likely to experience pain.

Could somebody speak to that?

Mr. MAIXNER. Yes, Senator. I could speak to that. I think that one's socioeconomic status actually may be a surrogate marker of environmental exposures; the type of exposures that puts one at risk for the development of a variety of chronic pain conditions.

We know that physical injury is one such physical environmental exposure that can activate genetic pathways that lead to pain conditions. Individuals in lower socioeconomic classes are prone and experience much greater physical labor, and are more prone to physical injury.

We also know that distress, psychological distress is also a big driver of genetic pathways that can lead to the up-regulation of pain processing and affect a mood that our pain patients experience. Again, lower socioeconomic status, I believe, is a surrogate marker for the amount of distress, the environmental exposure. One of the important environmental exposures, in addition to injury that can drive these pain systems—

Senator SANDERS. So you are saying environmental exposure as stress. In other words—

Mr. MAIXNER. As stress.

Senator SANDERS. Struggle in terms of how to feed your family, or take care of your child, or go to work.

Mr. MAIXNER. Exactly.

Senator SANDERS. Fix a car that broke down.

Mr. MAIXNER. Right.

Senator SANDERS. That contributes to illness, which contributes to pain.

Mr. MAIXNER. And produces the emotionality that we have just heard about that, in fact, can influence the immune system; the ge-



netics of the expression of genetic pathways. These are what I call "environmental exposures," that are of higher density and higher magnitude in individuals who fall within social economic classes of the lower tiers.

Senator SANDERS. Dr. Sarno.

Dr. SARNO. I would like to suggest a more Freudian, if you will, or psychodynamic explanation, and that is that poor people are poor and they are angry. They are furious, as a matter of fact about what society has allowed to happen. That fury will evoke physical symptomatology, believe it or not, as a defense against a rage. They cannot rage and rage, so what happens is that they get sick, and I believe that this is an extremely common phenomenon.

Senator SANDERS. I mean, rather than burning down the Capitol, they are turning that anger against themselves, right?

Dr. SARNO. Exactly.

Senator SANDERS. Let me ask—yes, Dr. Pizzo.

Dr. PIZZO. One comment, because I think this is a very important discussion, and I am glad you raised the issue very much.

I think one other facet that extends from what Dr. Maixner said is that there is an interrelationship between acute pain and chronic pain. If you are not able to access care because of socioeconomic limitations, there is a probability that what might have been a self-limited problem becomes a more chronic and persistent one.

So from a preventative strategy and an economic strategy, early intervention is certainly better than delayed intervention.

Senator SANDERS. Which is why some of us, among other things, are trying to build community health centers all over the country.

Dr. PIZZO. Yes.

Senator SANDERS. I wanted to ask one other question. I do not know if it was—I apologize for being late. Are we going to hold a hearing, Mr. Chairman, in a couple of weeks on dental care access? My understanding is that one of the major reasons for absenteeism among children is dental problems and toothaches, and we have a huge problem there as well.

Does anybody want to say anything about dental care and lack of dental access, and tooth pain, and so forth?

Mr. MAIXNER. I would just like to note that this continues to be an evolving problem especially amongst the lower socioeconomic population that many of us in the academic community serve.

Access to care for children still remains a problem, especially as it relates to good pain services and pain management. It is really a neglected area of pain management and we find it in the general community. Patients have great difficulty finding access for this type of treatment.

Senator SANDERS. I think you have a whole lot of children and other people are walking around with teeth that are rotting in their mouths, and causing infections, and it is very painful.

Dr. PIZZO. Right. That is right. In fact, our Institute of Medicine report that the numbered 116 million Americans suffering from pain did not include children in that number. Missing from that number is children, and children do suffer pain, as you well recognize.

Senator SANDERS. Good. Chairman, thank you.

The CHAIRMAN. That is in the area of the kind of acute pain that then leads later on to chronic pain.

Dr. PIZZO. That is right.

The CHAIRMAN. That kind of acute pain is, perhaps, more easily diagnosed early on and the question is: do they have access to that kind of diagnosis and that kind of treatment?

Dr. PIZZO. That is right. Exactly.

The CHAIRMAN. Dr. Pizzo, have you ever read any of Dr. Sarno's books: "Mind Over Back Pain," 1984; "Healing Back Pain," 1991; "The Mindbody Prescription," 1998; or "The Divided Mind," 2006?

Dr. PIZZO. No, I have not read them.

The CHAIRMAN. OK. That is OK. Dr. Maixner, have you ever read any of his books?

Mr. MAIXNER. I have not, but I am very familiar with James-Lange and Cannon's theories which, I think, are elaborated, I think, quite well in the books is what I would guess.

The CHAIRMAN. Miss Veasley, have you ever read? OK. Have you read your books, Dr. Sarno? No.

[Laughter.]

Here is why I ask that question. You cannot read everything. Now, Ms. Veasley told her story. I am going to tell you my story and why Dr. Sarno is sitting there, and why as chairman I had him here.

I have always been healthy. Jet pilot in the Navy, physically active all my life, took pride in my physical health. In 1988, I just checked with the doctor's office over here. I did not know it was that long ago. In 1988, I had an episode with my back, extremely painful.

I was walking down the hallway right out here in the Dirksen Building and pain hit my back so hard, I fell right on my butt, right out here. Kind of embarrassing, you know. I did not know what was happening to me.

It got a little bit better, but at one point, I was working on the American's With Disabilities Act, of all things, as the chairman of the subcommittee of this committee, and I could not even walk back and forth. I had to put a cot over in the Capitol for me to lie on.

Shortly after that, I had an MRI. They looked at the MRI and said, "Well, you've got a bulging disc—cause you some problems. You should take an anti-inflammatory." So I did. The pain went away. About 3 years after that, this is in the mid-1990s, again, I got back pains so bad, I was in Los Angeles. I was in a hotel room. I had to go to the bathroom. I could not even get—I had to crawl to get to the bathroom.

I came back here, had another MRI. "Well, you still have a bulging disc, but there's this little hole down there where all your nerves go through." That is my layman's term of putting it. "And that thing is not so—maybe you need to have that thing opened up or something like that." I thought about that for a while and I dismissed it because my back pain went away.

After a while, it went away, but every time it would come, I could barely sit. I could barely stand. I could barely move. Painful. I even had a chiropractor come into my office once. I had to take a plane trip someplace, he had to work over my back so I could

even get on the airplane, and actually it worked. Chiropractic worked, made me feel better, anyway, long enough to get on the airplane.

Then in 2004, I had another episode and it was really bad, and I remember I was at the National Convention up in Boston. I could barely move. In fact, I could not. I curtailed my activities there.

I came back and that was my third MRI. I sent them up to the Hospital for Special Surgery in New York to have them looked at. I wanted to get another opinion. Well, "Yes, I probably needed steroid shots and I needed to have that hole opened up," whatever that was.

I had breakfast one morning with Mr. Ira Brind, he is a former chair of the Thomas Jefferson University Hospital in Philadelphia, just a friend of mine. I told him I was not looking forward to this but,

"I had checked with the doctors here and they said I probably needed to have back surgery. In fact, one of the doctors had told me they had had back surgery and they were fine."

I really was not looking forward to that. That is what I told Ira. I said, "I guess I am going to have to have this back surgery. Plus, it has been going on for all these years."

He said,

"Don't do it. Don't do this. I am going to send you something.

I am going to send you a CD, and I am going to send you a book, and read those first before you take any action."

I got them the next day; he sent them down the next day from Philadelphia, and it was a CD and a book by Dr. Sarno, "Healing Back Pain." I read this through and I thought, "You know, that sounds like me. That really sounds like me." So I began to follow his regimen and that was in 2004.

I have not had a back pain since. I have never had any surgery. I have never had steroid shots or anything like that. I have not had any back pain since. Now, that is not quite true. Every once in a while, I do get a little tinge of back pain, but I know what is causing it. I have the knowledge that I know what is causing it.

Now, I am going to expose myself here to this audience and whoever else is watching. Now, sometimes when I tell people this, they think I am nuts. They say, "Well, what do you do?" And I said, "It's very easy. I talk to my back," and what I say is basically,

"I don't have cancer. I don't have anything wrong with my spine. I don't have any injuries. So therefore, it's coming from stress. Somehow, I'm being stressed out, and my spinal nerves and stuff are being deprived of oxygen, and that's what's causing it. What I need to do is ignore that and I need to go about my daily activities just as though I was completely well."

When I do that, it goes away.

I do not know that the IOM is looking at this. Now, you might say, "Well, that's just you."

This is a survey that was put in the book, "In 1999," and again, this is a small cohort.

"They had 104 patients on whom data was collected. The following year, they reached 85 of the group to determine out-

come. There were 39 males and 52 females in the group, and they were interested in the outcome.

"The categories for level of pain risk follows: 37 patients reportedly now had little or no pain; 22 patients reported they were not 80 to 100 percent improved; 13 patients reported they were 40 to 80 percent improved; 13 patients reported no change to 40 percent improvement; 46 patients reported they were now unrestricted physically. These figures are extraordinary when one considers that the treatment of this physical disorder is educational augmented in some cases by analytically oriented psychotherapy.

"Seventy percent of this group had good relief from pain and seventy-five percent were restored to normal or near-normal physical function."

I wonder why we are not looking at things like this.

