

**Minutes**  
**Interagency Pain Research Coordinating Committee Meeting**  
**March 27, 2012**

The inaugural meeting of the Interagency Pain Research Coordinating Committee (IPRCC) was convened on March 27, 2012, at 8:30 a.m. in Wilson Hall, Building 1, National Institutes of Health, 1 Center Drive, Bethesda, Maryland. In accordance with Public Law 92-463, the meeting was open to the public. Dr. Story Landis presided as Chair. The meeting was adjourned at 4:40 p.m.

**Committee members present:**

Dr. Story Landis, IPRCC Interim Chair and Director, National Institute of Neurological Disorders and Stroke (NINDS); Terrie Cowley, The TMJ Association; Dr. Ronald Dubner, University of Maryland Dental School; Elizabeth Gilbertson, Unite Here Health; Dr. Carmen Green, University of Michigan Medical Center; Dr. Charles Helmick, Centers for Disease Control and Prevention; Dr. Audrey Kusiak, Department of Veterans Affairs; Tamara Liller, National Fibromyalgia Partnership, Inc.; Dr. Sean Mackey, Stanford University; Dr. Christine Miaskowski, University of California, San Francisco; Dr. Bob Rappaport, Food and Drug Administration; Dr. Richard Ricciardi, Agency for Healthcare Research and Quality; Dr. Wally Smith, Virginia Commonwealth University; Dr. Martha Somerman, National Institute of Dental and Craniofacial Research; Major General Richard Thomas, Western Region Medical Command; Tina Tockarszewsky, The Neuropathy Association; Mary Vargas, Stein & Vargas, LLP; and Christin Veasley, National Vulvodynia Association. Ex officio members present: Dr. Patricia Grady, National Institute of Nursing Research (NINR); Dr. Josephine Briggs, National Center for Complementary and Alternative Medicine (NCCAM), and Dr. David Shurtleff (attending for Dr. Nora Volkow), National Institute on Drug Abuse (NIDA).

**Committee member absent:**

Dr. Michael Moskowitz, Harvard Medical School

**Other Federal staff present:**

Dr. Paul Scott, NINDS; Dr. Riju Srimal, NINDS; Ruth Linn, NINDS; Kelly Baker, NINDS; Dr. Linda Porter, NINDS; Marian Emr, NINDS; Shannon Garnett, NINDS; Dr. Isabel Garcia, NIDCR; Dr. Amy Adams, NIDCR, Dr. John Kusiak, NIDCR; Dr. Michael Iadarola, NIDCR; Dr. Lisa Begg, OD; Dr. Barbara Mittleman, OD; Dr. David Thomas, NIDA; Dr. Chris Ramsden, NIAAA; Dr. Houman Aranj, NEI; Dr. Wen Chen, NIA; Dr. Sandrine Pirard, SAMHSA; Colonel Chester Buckenmaier, US Army

## **Members of the public present:**

Kathy Sheehy, Children's National Medical Center; Paul Kuehl, Medtronic; Juan Mendoza, NFP, Inc.; Cameron Seward, Purdue Pharma.

## **Call to Order and Opening Remarks**

Dr. Landis called the meeting to order and welcomed all in attendance to the first meeting of the newly established IPRCC. She proceeded to highlight the Affordable Care Act pain provisions that directly led to the formation of the committee and provided an overview of the meeting agenda. She thanked all the members for their participation and expressed her hope that the committee would work collaboratively to identify the most pressing needs and opportunities in pain research.

## **Introduction of Federal IPRCC Members and Brief Summary of Related Activities**

The federal members of the committee briefly introduced themselves and their pain portfolio activities. Dr. Richard Ricciardi, Health Scientist at the Agency for Healthcare Research and Quality (AHRQ), stated that the mission of the agency revolves around health care quality, safety, and efficiency and supports a large portfolio of comparative effectiveness research involving multiple interventional and observational studies.

Dr. Charles Helmick, a Senior Medical Epidemiologist working with the arthritis program at the Center for Disease Control and Prevention (CDC), mentioned that although the agency is best known for its work with infectious diseases work, its main areas of focus include chronic disease and environmental health.

Major General Richard Thomas, Commanding General at the Western Regional Medical Command, led a Department of Defense (DoD) task force in collaboration with the Department of Veterans Affairs (VA) to study pain management in the military population. The task force produced a report in 2010 and established a defense veterans' center for integrative pain management.

Dr. Audrey Kusiak, Portfolio Manager in the Office of Research Development at VA, highlighted the department's mission to provide health care for veterans and stated that the department is primarily interested in pain resulting from deployment-related trauma and injuries leading to a broad portfolio of basic, translational, and clinical research.

