Testimony
Before the Committee on Health, Education, Labor, and Pensions
United States Senate

Statement of

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Wednesday, February 14, 2012

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 13th, 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" [1] 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[2] 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

[1] http://iom.edu/Reports/2011/Relieving-Pain-in-America-A-Blueprint-for-Transforming-Prevention-Care-Education-Research.aspx
[2] http://painconsortium.nih.gov/

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 approaches 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 towards developing a framework to execute this strategy. Coordination and efficient use of resources are more always 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 towards 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 FY 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 website[3]. 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 U.S. 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

[3] http://projectreporter.nih.gov/reporter.cfm

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[4], which includes researchers with clinical, epidemiological, and basic research expertise, all working collaboratively. The Network embraces a systemic—or whole-body—approach in the study of interstitial cystitis/painful bladder syndrome (IC/PBS) and chronic prostatitis/chronic pelvic pain syndrome (CP/CPPS).

[4] http://www.mappnetwork.org/

On a trans-NIH scale, the NIH Blueprint for Neuroscience Research[5] 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).[6] 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

[5] http://neuroscienceblueprint.nih.gov/
[6] http://www.altarum.org/project-highlights-pain-education

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.[7] 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.[8] 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.[9] 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.[10] 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

[7] Supplement to J. Pain, 2001 Nov: 12 (11); T1-T108; http://www.jpain.org/issues?issue_key=S1526-5900%2811%29X0013-5
[8] Fink DL et al. Ann Neurol. 2011 Aug;70(2):207-12.
[9] Tegeder I et al. Nat Med. 2006 Nov;12(11):1269-77.
[10] deCharms RC et al. Proc Natl Acad Sci U S A. 2005 Dec 20;102(51):18626-31.

chronic pain conditions.[11] 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.[12] In addition, well controlled, methodologically sound, NIH-funded studies have examined the effectiveness of alternative therapies, such as tai chi for fibromyalgia[13] or massage therapy for lower back pain[14], 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.

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[11] Noseda R et al. Nat Neurosci. 2010 Feb;13(2):239-45.
[12] Xu ZZ et al. Nat Med. 2010 May;16(5):592-7.
[13] Wang C et al. N Engl J Med. 2010 Aug 19;363(8):743-54.

[14] Cherkin DC et al. Ann Intern Med. 2011 Jul 5;155(1):1-9.