Now, I have one more story. I have a near relative of mine, a close relative of mine. She was diagnosed with fibromyalgia; terrible pain. She is a young woman. And, because of my connections and things with NIH and stuff, I found some of the best doctors to talk to her about her fibromyalgia, and they did. She lives up in Pennsylvania, and so I would talk to her every so often, ask her how she is getting along, and nothing was getting better. She had withdrawn from her family, withdrawn from things. I do not want to go into this in too much depth.

Last year, I checked up on her. I wanted to check up on her, see how she was doing. She said, "You know, I think I've cured my fibromyalgia." I said, "Really? Was it that last doctor I set you up with?" She said, "No, a friend of mine gave me this DVD and a book by this Dr. Sarno in New York." Now, I had never mentioned his name to her. I had not thought about him in that context, and she now is, I would not say totally pain-free, but she is over her fibromyalgia.

When I see two things like this, one personal to me, my own self, and another with a close relative, I wonder why is this not being looked at? Dr. Pizzo, why is this not being looked at?

Now, Dr. Maixner, I am going to go with you, Dr. Pizzo too, but what Ms. Veasley said here is very important. She says,

"It is logical to ask, 'Why not see a different doctor or get better treatment?' The answer was recently summarized by a leading pain physician in the journal *Lancet*. 'Overall, currently available treatments provide modest improvements in pain and minimum improvements in physical and emotional functioning. The quality of evidence is mediocre and has not improved substantially during the last decade.'"

Dr. Maixner, not to pick on you or anything.

Mr. MAIXNER. Right.

The CHAIRMAN. You said, here on this page, "I submit that we now possess the tools and knowledge to conquer this epidemic and to bring relief to many millions worldwide." I read what was in *The Lancet* saying that, "The quality of evidence is mediocre and has not improved substantially during the last decade," and there are other things that are not being looked at. I do not know that we

do have the tools and knowledge right now, unless we start looking at all these other methodologies.

Now, again, I am talking about chronic pain that is not the result of cancer or putting my hand in a fire.

Mr. MAIXNER. Right.

The CHAIRMAN. Or tooth problems or things like that.

Mr. MAIXNER. Right.

The CHAIRMAN. I am talking about chronic pain that seems, during diagnosis, to have no physiological basis that they can find, and that is where you go from doctor, to doctor, to doctor, to doctor.

Mr. MAIXNER. Exactly.

The CHAIRMAN. That is why I wondered, do we really possess the knowledge and tools or not? I know Dr. Pizzo wanted to respond, but I am going to ask Dr. Maixner.

Dr. PIZZO. That is great.

Mr. MAIXNER. Let me comment on a few of your comments, Senator.

As you articulated the back problem, brought me back to my own at the age of 18, baling hay, southern Iowa, I ruptured a disc, and as you recounted your story, my lower back began to ache, again, the emotional response, the tension that was just spoken to.

I do want to note, though, that there may be a misunderstanding about the nature of the IOM report and its perspective on the importance of behavioral interventions. Again, the primary tenet of the report is that chronic pain conditions where there is a major mismatch between what we see pathologically and what the patient experiences is best explained by the biopsychosocial model.

Within that is the psycho component of it, where there are very good demonstrations of what we call cognitive behavioral therapies, educational therapy, awareness therapy, self therapies, which are part of the overall rubric that multidisciplinary pain programs use. There is actually reasonably good so-called meta-analyses using both operant, what is called operant behavioral therapies and cognitive behavioral therapies, some of which you have just described in your own case that are effective in some patients.

One of the challenges that we have is really trying to identify those subpopulations that will respond, like you and like I, when we engage our own intrinsic cognitive behavioral methods to alleviate this pain. I do think that the IOM report, from my reading of it, has tried to capture that.

The issue is if it is not common practice across the United States in part because of reimbursement issues. The psychologists are not reimbursed well for their therapies. That is why I advocated bundled services, bundled reimbursements in multidisciplinary pain programs, which allow this type of educational perspectives to occur.

I do think that the IOM report has noted this very important therapeutic intervention.

The CHAIRMAN. I just noted it, but is it minuscule?

Mr. MAIXNER. It is minuscule.

The CHAIRMAN. Minuscule?

Mr. MAIXNER. I would agree with that.

The CHAIRMAN. And yet—

Mr. MAIXNER. One other comment too. From our own research, we are finding that one of the primary domains of risk is what is called somatic awareness. That is the ability of the individual patient to sense both the internal milieu as well as the external environment, and it is our belief this represents augmentation or excitement of the central nervous system, that sensory stimuli are actually augmented in their processing. This allows us to think about our lower back pain, and those pathways in the brain involved in back pain, actually can rekindle and show expression again.

We believe that that is one of the targets, one of the targets for intervention trying to decrease somatic awareness which may be influenced by the emotionality of the memory that we generate.

The CHAIRMAN. I do not know if that was inherent with me or you, but can people be taught this?

Mr. MAIXNER. Yes. Not all individuals can respond, though. So I think that is the trick.

The CHAIRMAN. OK. Dr. Pizzo, I am sorry.

Dr. PIZZO. First of all, thank you so much for sharing your personal story, which is deeply meaningful and moving, and I am glad that you are doing well. I would say just a couple of other things, if I may.

First, the IOM report that I chaired, along with others, was not a call to a specific intervention or therapy, but a call to action. It really identified the problems broadly. It did not identify what roots specifically should be taken for any one individual and did recognize, just as you have heard, that there will be different approaches for different individuals.

Now, I would say that like you, all of our lives are shaped by our personal experiences. Mine comes from being a pediatric oncologist, someone who lived through the era of HIV in children and the impact of that illness on pain. It comes from being the spouse of someone who suffers from fibromyalgia, who has had decades' worth of chronic pain. I have witnessed on a personal level that approach to intervention of very different sorts from psychological and psychiatric, to pharmacological and behavioral, and physiological and physical can have varying degrees of impact.

The point being there is not, unfortunately, a single solution, and I think that really underscores part of the message. If there was a single solution to the problem affecting 116 or more million people in this country, we would celebrate it and embrace it.

What we have recognized is that while there are therapies that can impact some, many need and would benefit from other innovations and interventions, and we need to work on that as well. And not lose sight of those who have tried and have not yet benefited from the medical therapies that are available today.

The CHAIRMAN. You are absolutely right, and that is why during all my tenure here in the Senate as Chair of this committee, of being on this committee, chair of the Appropriations Committee on NIH, I always wanted to open the doors and windows to everything. I want a lot of issues looked at. I do not want anything just dismissed out of hand. After all, it was my legislation that started the Complementary and Alternative and Integrative Medicine.

Dr. PIZZO. I was at the NIH when you did that, and very proud that you did.

The CHAIRMAN. Not that I say that this is the answer, but we ought to be looking at these things.

Dr. PIZZO. Right.

The CHAIRMAN. And examining them, just like what happened with me. I am not saying it is going to work for everybody, but at least it ought to be looked at—

Dr. PIZZO. That is right.

The CHAIRMAN. And researched and tried.

Dr. PIZZO. That is right.

The CHAIRMAN. I mean, it ought to be a part of it, not just some little footnote someplace, but really, really delved into. Miss Veasley, yes.

Ms. VEASLEY. I think you sharing your story, mine, and the millions of others really points out that we just do not understand pain. There are multiple pathways by which people can develop pain and effectively treat pain. And, similar to what you discussed, I have done all kinds of mind-body techniques, relaxation, stress reduction, exercise, yoga, biofeedback, all of these things and I, too, in a little different way.

I am a person of faith. I also speak to my pain a little different way. But I can tell you that I am still left with severe pain and it is only on the left side of my body. I was hit by a car on my right side; I only have pain on the left side of my body.

While your experience is very real, mine is very real, as are all of these others. We really cannot expect to understand pain when we are not researching it. When the United States spends 96 percent less than it does on diabetes, heart disease, and cancer, how can we expect to understand all of these mechanisms?

There is genetic evidence that people are predisposed to develop either heightened or less pain. There are studies and documentation of people who are born without the ability to sense pain at all, which is not to their advantage because they end up injuring themselves, but this is evidence that there is a genetic component there.

There is also evidence that pain can actually be a dysfunction of the pain sensing network in our body itself. It can be a dysfunction or a disease of the central and peripheral nervous system.

What you said brings us right back to the same point. We are never going to be able to tease all this apart until we have an adequate research effort that looks at all of this.

The CHAIRMAN. I could not agree more. I am sorry. Senator Whitehouse, I sort have been dominating the question and answer.

Senator WHITEHOUSE. That is fine.

The CHAIRMAN. I hope you forgive me.

Senator WHITEHOUSE. I am set. Thank you very much. I appreciate very much the witnesses' work in this challenging area.

I would invite anybody who wishes to respond in the form of a response to a question for the record, with thoughts about the ways in which the paper and electronic recordkeeping of the health care system can be improved, to improve awareness about peoples' pain conditions, forcing the issue of vital signs, making sure electronic health records address this. I would be delighted to get your more thorough answers in writing, so that we can evaluate them. I appreciate it.

Again, Chairman, thank you.

The CHAIRMAN. Thank you. Dr. Sarno, I have been kind of picking on you lately here. Do you have anything else to add at all to what we have been saying? You have been doing this for 40—

Dr. SARNO. Five.

The CHAIRMAN [continuing]. Forty-five years. You have seen a lot of patients. Do you have anything else to add to that?

Dr. SARNO. Not really. It is just the idea that in medicine in general, there is a tendency to look at things from the anatomical and physiologic point of view. And perhaps not recognize the impact of emotions on the physiology, and that is the only thing that I would say. Keep an open mind about that because I believe that there are—

The CHAIRMAN. I hope that we will do more research in that area. That is what I hope that this group will now start to take a closer look at.