Dr. Bob Rappaport, Director of the Division of Anesthesia and Analgesia Products in the Center for Drug Evaluation and Research at the Food and Drug Administration (FDA) explained how the FDA is both a regulatory and public health agency and is currently interested in developing better analgesic products.

Dr. Martha Somerman, Director of the National Institute of Dental and Craniofacial Research at the National Institutes of Health (NIH), highlighted many of the scientific areas of focus and pain

research activities at the NIH, including the NIH Pain Consortium – the main coordinating body for pain research at NIH with representation from over 20 NIH institutes, centers, and offices.

After introductions, there was a discussion about inviting representatives from other federal agencies including the Substance Abuse and Mental Health Services Administration (SAMHSA) and the Health Resources and Services Administration (HRSA) to present at future IPRCC meetings or to serve as ex-officio members of the committee.

### **Introduction of Public and Scientific IPRCC Members and Brief Summary of Pain Highlights, Opportunities**

Ms. Terrie Cowley, President and Co-founder of the TMJ Association, shared her personal experience as a pain sufferer and highlighted activities organized by the TMJ Association including joint scientific conferences with NIH. The TMJ Association is also a part of the Chronic Pain Research Alliance - an umbrella pain organization focusing on overlapping chronic pain conditions affecting women. She concluded her introduction by stating, “we want the best damn science this country can give us” - a quote used by the Institute of Medicine (IOM) pain committee in their 2011 report, *“Relieving Pain in America: A Blueprint for Transforming Prevention, Care, Education, and Research”*.

Dr. Ron Dubner, Professor at the Department of Neural and Pain Sciences at the University of Maryland Dental School, currently focuses on central nervous system mechanisms of persistent pain and the transition from acute to chronic pain and is a principal investigator with the NIH-supported Orofacial Pain: Prospective Evaluation and Risk Assessment (OPPERA) study on TMJ disorders. Previously, he was chair of the Department of Biomedical Sciences at University of Maryland and directed an intramural branch at NIH investigating pain mechanisms and control.

Ms. Elizabeth Gilbertson is Chief of Strategy for Unite Here Health - a union-sponsored non-profit health benefits fund providing health benefits to immigrant, low-income workers mostly in the hospitality industry. Ms. Gilbertson mentioned her background in nursing and public health advocacy and talked about her interest in improving pain care accessibility among low-income service workers.

Dr. Carmen Green is a tenured Professor at the University of Michigan in the Department of Anesthesiology, Obstetrics, and Gynecology as well as at the Health Management and Policy School of Public Health. She is a practicing pain medicine physician and anesthesiologist at the University of Michigan Health System and is affiliated with the American Cancer Society and the National Center for Medical Rehabilitation Research. Her research focuses on women’s health, minority health, aging, and the unequal burden of pain.

Ms. Tamara Liller is the President and Co-founder of the National Fibromyalgia Partnership, which includes members from the patient and medical professional communities. The Partnership disseminates information on fibromyalgia, maintains contact with fibromyalgia organizations around the world, and is particularly interested in the practical results of pain dependency issues in addition to the causes and treatment of fibromyalgia and pain.

Dr. Sean Mackey is Chief of the Pain Medicine Division and Associate Professor of Anesthesiology, Neurosciences and Neurology at Stanford University School of Medicine. He oversees a large multidisciplinary pain center and pain fellowship program and is director of a NIH funded systems neuroscience pain lab to predict, prevent, and alleviate pain. His areas of focus include the human pain condition, central neural mechanisms, individual differences in pain, plasticity in pain, opioid use, causes of pain persistence, and development of agents to reduce pain. Dr. Mackey is also Vice-President of the American Academy of Pain Medicine and was a member of the IOM pain committee.

Dr. Christine Miaskowski is a Professor and Associate Dean for Academic Affairs at the University of California, San Francisco and the first nurse to receive the American Cancer Society Clinical Professor Award. Dr. Miaskowski shared personal experiences that led her to earn an advanced degree in neurophysiology and listed a number of her ongoing cancer pain studies in the areas of pain management and education, inter-individual variability in pain symptom experience, and pain symptom clusters.

Dr. Wally Smith is a Professor at the Virginia Commonwealth University Medical School in Richmond and a general internist by training. His main area of focus is sickle cell pain and he is involved with a sickle cell disease clinical network, a cooperative study on hydroxyurea, as well as the Pain in Sickle Cell Epidemiology Study (PISCES), which is largest cohort study of daily pain and sickle cell disease with 30, 000 patients. He also mentioned his interest in pain information dissemination strategies and expanding pain treatment to patients currently lacking access.