To try to sum up, Dr. Pizzo, thank you. You talked about how much we are spending a year and how much is coming from our Federal and State budgets, this is a huge impact on our financial wherewithal. You said that it is a moral imperative. I believe that. It is a disease in its own right, and I think you also said we need collaboration. We need a lot of collaboration among a lot of different disciplines to really look at this.

Dr. Maixner, you talked about the barriers, the mismatch of money at NIH. I could not agree more. We are going to take a look at that. This committee will, well, my other committee that I wear another hat on, the appropriations committee, we are going to look at that. You talked about education. Only nine sessions in medical school on this, on something so prevalent, and I sort of said that at the beginning. How do we get our residencies more in tune with diagnosing people and focusing on pain?

You also mentioned the doctor shopping and what is happening there. Again, we need to educate our doctors, our practitioners, and our primary care people a little bit better than what we have been doing in the past.

Miss Veasley, you bring a very poignant, personal story to this. There are a lot of people like you around this country, maybe not with vulvodinia, but with fibromyalgia, irritable bowel syndromes, back pain, all kinds of things that we need to know more about, and how we do more research, get more research into these areas. No doubt about it. You bring a very strong personal story.

Dr. Pizzo said, "We need new, innovative therapies that we may not know about." I think that is pretty profound. "We need new innovative therapies we may not know about." How many people out there on this committee and others do not know about 45 years of practice, and treating people, and honing this to a fine degree on how you treat people with chronic pain that has no—now this is where I should not practice medicine without a license—but without a physiological basis.

I think that Dr. Sarno mentioned that the first thing to do is also always look at that. You do that first, and then if there is nothing there, then you have to move to a different modality.

This is my own statement. I think there are too many people in our society, this is what you have talked about, Dr. Maixner, some of us are equipped somehow, different people think different ways.



Different people can cope with things differently and assess things differently. There are just too many people in our country that think there is a pill, a drug, or a surgery that is going to cure whatever you have. I think maybe we have been brought up to think that, and that there is something out there, "If I just get the right pill, the right drug, the right surgery, it's going to cure me." I do not know that we have put enough into the up front prevention.

I guess I will close on this, that when I think about prevention in the area of pain, it is educating not just the doctors and the residencies, but people when they go through school. That they are knowledgeable about pain, and chronic pain, and what causes pain, and how you deal with these things. So that they become more knowledgeable about their own systems and how different things affect them. Then maybe we will not always be thinking that we can just do whatever we want. There is a pill, or a drug, or a surgery out there that is going to cure what ails us.

There is a lot here. I mean, we have to do more research in this area, but it has to be broad. I will continue to say that this whole area of mind-body cannot be just a footnote. It has to be integral to this whole search that we are doing on how to relieve so many people that have real pain, real pain. Not in your head; it is in your body. Where it comes from, we do not know yet, but that is the one thing I have learned from Dr. Sarno that this is real, physical pain. It is not in your head. It is real, physical pain.

I thank you all very much. I thought this was a very enlightening session and I appreciate all the wonderful work you do. I look forward to working with you on the committee itself in the future, and to do what we can to approach this issue of pain in a thorough, holistic, comprehensive method than we have been doing in the past.

I ask unanimous consent that testimony from the Chronic Fatigue and Immune Dysfunction Syndrome Association of America be submitted for the record in memory of Christie Gaffe of Williamsburg, IA.

I also ask unanimous consent that testimony from the American Cancer Society Cancer Action Network be submitted for the record.

[The information referred to may be found in Additional Material.]

If there is nothing else to add, then the record will also remain open for 10 days for any statements or questions from other members of the committee.

With that, the committee will stand adjourned. Thank you.

[Additional material follows.]

## ADDITIONAL MATERIAL

## PREPARED STATEMENT OF SENATOR ENZI

Anyone who has ever had a serious injury or condition knows how difficult managing pain can be. For over 100 million Americans affected by chronic pain, the challenge of dealing with pain is ever-present in their lives. While pain is experienced differently by each individual, there are some common challenges faced by folks that range from access to care in rural areas to the need for new treatments and therapies. I look forward to today's hearing, and thank the witnesses for being here and presenting their perspectives on how we can better prevent, treat, and manage pain and overcome the challenges presented by pain.

Research has played a crucial role in our understanding of pain—both in how it can be useful to warn of damage to our bodies, but also how it can be harmful and how we can attempt to mitigate it. Thanks to the work of scientists and researchers across the country, including at many academic institutions and at the National Institutes of Health, we now have a better grasp of the biology of pain which has, in turn, informed the development of more effective therapies and improved pain management. Still, we must continue to focus on how we can better leverage our precious research dollars to improve the prevention, treatment, and management of pain. The Institute of Medicine (IOM) report, "Relieving Pain in America: A Blueprint for Transforming Prevention, Care, Education, and Research" highlighted some of these research challenges, and NIH has already acted on some of the report's recommendations.

I look forward to the testimony of Dr. Tabak and hearing about the latest research being conducted at NIH, and also of Dr. Maixner about his work in pain research. Several initiatives in the past sought to ensure the coordination of Federal research efforts to ensure we are avoiding duplicative efforts, including through the creation of the NIH Pain Consortium to promote collaboration across the Institutes and Centers.

Another critical component of managing pain is educating pain care professionals and patients alike. The report highlighted the need for improving the understanding of health professionals and the general public on the complexities of pain and the challenges of managing chronic pain. The patient and the provider both benefit from improved pain assessments and more targeted treatments and management strategies. Many health professional and pain associations and academic institutions have been seeking to improve provider understanding of pain, available treatments, and how to best manage pain.

Pain is based on the individual, so I understand a one-size-fits-all approach will not work. The witnesses on the second panel will speak to the challenges of research, providing care, and living daily with pain. I want to thank the witnesses who have dedicated their time to educating and teaching us about their story and the discoveries they have made in this area. I hope that we continue to make progress addressing pain in America.

## PREPARED STATEMENT OF SENATOR HATCH

I would like to thank Senators Harkin and Enzi for convening today's hearing on such an important issue affecting millions of American patients and caregivers. I also thank our witness panels for joining us today.

Every American experiences pain; and millions suffer from chronic, debilitating pain that interferes with their everyday lives. Chronic pain impacts not only individual sufferers themselves, but also their families, friends, employers, co-workers, and communities.

This report was authorized by bipartisan legislation entitled the National Pain Care Policy Act which I co-authored.

Pain is the most common reason Americans seek health care services and is also a leading cause of disability, yet most pain sufferers fail to get proper assessment, diagnosis, treatment and management of their pain. Additionally, health care providers often face challenges to learning about or providing appropriate pain care management.

I look forward to hearing about potential solutions to resolving these challenges in the most fiscally responsible and efficient ways possible. Again, thank you all for being here today and I look forward to hearing your testimony.

PREPARED STATEMENT OF ROBERT E. SHAPIRO, M.D., PH.D., PRESIDENT, ALLIANCE FOR HEADACHE DISORDERS ADVOCACY; PROFESSOR OF NEUROLOGY, UNIVERSITY OF VERMONT COLLEGE OF MEDICINE

Chairman Harkin, Ranking Member Enzi, and members of the HELP Committee, thank you very much for providing me with this valuable opportunity to discuss the impact of headache disorders in our country.

My name is Bob Shapiro. I am president of the Alliance for Headache Disorders Advocacy, a coalition of 10 national and regional not-for-profit organizations advocating on behalf of Americans with disabling headache disorders. I am also a practicing physician, research scientist, and a professor of neurology at the University of Vermont College of Medicine.

## HEADACHE: THE SCOPE OF THE PROBLEM

Headache in America is a wholly misunderstood phenomenon. Half of Americans will experience some type of headache this year,<sup>1</sup> and more than 90 percent of Americans will experience headache in their lifetimes.<sup>2</sup> While mild headaches are a nearly universal human experience, their near ubiquity combined with a century of direct-to-consumer promotion of inexpensive over-the-counter analgesics, has reinforced an impression that headaches are only a minor problem except for those with a low tolerance for pain. This is profoundly mistaken.

In fact, headache is a symptom that is common to a broad category of neurological disorders. Chronic migraine, post-traumatic headache, chronic daily headache, cluster headache and related disorders exact tremendous social, economic, and personal burdens that collectively comprise a smoldering and neglected major public health crisis. However, due to broad public familiarity with mild headaches and their near-absence of fatal complications, these incapacitating disorders are caught in a blind spot of public inattention. While they are highly prevalent, costly, and disabling, they are nonetheless stigmatized and dismissed.

First, some facts may be useful:

- Headache disorders result in more than \$31 billion in annual U.S. direct and indirect economic costs,<sup>3,4</sup> exceeding the estimated annual U.S. costs of epilepsy, asthma and ovarian cancer combined.<sup>5</sup> Furthermore, recent data suggest that total U.S. costs due to headache disorders may actually be three times higher than previous estimates.<sup>6</sup>

- Headache is the most common symptom of concussive or mild traumatic brain injuries. Among veterans of the Iraq/Afghanistan conflicts, 37 percent of servicemen and 57 percent of servicewomen reported ongoing migraine if there was a deploy-

ment history of concussive injury and any pre-deployment history of migraine.<sup>7,8</sup> More than 500,000 concussions in the United States are sustained annually by children playing tackle football.

- World Health Organization (WHO) data indicate that migraine is the 19th leading cause of life lived with disability,<sup>9,10</sup> and by itself results in more lost years of healthy life (“disability-adjusted life years”) in the United States annually than multiple sclerosis, epilepsy, ovarian cancer, and tuberculosis combined.<sup>11</sup>

- Almost one in five Americans (approximately 60 million people) will experience an attack of some form of migraine this year. Fewer than half of these people have formally received this diagnosis.<sup>12,13,14,15</sup>

- 75 percent of adult Americans with episodic migraine are women,<sup>13</sup> predominantly of childbearing age, however the very high prevalence of migraine overall means that it is not just a women’s disorder.

- 4 percent of Americans have headaches of more than 4 hours duration, at least 15 days per month,<sup>12</sup> defined as “chronic daily headache.”

- Severe headaches disproportionately affect individuals with low-income or limited education, as well as some minority groups such as Native Americans.<sup>16,17</sup>

- Cluster headache, a recurrent episodic disorder virtually unknown to the general public and typically unrecognized by physicians, is reputed to be the most severe pain that humans can experience. More than half of cluster headache sufferers have recurrent thoughts of suicide.<sup>18</sup> It has a prevalence of approximately 1 in a 1,000, comparable to multiple sclerosis.

- Migraine with aura increases the risk of cardiovascular disease and is linked to more than 1,500 deaths in the United States annually, even after all other known risk factors have been accounted for.<sup>19,20</sup> Americans with migraine with aura or frequent migraine are also more than three times more likely to attempt suicide than those without migraine, irrespective of the presence of depression.<sup>21,22</sup> Migraine is highly co-morbid with depression, anxiety, asthma, epilepsy, substance abuse, obesity, and multiple other disorders which compound disability and suffering.<sup>23</sup>

#### HEALTH CARE FOR HEADACHE DISORDERS

Given the broad scope and huge burden of headache disorders in America, what healthcare resources are arrayed to manage the problem? Unfortunately, headache disorders have historically been neglected by practicing physicians. Early formulations of migraine described it as a psychiatric disorder<sup>24</sup> or stigmatizing<sup>25</sup> misbehavior particularly afflicting women of weak constitution but otherwise having no physical abnormalities. Such impressions have led generations of physicians to a well-entrenched dismissal of migraine as a non-serious malady of complainers.

Unsurprisingly, few doctors have chosen to care for patients with headaches. While headache is the primary clinical focus area for more than half of America’s approximately 7,000 neurologists,<sup>26</sup> a total of only 290 U.S. physicians are certified by the United Council of Neurological Subspecialties (UCNS) as having specialty training in Headache Medicine.<sup>27</sup> On average there is only one UCNS certified U.S. headache physician for approximately 43,000 Americans with chronic daily headache or approximately 200,000 Americans with migraine. A survey in 2004<sup>28</sup> found that most academic neurology departments in the United States did not actually have a dedicated headache specialist on faculty and there are currently only 17 UCNS accredited fellowship programs in the United States to train new headache specialists.<sup>29</sup> With few academic mentors and clinical training program opportunities, the outlook for recruitment of new headache medicine providers and clinician-scientists is bleak. It would be inaccurate to say that organized medicine has abandoned headache patients; it never took them seriously to begin with.

An unintended consequence of recent health care reform presents a further potential threat to patient access to headache care. To promote primary and preventative care, the Patient Protection and Affordable Care Act of 2010 (PPACA) provides for incentive bonuses to cognitive care providers, but only for those providers of particular primary care specialties.<sup>30</sup> That is, under PPACA, incentives are only accorded to certain types of doctors rather than just to the type of medicine practiced. While headache care is very heavily weighted to cognitive over procedural care and headache medicine providers often provide primary or principal medical care, almost all headache medicine providers are ineligible for the PPACA incentives: 85 percent of UCNS certified headache providers are neurologists<sup>27</sup> and neurology is not a medical specialty cited under the provision. Furthermore, recent proposals to resolve the failed Medicare Sustainable Growth Rate reimbursement formula have included consideration of steep cuts to procedural medical specialties. In this case, neurologists would also be inappropriately grouped with surgeons rather than with internists for these purposes. Ineligibility for PPACA incentives, combined with imposi-

tion of significant Medicare reimbursement cuts, could render already financially tenuous headache care practices as unviable. Such an outcome would be especially problematic for patients with headache disorders since they often rely on headache providers for delivery of their primary or principal medical care.

Therapeutic options for headache disorders are few. Over the past 50 years, only one novel drug, sumatriptan,<sup>31</sup> has been developed specifically for the acute treatment of migraine and subsequently approved following an FDA priority review. While the approval of sumatriptan in 1992 was a breakthrough, the drug does not work immediately, it is ineffective in 40 percent of attacks and a quarter of migraine patients<sup>32</sup> and it is contraindicated in many other patients with cardiovascular disease. Six “me-too drugs”,<sup>31</sup> that are structurally and therapeutically similar to sumatriptan, were subsequently FDA approved, but these have not substantially changed the landscape of available therapies. Moreover, sumatriptan remains expensive even though it is now available in generic form.

Opioid medications, which are a mainstay of therapy for acute pain conditions, have a very limited role in the care of recurrent headache disorders such as migraine. Opioids characteristically render other headache medications less effective and their use in migraine significantly increases the risk for worsened attack severity and frequency.<sup>33,34</sup> However, because of the relatively higher cost of triptans and generally inadequate knowledge of headache practice among both primary care providers and insurance carriers, 20 percent of U.S. migraine patients must still rely on opioid and barbiturate medications for the acute treatment of attacks.<sup>35</sup>

Four drugs are FDA-approved and marketed for the prevention of episodic migraine and one drug for the prevention of chronic migraine. All of these drugs were initially FDA-approved for other medical indications, all have significant potential side effects limiting tolerability, none are curative, and many patients are not responsive to any of them.

#### RESEARCH ON HEADACHE DISORDERS

Headache disorders research has never been adequately funded. Perhaps taking a cue from physicians, the National Institutes of Health has also neglected headache disorders, and very limited funding for headache disorders research has been available through the Department of Defense, private philanthropies, or any other sources. In 2011, the NIH expended \$21 million on all headache disorders research, comprising less than 0.07 percent of the overall budget.<sup>36</sup> Moreover, NIH estimates an actual decline in such funding to \$20 million through fiscal year 2013.<sup>36</sup> While the NIH has sponsored at least six investigator conferences and “workshops” over the past 4 years to discuss the planning for headache disorders research,<sup>37</sup> it has not issued any Request for Applications (RFAs) or other Funding Opportunities with funds set-aside to prioritize the actual conduct of such research. In fact, only once has the NIH ever issued an RFA on migraine research<sup>38</sup>; it funded a total of four grants in 2007 but did not appreciably increase overall funding for the disorder. The NIH has not funded a research grant on cluster headache in more than 25 years. Two NIH standing peer-review study sections each have one headache research scientist currently serving a 3-year term, though neither study section is otherwise focused on the review of headache disorders grant proposals.<sup>39</sup>

In this climate of poor research funding and uncertain grant proposal review, few seasoned scientists have entered the headache field. Furthermore, promising early-stage scientists are often led by their academic mentors to consider this to be a dead-end career track, thereby exacerbating the shortage of investigators. Of 14,229 research presentations at the 2006 annual meeting of the Society for Neuroscience, only 22 were related to headache disorders.<sup>40</sup> Over the past 35 years, the pre-eminent science journals *Nature* and *Science* have each published only one research report related to migraine. High-impact general medical journals publish almost nine times as many articles on asthma as on migraine.<sup>41</sup> Of the progress that has occurred in migraine research in the past two decades, a disproportionate number of seminal findings have emerged from non-U.S. laboratories. For example, of the eight genes for migraine susceptibility that have been identified to date, seven of them were discovered by non-U.S. investigative teams.<sup>42 43 44 45 46 47 48 49</sup>

#### MIGRAINE AND EPILEPSY: SIMILAR DISORDERS, DIVERGENT RESEARCH PATHS

Regarding the direct benefits to patients that can result from NIH research funding, an instructive comparison can be made between two highly similar disorders, migraine and epilepsy. Both are paroxysmal brain disorders that share in common some identified genes, brain events, and medications.<sup>50</sup> They also often occur together in the same individuals. While both may be disabling, according to WHO

data,<sup>11</sup> migraine results in 3 times more lost years of healthy life as epilepsy annually in the United States. Migraine is also far more prevalent and costly overall.<sup>51 52</sup>

By contrast to migraine however, the NIH has invested well in epilepsy research over the past 20 years.<sup>36 51</sup> In 2011, NIH expenditures on epilepsy totaled \$152 million versus \$16 million for migraine. NIH epilepsy programs have included a “benchmarks” initiative to guide new investigators and a remarkably successful, cost-effective, and largely unsung, early-stage screening program to identify promising new drugs.<sup>51 53</sup> The NIH also has a standing peer-review study section that is largely and specifically devoted to ensuring fair and informed review of epilepsy grant proposals.<sup>54</sup> The returns on this investment for epilepsy have been impressive. Over the past 20 years, while FDA approvals for novel migraine drugs have languished, patients with epilepsy have benefited measurably by the FDA approval of 14 novel anti-seizure medications, and even more drugs are in late stage clinical trials.<sup>51</sup>

The comparison between migraine and epilepsy drug approvals starkly underscores the pivotal role that NIH-funded fundamental and translational research plays in drug discovery. In the case of migraine, the pharmaceutical industry has simply not delivered on its own. The recent successes in epilepsy drug development offer the clear promise that with comparable NIH investigator-initiated research funding, fair and informed peer-review of grant proposals, and implementation of a robust NIH migraine drug screening program, multiple novel and effective therapies would emerge for patients with headache disorders.