Ms. Tina Tockarszewsky serves as President and CEO of the Neuropathy Association, which represents a broad range of neuropathies and neuropathic pain conditions. The Association funds research on underlying mechanisms and treatments for neuropathy and Ms. Tockarszewsky highlighted their educational and awareness work in changing public perceptions of neuropathy and neuropathic pain from being a disease of aging to one that strikes people in their prime. The Association hosted the first-ever national Neuropathy Summit in 2010, and works with fifteen Association-designated neuropathy centers of excellence at major medical centers across the U.S.--many with VA appointments--to provide resources knowledgeable about all forms of neuropathy who are also conducting active neuropathy research.

Ms. Mary Vargas introduced herself as a lawyer with a background in disability discrimination, primarily involving deafness and hearing disabilities. Her personal experience with pain led to an interest in pain care access and discrimination issues. She currently serves as the Chair of the Board of Directors at the American Pain Foundation, which includes doctors, researchers, pharmacists, nurses, caregivers, and patients among its members. Describing an incident where the Foundation received three referrals within one week about pain patients seeking assisted suicide, she emphasized the research and healthcare communities' responsibility in helping people suffering from pain.

Ms. Christin Veasley, Executive Director at the National Vulvodynia Association, shared her personal history with pain resulting from a car accident and subsequent experience with vulvodynia. The National Vulvodynia Association promotes pain research by funding a pilot grant program to enable investigators to apply successfully for grants from NIH and other

organizations as well as supporting career development awards. NVA has worked with CPRA since 2008 to focus on overlapping chronic pain conditions affecting women and Ms. Veasley emphasized the importance of pain research in addressing needs of pain patients.

Dr. Landis introduced the IPRCC ex-officio members and NIH staff members assisting the committee.

### **Welcoming Remarks and Charge to Committee**

*Dr. Francis Collins, MD, PhD, Director, National Institutes of Health*

Dr. Francis Collins joined the meeting to welcome the committee members and present them with the committee charge. In his opening remarks, Dr. Collins cited historical examples of pain management and highlighted the continuing burden of acute and chronic pain today. He referred to the high economic burden of pain as determined by the Institute of Medicine (IOM) Pain Report and supported the report's call for a coordinated research effort to alleviate pain. He reported that in fiscal year 2011 NIH invested \$386 million in direct support of chronic pain research and cited examples of greater coordination in pain research at NIH, including the NIH Pain Consortium, the NIH Blueprint for Neuroscience Research Grand Challenge in Pain, and the newly launched NIH Centers of Excellence in Pain Education initiative. Dr. Collins next presented the committee charge to the members and urged them to work collaboratively towards achieving the specific goals outlined in the charge, namely to (a) develop a summary of advances in federally-supported pain care research; (b) identify critical gaps in basic and clinical pain research (c) make recommendations to ensure that the federal pain activities are free of unnecessary duplication of effort; (d) make recommendations on how best to disseminate information on pain care; and (e) make recommendations on how to expand public-private partnerships to support pain research. Finally, Dr. Collins underscored the current challenging fiscal circumstances at NIH with the agency's purchasing power to support research dropping by 20% since 2003 and stressed the need for better coordination as well as cost-effective partnerships and synergies across public and private sectors to support future endeavors in pain research..

### **Institute of Medicine Report “Relieving Pain in America: A Blueprint for Transforming Prevention, Care, Education, and Research”**

*Dr. Sean Mackey, MD, PhD, Chief, Division of Pain Management, Department of Anesthesiology, Stanford University*

Dr. Mackey opened his presentation by providing background information and context for the 2011 IOM report entitled “*Relieving Pain in America: A Blueprint for Transforming Prevention, Care, Education, and Research*”. As mandated by the Affordable Care Act, the Department of Health and Human Services contracted with IOM to assess the state of the science regarding pain research, care, and education and to make recommendations to advance the field. The IOM committee consisted of 19 members with Dr. Phil Pizzo (Dean, Stanford University School of Medicine) acting as chair and Dr. Noreen Clark (Director, Center for Managing Chronic Diseases, University of Michigan) as vice-chair. The committee conducted a literature review, commissioned a paper on the economic burden of pain, and gathered input from public workshops, public testimonies, and online solicitations.

Dr. Mackey highlighted four key areas in the report - public health challenges, care, education of providers, and research - and corresponding recommendations for removing barriers in each area. He reported that pain is a public health problem with an estimated 100 million people suffering from pain, not including children or people in the military, long-term pain care facilities, or prisons with an estimated financial cost of \$560 – 630 billion every year. There is a need to improve quality of data collection and reporting and the report calls upon the Secretary of HHS to create a comprehensive, population-level strategy for pain prevention, treatment, management, and research. Dr. Mackey emphasized that pain care should be tailored to individual experiences and existing barriers to adequate pain care including gaps in knowledge and competencies for providers need to be addressed. He also stressed that education is an integral component for transforming the approach to pain and education efforts should be directed towards patients, the general public, and health professionals. Finally, Dr. Mackey focused on the continuing need for research to translate scientific discoveries into effective therapies and outlined a number of report recommendations for advancing pain research including improved development of new pain control agents not limited to recycled medications, increased support for longitudinal research, and increased focus on interdisciplinary research and training. Dr. Mackey closed his presentation by laying out a blueprint with near-term and long-term goals for transforming pain prevention, care, education, and research.