#### A WAY FORWARD FOR AMERICANS WITH HEADACHE DISORDERS

The NINDS mission is “to reduce the burden of neurological disease.”<sup>55</sup> This mission cannot be realized without addressing a major source of that burden: the untended crisis of Americans with disabling headache disorders. Moreover, the persistent neglect of such a large source of U.S. disease burden indicates a lapse in NIH surveillance of sources of disease burden and a lack of a formal policy to take disease burden measures into consideration in prioritizing research funding. NIH must have a policy that ensures that any significant source of disease burden is never so grossly misaligned with the application of NIH resources in the future. We urge NIH to focus on the funding of innovative burden of illness research with the goal of developing measures that may guide public policy acceptable to a consensus of NIH stakeholders. Adoption of more objective criteria for the distribution of NIH funding, based in part on improved disease burden measures, should increase transparency, reduce the politicization of the NIH funding process overall, and ensure that all Americans are equitably benefiting from tax-payer funded research.

In the meantime, Americans with headache disorders warrant an NIH commitment of a magnitude at least equal to that currently directed toward alleviating epilepsy. We urge immediate and remedial attention to building NIH intramural and extramural programs for headache disorders research, and to implementation of the recommendations of the NIH Headache Research Planning Meeting Report of October 2011, “Opportunities and Priorities for Headache Research.”<sup>56</sup>

In particular, we believe that new NIH programs should include:

- *The establishment of regional academic headache disorders research and care “centers of excellence” to train clinicians in headache medicine and clinician-scientists to pursue research in this area.*

Without adequate NIH-funded research and academic programs devoted to headache disorders, there will continue to be limited, or non-existent, institutional support in medical schools for the training of headache medicine clinicians and clinician-scientists.

- *Major new and sustained set-aside funding of investigator-initiated fundamental and translational research on headache disorders, especially pertaining to identification of biomarkers and development of relevant models of disease.*

To attract and retain quality investigators to this field, it is necessary to ensure that adequate funding sources will be sustained and that peer-review of grant proposals will be informed and fair.

- *Establishment of a migraine drug screening program to foster early stage development of novel and effective therapies.*

Such a drug screening program could be implemented by extension of the established anticonvulsant screening program and might be mostly self-funded through modest fees assessed of pharmaceutical industry users and targeted to the Foundation for the NIH.

To assure access to effective headache care for patients, we urge inclusion of headache specialty providers in the incentive reimbursements that will be accorded to primary health care providers in health care reform, and also in the protections

from cuts in reimbursements which may result from resolution of the Medicare Sustainable Growth Rate formula.

#### HEADACHE PATIENT TESTIMONIES

I conclude with the unedited voices of a few, among thousands, of Americans who have recently provided comments on a petition urging congressional attention to headache disorders<sup>57</sup>:

SSGT Leslie W. from Brooklyn, NY writes:

As a combat vet served a tour of duty in Afghanistan, I have constant headaches and our VA doctors have no explanation for them

Michelle L. from Newport News, VA writes:

I have not shut myself off from life, my head pain has shut life off from me. I would hate to see another person go through life as lonely and afraid as I am at this very moment.

Joyce W. from Glen Rock, NJ writes:

My father suffered from cluster migraines. In 1980, he chose to end his life at age 52 rather than live with these headaches any longer. 32 years later and there are still no good answers.

Gail B. from Mexico, MO writes:

18-22 days a month I am in bed with a migraine, and NO ONE can help me. NO clinic, no headache specialist & no neurologist. lost my career, my marriage & my life. My son received a TBI from an IED in Iraq, he now suffers also but with memory loss, yet he's deployable. Go figure.

Rose H., Colorado Springs, CO writes:

Little by little I'm losing more and more of my life to migraines . . . my job, school, friends and all of the events I cannot attend due to the debilitating pain, visual disturbances and all of the other symptoms of migraines. Please help me get my life back by recognizing migraines as the taker of lives they are and bring about the changes necessary for better understanding and treatment.

Kathy B. from Alta Vista, KS writes:

chronic migrainer here . . . getting worse not better and the meds aren't working. . . . lost my normal life everything revolves around my migraines I have no life anymore only horrible days and semi functional days

Alicia H. from Arlington, OR writes:

You have no idea how bad this can be until you see your best friend laying under a table in the fetal position screaming. With their eyes bleeding from the pressure.

Lorri P. from La Marque, TX writes:

I have suffered from Migraine headaches for more than 26 years. Due to Migraines, I left active duty military, I have missed out on much of my daughters' lives growing up, I have placed undue stress on my marriage and have been on full disability for the last 4 years. This is not living.

Catherine H. from Wasilla, AK writes:

I was forced to seek social security disability at age 45 for migraine. I have now been on disability for over 18 years. I never realized my full potential in earnings nor did I really utilize my college education. Indeed, I was forced to declare bankruptcy and will probably spend the remainder of my adult life on public assistance, food stamps and HUD housing assistance to augment my Social Security Disability income. The financial loss includes lost taxes on a professional income, loss because of bankruptcy and a loss to the Nation in public assistance to support me that includes almost 20 years of medical costs for migraine drugs at between \$1200 \$200 per month!

Misty S. from Washington, DC writes:

PLEASE, PLEASE, PLEASE increase funding for research and clinical trials to find the cause of CLUSTER HEADACHE attacks. Over the past 20 years, I have been to countless doctors and tried over 35 ineffective medications with horrible side effects. I just want to be able to live and enjoy life rather than dreading with fear my next CLUSTER HEADACHE attack.

Carrie S. from Charlotte, NC writes:

So many of us have to stop working and live on government aid because of headache disorder disabilities. With lack of education, funding for research, and new treatment options, we have no other option than to continue living this

way. Give the Nation education, research funding, and new treatment options, and I guarantee that you will be shocked at how many Americans will benefit and be able to go back to work, thus paying back into the system. Help us so that we can help you.

Kenneth B. from Santa Monica, CA writes:

Many more people are suffering than anyone knows as you can't see it like if someone had a broken arm for example. Millions of us are suffering in silence and only more research will bring an end to our problems . . .

Susan V. from Lake Forest, IL writes:

Adolescents suffer greatly as well and the school system has no provisions to accommodate this malady and continue their education. Many end up dropping out and having to figure out an education on their own later in life. What a waste of talent & potential.

Patricia D. from Highland, CA writes:

I have suffered with migraines since the age of 13. It has now been 34 years with no answers as to why I am getting them or a medicine that helps. Sad to say I have gotten a migraine every day of my life for numerous years. I am tired, depressed and have lost my joy. I have exhausted the help of 4 neurologists and 2 pain specialists in the past 10 years. I've left doctor appointments crying because I was told, "I have done all I can to help you. There is nothing left to try." My family has spent thousands of dollars to try and help me because my insurance would not cover different treatments and medicines. I have tried to get into migraine trials but after they see all that I have tried and medicines I have taken they deny me. Unless you walk in the shoes of a chronic daily migraine sufferer, you cannot relate! No matter how much you try you will never understand what we go through. My prayers are out to all who suffer from debilitating headaches!

Sandy S. from Des Plaines, IL writes:

Signing this with a migraine, hoping someone we elected will listen to us for a change.

Thank you very much for your attention.

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PREPARED STATEMENT OF JENNIFER SPOTILA ON BEHALF OF THE CHRONIC FATIGUE  
AND IMMUNE DYSFUNCTION SYNDROME (CFIDS) ASSOCIATION OF AMERICA

SUMMARY

This testimony is submitted on behalf of the CFIDS Association of America, in loving memory of Christy Gaffey of Williamsburg, IA. Christy lost her battle with chronic fatigue syndrome (CFS) and interstitial cystitis on February 9, 2012 at the age of 52. She was an advocate for these medical conditions and, in days of better health, participated in lobby days organized by the CFIDS Association. With this testimony at today's hearing chaired by Senator Tom Harkin—her Senator—we recognize Christy's life and the voice she once gave to all who have been jailed by chronic pain conditions. We implore, in Christy's memory and for all those who have been lost too early to these conditions, that today's hearing mark the beginning of serious action to address and curb the personal, family, community, State and national toll exacted by conditions marked by chronic pain.

ABOUT CFS

Also known as chronic fatigue and immune dysfunction syndrome (CFIDS) and myalgic encephalomyelitis (ME) or ME/CFS, CFS is a complex illness that results in a constellation of debilitating symptoms, including incapacitating fatigue (experienced as profound exhaustion and extremely poor stamina), sleep difficulties and problems with concentration and short-term memory. The hallmark of CFS is post-exertional relapse, a worsening of symptoms following even minor physical or mental exertion that persists for days or weeks. It's also accompanied by pain in the joints and muscles, tender lymph nodes, sore throat and headaches. It often has an acute, flu-like onset within hours or days.

ABOUT THE CFIDS ASSOCIATION OF AMERICA

The Association's mission is to make CFS widely understood, diagnosable, curable and preventable. Our strategy is to stimulate research aimed at the early detection, objective diagnosis and effective treatment of CFS through expanded public, private and commercial investment. Second only to the Federal Government in funding initiatives for CFS, since 1987 the Association has invested more than \$30 million in initiatives to end the life-altering disability, stigma and isolation of CFS. The CFIDS Association of America is a member of the Chronic Pain Research Alliance. For information and resources, visit [www.research1st.com](http://www.research1st.com) or [www.cfids.org](http://www.cfids.org).

Chronic fatigue syndrome is the name of my illness. I cannot count the number of people who have said to me, "I had no idea that CFS had pain as a symptom." But it does. Think about the last time you had the flu. Did you lie in bed, shaking and aching all over, too weak to sit up? Yes. That is what my pain is like, but it is like that every day. Pain is always with me. It follows me around like my shadow. Just as a shadow changes shape with the light, my pain expands, contracts, and tries to swallow me whole. There is nowhere I go, nothing I do that is unaffected by pain.

Aching, throbbing, heavy, sharp, tingling, stabbing, crushing—all these words cannot fully describe my pain. Sometimes I lie in bed, weighed down by it. Or I might be sitting up and feel pain like a lance through trigger points in my back.

My wrists ache, my toe joints hurt. One day, it's my calves that tighten and cramp. Another day, my neck pinches and headaches loom. There are times when my whole spine is on fire and nothing I do alleviates the pain. There are times when the gentlest touch is more than I can bear, even my husband's hand on my arm or my hair brushing against my neck.

I've worked with physical therapists. One said there was no hope when my body did not respond to the prescribed program. My current physical therapist has made great progress in loosening the trigger points in my back, but there has been no change in my overall pain level or experience. The catch-22 is that the exertion of going to physical therapy twice a week and the daily stretching regimen does, in itself, increase my pain. I tried acupuncture, too. The needles are supposed to be painless, but I felt ropes of fire shooting out from every needle site.

I've consulted with pain management experts. Over the years I've tried aspirin, bextra, celebrex, cymbalta, flexeril, gabapentin, ibuprofen, imitrex, lidocaine injections, lidoderm patches, lyrica, pamelor, percocet, soma, topomax, tylenol 3, tramadol, venlafaxine, vicodin, and wellbutrin. Most of these medications either did not help, or helped but came with intolerable side effects. Pamelor caused dreadful acid reflux. Topomax caused flashing lights in my peripheral vision. When my doctor decided to discontinue venlafaxine, it took me more than 2 months to wean off the dose and even then I endured withdrawal symptoms. I developed a frightening hypersensitivity reaction to tramadol, forcing me to discontinue the one drug that worked very well for me. Opiates like percocet and vicodin were a dream come true. The few weeks I was on percocet after the tramadol hypersensitivity were the only pain-free weeks I have had in more than 15 years. No doctor is willing to prescribe them for me long term. Instead, my pain management doctor believes the goal is to keep my pain manageable, not to make me pain-free.

Pain is intertwined with fatigue like a snarl of barbed wire. Being in pain makes me more tired. Activity makes me more tired and increases the pain. I always have to be careful about my physical position—legs and back fully supported, neck not too bent. Some days, I cannot get out of bed at all. Even when I am able to function, pain limits what I can do. I am fortunate not to have intense, localized pain that might prevent me from reaching for an object or moving in a specific direction. Instead, the pain hovers in the background, creeping ever higher. The generalized ache grows stronger and louder until it overwhelms every thought or intention. I might take a few steps out of my cell but pain, my jailer, will always shove me back in and slam that cell door shut.

On good days, I get through the day with a few hours of activity such as cooking or paying bills. By the time dinner is over and the dishes are done, I am on the verge of collapse. A hot pack and bed by 7 p.m.—I feel like a 90-year-old invalid. On bad days, I max out on all my pain medications. If I am very lucky, the medications will keep the pain to a tolerable level. There have been many nights when all I could do was whimper. More than once, I have contemplated going to the emergency room for pain relief on nights like that. But what would they do for me? How would they view me, a 40-something with normal blood work who insists she needs medication for intractable pain? I have never bothered to find out.

Living with this pain is like juggling while riding a unicycle. One lapse of focus, one dropped ball and everything comes crashing down. The delicate balance of rest, medication, and physical therapy will keep the pain at bay, but inevitably, something destroys that balance and the pain comes roaring back. No one can pedal a unicycle indefinitely. I try my best, but sometimes, living with this pain doesn't feel much like living at all.

#### PREPARED STATEMENT OF THE AMERICAN CANCER SOCIETY CANCER ACTION NETWORK (ACS CAN)

On behalf of millions of cancer patients, survivors and their families, the American Cancer Society Cancer Action Network (ACS CAN), the advocacy affiliate of the American Cancer Society commends the Senate Health, Education, Labor, and Pensions Committee (HELP) for holding this important hearing to address the public health impact of pain in America.

More than 1.5 million new cases of cancer will be diagnosed this year. Pain remains one of the most feared and burdensome symptoms for these cancer patients, as well as for survivors and their families. Approximately 30 percent of patients newly diagnosed with cancer, 30–50 percent of patients undergoing treatment, and 70–90 percent of patients with advanced disease experience pain. Pain can also continue into long-term survivorship, often persisting for years after cancer treatment concludes.

It is disheartening that while nearly all cancer-related pain can be relieved, its prevalence and its under-treatment have remained consistently high and largely unchanged for more than four decades.<sup>1</sup> The situation is even worse for the 116 million American adults experiencing chronic non-cancer pain, particularly among our Nation's medically underserved and most vulnerable populations.

The Institute of Medicine's comprehensive 2011 report, *Relieving Pain in America*, provides an essential, evidence-based blueprint for addressing this preventable suffering, highlighting consensus expert recommendations to advance pain control research, education, awareness and access. Public awareness about pain is essential to adequately equip patients and families with knowledge they need to demand more from the health care system to both save lives *and* help stop their suffering. Pain, worry and other symptoms and side effects of cancer and its treatment, for example, are not just inevitable consequences of chronic illness. They typically can be controlled. The public needs to expect that health care professionals and the health care system do more to treat the burden of illness and preserve their quality of life.

People in pain are also the most disempowered. They are often too sick to advocate for themselves, and their caregivers are too overwhelmed. Frequently patients' families will ask, "What am I doing wrong?" Oftentimes patients think that they are alone, and that their struggle with chronic pain is unique to their situation, or by fault of their own—but it is not. Our Nation's health care system simply is not set up to deliver pain care efficiently and in a manner that is most beneficial to patients. Patients and families need our help to address this needless suffering so they can understand that pain care is available and know what they need to ask for. Health professionals and health systems in turn need to be ready and able to provide quality pain care for every patient, at every bedside, in every care setting.

The 2011 IOM report also suggests the need for directed pain research, which is essential for building the evidence base that will guide clinical practice and delivery of quality pain care. It also calls for enhanced professional training in pain assessment, management, and prescribing core competencies. Despite only very limited exposure during their professional training, medical, nursing and pharmacy professionals do recognize the importance of pain management to quality health care. However, they also acknowledge that there is room for improvement in delivering quality pain and symptom management, doctor-patient communication, and coordination and continuity of care. Specialized training emphasis for pain assessment and care is also essential among professionals who routinely care for children and young adults living with pain, such as pediatric and young adult cancer populations, as well as health professionals caring for other medically underserved populations, including racial and ethnic groups, where health disparities are prevalent.

ACS CAN has been actively involved in advocating for the development and delivery of the *Relieving Pain in America* report, and is equally committed now to helping ensure implementation of the report's recommendations. We stand ready to work with Congress, the Department of Health and Human Services, the health care community, and the many Federal and State agencies and enforcement officials that will need to be involved in addressing the IOM recommendations so we can together promote better care and improved quality of life for all people living with pain.

RESPONSES TO QUESTIONS OF SENATOR HARKIN AND SENATOR HATCH  
BY LAWRENCE A. TABAK, D.D.S., PH.D.

SENATOR HARKIN

*Question 1.* Thank you for your testimony at our hearing, "Pain in America: Exploring Challenges to Relief". At the hearing you touched on what the agency was doing with respect to implementing the IOM report recommendations. Can you elaborate on this response and provide a clear sense of the specific steps the Department of Health and Human Services is taking to implement the IOM report's recommendations?

*Answer 1.* The IOM report, *Relieving Pain in America: A Blueprint for Transforming Prevention, Care, Education, and Research* included a number of recommendations to the Department of Health and Human Services for improving pain prevention, care, education, and research. It specifically directs five recommendations to the NIH for improving the state of pain research in the United States. These recommendations are described below:

<sup>1</sup>Van den Beuken-van Everdingen MHN, deRijke JM, Kessels AG, et al. Prevalence of pain in patients with cancer: a systematic review of the past 40 years. *Ann Oncol.* 2007;18:1437–49.

In its first recommendation, to be implemented by the end of 2012, the IOM report asks NIH to designate a lead institute at the NIH responsible for moving pain research forward and increase the support for and the scope of the Pain Consortium. In response to this recommendation, the NIH Director has designated the NINDS as the specific IC to lead NIH's pain research efforts. Dr. Story Landis, the NINDS Director who chairs the Pain Consortium Executive Committee will lead enhanced coordination of trans-NIH pain research efforts. In 2011, the NIH Pain Consortium increased its level of trans-NIH collaboration and coordination and supported a number of pain disorder workshops and conferences on chronic fatigue syndrome, vulvodynia, sickle cell pain, temporomandibular joint disorders, and overlapping chronic pain condition. The Consortium also established new trans-NIH working groups on chronic lower back pain and overlapping chronic pain conditions.

NINDS will also establish a dedicated office to support the activities of the NIH Pain Consortium and the newly created Interagency Pain Research Coordinating Committee (IPRCC). The IPRCC has been tasked with developing a summary of federally funded pain research advances and identifying critical gaps in basic and clinical pain research. The IPRCC will also make recommendations on how to avoid duplication of research effort, best disseminate information on pain care, and build public-private partnerships to expand pain research. During the Committee's inaugural meeting on March 27, 2012, Dr. Sean Mackey, who served on the IOM report panel and is now a member of the IPRCC, will brief the IPRCC on the IOM report.

The IOM report also recommends that the NIH work with other agencies and research groups to improve the process for developing new agents for pain control, increase support for interdisciplinary research in pain, increase the conduct of longitudinal research in pain, and increase the training of pain researchers by end of 2015. NIH is currently moving forward with a number of activities in response to these near-term recommendations as detailed below.

*(i) Improve the Process for Developing New Agents for Pain Control*

The NIH and FDA are involved in a high level NIH-FDA leadership council that is exploring better coordination of NIH and FDA efforts to improve regulatory science and overcome hurdles in the drug development pipeline. Members of the NIH Pain Consortium currently participate in an advisory committee for the Analgesic Clinical Trial Translations, Innovations, Opportunities, and Networks (ACTTION) initiative, a public-private partnership program sponsored by FDA to streamline the discovery and development of analgesics. In May 2012, NIH and the FDA plan to hold a state of the science workshop on assessing opioid efficacy and analgesic treatment in conjunction with the 7th Annual NIH Pain Consortium Symposium focusing on advancing pain therapies. NIH is also conducting research to develop medications for chronic pain that could circumvent the problematic side effects (e.g. tolerance and dependence) of many current medications.

*(ii) Increase Support for Interdisciplinary Research in Pain*

As a member of the IPRCC, NIH is currently conducting a portfolio analysis of federally funded pain research to determine current investments in basic, translational, and clinical pain research and the IPRCC will continue this effort with the input of designated individuals from the relevant Federal agencies. These efforts will inform strategies for increasing support for interdisciplinary research in pain.

*(iii) Increase the Conduct of Longitudinal Research in Pain*

NIH currently funds several large-scale longitudinal studies on pain. For example, the Orofacial Pain: Prospective Evaluation and Risk Assessment (OPPERA) is a \$19 million study tracking 3,200 initially healthy male and female volunteers, ages 18–44, to identify risk factors associated with the development of temporomandibular joint and muscle disorders (TMJDs). Preliminary results have found important mutations linked to these disorders. The Spine Patient Outcomes Research Trial (SPORT) is studying the effectiveness of different treatments for low-back pain. The Patient-Reported Outcomes Measurement Information System (PROMIS) is creating psychometrically robust patient-reported banks of questions to measure pain in clinical trials for various chronic diseases, while the Multidisciplinary Approach to Chronic Pelvic Pain (MAPP) Research Network is focusing on how and why people develop urologic chronic pelvic pain disorders, and how their disease changes over time. It also examines genetic, behavioral/lifestyle, environmental, and other factors as contributors to disease. As part of the IPRCC, NIH is also assessing current research to help inform the gaps and opportunities for increasing support for longitudinal studies in pain.

*(iv) Increase the Training of Pain Researchers*

In addition to current training programs, NIH recently launched new initiatives to increase the number of training opportunities for pain researchers. For example, the National Institute of Nursing Research currently holds an intramural Methodologies Boot Camp on the NIH campus to develop improved research capacity in the science of pain. The National Institute of Dental and Craniofacial Research will support new Institutional Career Development Awards for Enhancing Research Capacity in TMJD and Orofacial Pain (K12) to develop independent clinical scientists. In a new trans-NIH effort, led by the National Institute on Drug Abuse, NIH plans to support new Centers of Excellence in Pain Education (CoEPs) at dental, medical, nursing, and other professional schools to develop and disseminate pain management curriculum resources for health care professionals and to provide leadership for change in pain management education. Finally, as a member of the IPRCC, NIH is compiling information on Federal training programs which will inform the consideration and development of additional training programs.

SENATOR HATCH

*Question 1.* Should research funding for chronic pain illness be based on an illness's patient population?

Answer 1. When setting priorities for specific conditions or disease areas, NIH takes into account a number of factors, including disease burden. The specific amount of NIH funding for a particular disease, however, is largely determined by the state of the science and the extent of highly meritorious research proposed by the scientific community. For example, if basic research or related disease-specific research suggests promising hypotheses to test, proposals to test these hypotheses may be submitted to NIH and may be funded if found to be scientifically meritorious. If there are too many gaps in knowledge, however, the most productive next step may be to encourage more basic research until new hypotheses are developed. NIH continually evaluates what is known, what is not known, and what we need to know to solve the problem before us—identifying knowledge gaps and developing the roadmap to solutions.

NIH supports research in many chronic pain illnesses including neuropathic pain, cancer pain, musculoskeletal pain, chronic fatigue syndrome, migraine, endometriosis, fibromyalgia, interstitial cystitis, temporomandibular disorders (TMJD) and vulvodynia among others. Chronic pain can also become a disease in and of itself and can manifest as a persistent pain state that outlasts an acute injury or illness, or arises in the absence of an identified causative mechanism. NIH research on understanding and treating pain in general, such as investigating factors involved in the transition from acute to chronic pain, complements research on specific conditions, and together these contribute to a significant research portfolio aimed at alleviating the suffering of a large population of patients.

*Question 2.* The term “central pain” was originally used to describe a condition that occurred in individuals who, following a stroke or spinal cord lesion, subsequently developed pain. In this case “central” referred to the fact that the lesion leading to pain occurred within the CNS—either spinal cord or brain. More recently, however, the term has expanded to describe any CNS dysfunction or pathology that may be contributing to the development or maintenance of chronic pain. Another term that has often been used to describe this same phenomenon is “central sensitization.” What might be the best way to research central sensitization?

Answer 2. Central pain or central pain syndrome is caused by injury or a disease process that causes dysfunction of a part of the central nervous system (CNS). It can be caused by stroke, tumors, trauma, seizures, or pathology associated with diseases of the CNS, such as multiple sclerosis or Parkinson's disease. The extent and characteristics of central pain are variable, but are related to the affected neural structures. Central sensitization differs somewhat from central pain; it is an amplified response of the CNS to painful or non-painful sensory input. This hypersensitivity of the CNS contributes to inducing and maintaining a persistent pain state in many chronic pain conditions. NIH funds research on understanding the underlying mechanisms of central sensitization and identifying the multiple and varied contributions of dysfunctional changes in the CNS that lead to and maintain persistent pain. For example, work supported by NIH is exploring the role of increased activity of neurotransmitters (chemicals involved in transmitting signals from one nerve cell to another) in enhancing neuronal activity in response to pain. NIH-funded research has also demonstrated the role of increased activity in certain brain structures in contributing to amplified pain signals or in causing or maintaining persistent pain. For instance, repeated activation of certain brainstem neurons

causes an increase in their activity associated with a transition from episodic to chronic daily headaches.

Approaches to studying central sensitization must include research on the altered neuronal activity or “plasticity” at multiple levels of the CNS. While there has been extensive research on altered signaling pathways and neuronal responses throughout the central nervous system, a strategy is needed to integrate information on how these changes interact in persistent pain states. Brain regions previously not considered to be involved in pain are emerging as candidate regions with improved imaging techniques. These brain areas need to be further explored for their neurobiological contributions to pain, as well as their functional outcomes in maintenance and recovery from pain. Emerging imaging techniques, including resting state fMRI offer a powerful tool for understanding how pain alters normal patterns of neuronal connectivity in the brain and can be exploited to determine whether changes are unique to different pain conditions, can be used to predict analgesic response, or can serve as a marker for transition to chronic pain and recovery. Such a multifaceted approach will add to the many potential therapeutic targets already being explored and facilitate development of drugs designed to block or reverse central sensitization.

*Question 3.* Since many chronic pain illnesses co-exist, should a certain percentage of research funding focus on the central nervous system as a common tying element before studying individual illnesses?

Answer 3. The NIH recognizes the important role of structural and functional changes in the central nervous system (CNS) as an underlying factor in persistent pain states, and a significant portion of the NIH pain research portfolio is focused on these areas. Since the description of central sensitization (an amplified response of the CNS to painful or non-painful sensory input) in 1983, understanding its role in persistent pain and its potential for novel drug development has been an important focus of basic and translational research (also see response to question 2). Various approaches and novel research techniques have contributed to a number of studies ranging from deciphering cellular and molecular changes in the nervous system to understanding altered functional neural circuits associated with chronic pain, as well as clinical studies on human pain conditions. NIH also recognizes that the basis for co-existence of multiple pain conditions in an individual is very likely linked to maladaptive changes in the central nervous system and is investing considerable effort and resources to this issue.

NIH funding levels are driven largely by scientific opportunity and by the amount of meritorious research proposed by investigators in the particular field. Disease-specific funding totals often do not reflect the likely benefits of basic research or research on other conditions that may inform that disease. New scientific opportunities often flow from NIH-sponsored research on broad scientific themes (such as genome projects, development of instrumentation, training in clinical research, or developments in basic science). Historically, support of these themes has often yielded insights and capacity to stimulate research to address specific diseases.

NIH supports a multi-faceted approach to studying pain, including understanding the underlying mechanisms such as the role of the CNS, deciphering the molecular and cellular basis of a number of chronic pain conditions, and developing therapies to treat chronic pain, to yield the most valuable insights and discoveries.

*Question 4.* Motor vehicle accidents have been identified as a major adverse event precipitating chronic pain illnesses. Which Institute at NIH is best designed to oversee longitudinal research to know the long-term adverse health effects of motor vehicle accidents?

Answer 4. Motor vehicle accidents are traumatic events that can cause multi-system injuries leading to a range of acute and chronic health problems, including musculoskeletal pain, neuropathic pain, psychological trauma, and emotional effects.

NIH supports extensive research and training on effects and treatments for different types of injuries caused by motor vehicle accidents and other traumatic events. NIH Institutes support academic research centers and training programs in trauma, burn, and wound healing; research on biological mechanisms and treatments for chronic neuropathic pain resulting from traumatic brain and spinal injury; and research on biomarkers, diagnostics, and clinical trials of interventions for traumatic brain injuries in general. Multiple NIH-funded studies are investigating the underlying processes and non-pharmacological treatments for chronic neck and back pain as well as research on post-traumatic stress disorder (PTSD) and emotional pain which may result from particularly serious vehicular accidents. NIH also supports a \$30 million, 5-year Medical Rehabilitation Research Infrastructure Network ([www.ncmrr.org](http://www.ncmrr.org)) to enhance the capability of researchers investigating func-

tional recovery and developing therapies to improve the lives of people with disabilities.

Given the breadth of injuries and chronic pain illnesses resulting from motor vehicular accidents, trans-NIH efforts—rather than those of one particular NIH Institute or Center—are best suited to address these research issues. For example, one of the Grand Challenges of the NIH Blueprint for Neuroscience Research (a cooperative trans-NIH effort among the 15 NIH institutes, centers, and offices that support neuroscience research) is focused on the Transition from Acute to Chronic Neuropathic Pain, and addresses the maladaptive neural changes that occur during the development of chronic pain. In addition, the NIH Pain Consortium with membership from 25 NIH Institutes, Centers, and Offices actively promotes collaboration on cross-cutting areas of pain research.

While NIH does not currently support longitudinal studies specifically targeting chronic pain resulting from motor vehicle accidents, it does support significant longitudinal research on various chronic pain disorders and traumatic head and spine injury. For example, the Spine Patient Outcomes Research Trial (SPORT) is studying the effectiveness of different treatments for lower back pain. Another longitudinal project is utilizing brain imaging to study functional recovery after traumatic brain injury.

*Question 5.* It has been suggested that studies are needed to closely follow the longitudinal development of fibromyalgia (FM) by following individuals from when they first develop acute symptoms, to when they develop co-morbid FM. Are there any current longitudinal studies for chronic pain?

*Answer 5.* NIH currently supports longitudinal studies on a number of chronic pain conditions including fibromyalgia (FM). The Self-Monitoring and Review Tool (SMART) Log Program offers a web-based self-management tool that enables FM sufferers to identify significant linkages between their personal symptom levels and their personal self-management efforts over time in order to plan their own optimal approach to disease management. Another longitudinal study will document for the first time the physical, psychosocial, and emotional outcomes of fibromyalgia in young adults over a prolonged (5 year) timeframe. A comprehensive set of measures, including pain, will be used to determine the outcome trajectories of the cohort compared to healthy controls. In the Multidisciplinary Approach to the Study of Chronic Pelvic Pain (MAPP) study, an “inception cohort” of people with new onset of interstitial cystitis/chronic prostatitis is being followed longitudinally to see who centralizes their pain and subsequently develops FM. NIH-supported research is also examining risk factors for developing several overlapping chronic pain conditions, including fibromyalgia.

In addition to fibromyalgia, NIH supports longitudinal studies on chronic pain disorders including lower back pain, pelvic pain, and temporomandibular joint disorders (TMJD). For instance, the Spine Patient Outcomes Research Trial (SPORT) is the first comprehensive study to look at the effectiveness of different treatments for lower back pain. SPORT also has shown that surgery is superior to non-operative treatments for the most common causes of severe lower back pain. Another longitudinal study has identified predictive markers of patients at risk of transitioning to chronic lower back pain by tracking brain changes. The Patient-Reported Outcomes Measurement Information System (PROMIS®) [www.nihpromis.org](http://www.nihpromis.org) is creating psychometrically robust patient-reported banks of questions to measure pain in clinical trials for various chronic diseases.

Studies on chronic pelvic pain syndromes include a comprehensive project with case-control and longitudinal studies to evaluate the role of infectious agents as causative factors and investigate biological and behavioral risk factors for developing chronic pelvic pain. A longitudinal population-based study will assess genetic and hormonal factors to determine prevalence, incidence, persistence, and remission of vulvodynia among a population of healthy women and those with new or repeat onset of the disorder.

The Orofacial Pain: Prospective Evaluation and Risk Assessment (OPPERA) is a longitudinal study of 3,200 initially disease-free subjects who are being followed for at least 5 years to see how many develop first-onset TMJD. The study is examining biological, psychological, and behavioral risk factors that may predispose individuals to develop TMJD and preliminary results suggest that TMJD may be associated with genetic variability and changes in how the nervous system perceives pain.

*Question 6.* The IOM report points out that developing more effective pain relievers and adapting the regulatory process to enable more efficient evaluation of potentially effective therapies remains a challenge. My understanding is that there are



promising therapies currently under review at the FDA. What is the status of new treatments for pain under review at the FDA?

Answer 6. The Food and Drug Administration (FDA or the Agency) continues to review the science and data related to pain products with public workshops and advisory committees. In late May, FDA will hold a public workshop to discuss the available data on the efficacy of analgesics in the treatment of chronic non-cancer pain (CNCp). In addition, we are planning to hold a public FDA Advisory Committee to provide a forum to discuss the data on the use of hydrocodone combination medications in the treatment of chronic pain, as well as the data on misuse and abuse of these products and the potential impact of their rescheduling. As for the status of particular drug products, confidentiality laws prohibit FDA from disclosing information about the pre-approval process, unless the manufacturer has already made that information public.

*Question 7.* The IOM Report discusses early childhood trauma as a strong indicator of development of chronic pain in adults in later life. How might this be researched to find psychological interventions as a preventative measure to developing chronic pain and curative measure to treat pain?

Answer 7. While the association between early childhood trauma and chronic pain conditions has not been studied extensively, there are a number of studies being supported by NIH institutes and Centers focused on understanding the links between trauma and the development of chronic pain that may aid in the development of ways to treat and prevent pain, including psychological interventions.

NIH-funded research compared prospective data from the Longitudinal Studies of Child Abuse and Neglect (5 prospective studies of child maltreatment) with retrospective information from adults with gastrointestinal symptoms and found that psychological, physical, or sexual abuse was significantly associated with abdominal pain and other symptoms. This approach of combining information from existing data bases with retrospective data will be useful in defining the association of early trauma with other chronic pain disorders and determining effective psychological and other intervention strategies. Ongoing studies funded by the National Institute of Diabetes and Digestive and Kidney Diseases (NIDDK) will collect retrospective data, genotype data, and early trauma information on adults with interstitial cystitis (bladder) pain and irritable bowel syndrome to determine their influence as risk factors in developing adult pain and other disease symptoms. The findings will help to determine how risk factors relate to treatment response and ultimately help to tailor therapies.

The National Institute of Mental Health (NIMH) supports research to understand the links between trauma exposure and the development of mental disorders such as depression, anxiety, and post-traumatic stress disorder (PTSD), as well as the development of co-occurring conditions, such as chronic pain. For example, NIMH is currently supporting research on post-trauma changes in the hypothalamic-pituitary-adrenal (HPA) axis—a brain-body circuit that plays a critical role in the body's response to stress. Emerging evidence suggests that prolonged malfunction of the HPA axis in response to stress can cause potentially *harmful* inflammation, which is associated with symptoms of chronic pain and other complications. Furthermore, each of these conditions has been reported as occurring more often in individuals with PTSD. Understanding the links between anxiety, inflammation, and chronic pain holds the potential for identifying new and more effective treatments and preventive interventions for children and adults following trauma exposure.

NIMH also supports research on understanding and treating the co-occurrence of depression and pain. For example, NIMH-funded researchers are studying the brain circuits of individuals with major depressive disorder to determine how the emotional processing of pain may bias the perception and modulation of the pain response. NIMH is supporting another project to develop a psychotherapeutic intervention tailored specifically for primary care patients with major depressive disorder and co-occurring chronic lower back pain. The study will establish the feasibility and acceptability of a research design for an eventual randomized clinical trial.

The *Eunice Kennedy Shriver* National Institute of Child Health and Human Development (NICHD) supports research on the effects of pain and stress very early in life. A research group funded in part by the NICHD recently released results from several studies that examined longer-term effects of pain and stress in infants born very premature (defined as babies born 32 weeks of gestation or less). One study showed that positive child-mother interactions helped lower stress in the extremely preterm children, whose initial stress hormone levels were much higher than other children's levels. Another study showed that children born very preterm developed cognitive problems including deficits in memory and problem-solving skills. Understanding how early stressors affect these infants' brain development

may help to find ways to make preterm infants' first weeks of life easier and to promote healthy development. Information from these studies is available online at <http://nichd.nih.gov/news/resources/spotlight/012612-effects-preterm-birth.cfm>.

[Whereupon, at 4:22 p.m., the hearing was adjourned.]