Dr. Miaskowski and Ms. Gilbertson opened the discussion with questions about the econometric analysis commissioned by the IOM pain committee. Dr. Miaskowski enquired about the breakdown of dollars spent on actual pain treatment versus lost wages while Ms. Gilbertson asked whether the report accounted for the economic impact of chronic illnesses co-existing with pain or for which pain was a secondary consequence. Dr. Mackey responded that the expense breakdown between treatment and lost wages was about equal and that the analysis had attempted to factor in costs due to co-existing illnesses. Ms. Liller raised the issue of low-cost or low-tech solutions to pain care and management. This was followed by an extensive discussion of issues related to pain education and training. Members discussed the possibility of novel approaches to transforming the clinical training culture, problems with training within the current paradigm of delivering care, lessons learnt from current or past education initiatives, and the committee's role in improving pain education. NIH staff members outlined the new Centers of Excellence in Pain Education initiative and highlighted current NIH training opportunities such as mentored career awards.

In response to a question from Ms. Cowley on the standardization of pain treatment, Dr. Mackey stated that while the IOM report does not address treatment guidelines, there are currently a number of evidence-based national guidelines available. Ms. Veasley asked whether there was an estimate or cost-analysis showing how much money would be saved by implementing the IOM report recommendations. In response, Dr. Mackey cited an estimate of \$64 billion in pain-related costs for California alone.

### **Brief Update on the NIH Response to the IOM Report**

*Dr. Story Landis, PhD, Director, National Institute of Neurological Disorder and Stroke, National Institutes of Health*

Dr. Landis provided a brief update on recent NIH activities that addressed many of the IOM report recommendations directed at the agency. The NIH Director designated the National Institute of Neurological Disorder and Stroke (NINDS) as the lead institute for pain at NIH. The NINDS Director will chair the Pain Consortium Executive Committee and NINDS will establish a dedicated office to support all activities of the NIH Pain Consortium and IPRCC. Dr. Landis highlighted activities supported or organized by the NIH Pain Consortium including a number of pain disorder conferences and two new trans-NIH working groups on chronic pain conditions. She emphasized NIH activities in partnership with FDA including the NIH-FDA Leadership Council, the FDA Analgesic Clinical Trial Translations, Innovations, Opportunities, and Networks (ACTTION) initiative, and a joint NIH-FDA state of the science workshop on assessing and advancing pain in May 2012. Additionally, NIH is funding a number of interdisciplinary studies and longitudinal research in pain and the IPRCC's portfolio analyses will inform new opportunities in these areas. Finally, Dr. Landis highlighted NIH efforts in pain education including the newly launched Centers of Excellence in Pain Education (CoEPEs) initiative, new institutional career awards in pain research, and ongoing training workshops in pain research capacity.

In response to a question by Dr. Green about the focus on diversity and gender-based differences in the pain experience, Dr. Landis and other NIH staff mentioned a number of ongoing and planned initiatives including the 2012 Summit on the Science of Eliminating Health Disparities, NIH projects on racial differences in palliative care and diversifying training in centers, as well as pain education at minority institutions under the new Centers of Excellence in Pain Education initiative. In addition, Dr. Dubner promoted a focus on wounded soldiers, while Dr. Miaskowski raised the question of how to address grant review recommendations. Dr. Landis suggested inviting Dr. Richard Nakamura, Acting Director of the Center for Scientific Review, to speak at a subsequent IPRCC meeting.

#### **FDA Analgesic Clinical Trial Translations, Innovations, Opportunities, and Networks (ACTTION) public-private partnership**

*Dr. Bob Rappaport, MD, Director, Division of Anesthesia and Analgesia Products, Center for Drug Evaluation and Research, FDA*

To inform the committee of possible public-private partnership models, Dr. Rappaport presented an overview of an existing public-private partnership - the FDA Analgesic Clinical Trial Translations, Innovations, Opportunities, and Networks (ACTTION) initiative. The ACTTION initiative builds on the Initiative on Methods, Measurement, and Pain Assessment in Clinical Trials (IMMPACT) to develop novel analgesic drugs by exploring flaws in current analgesic clinical trial design, testing novel designs, and standardizing data presentation for analyses. A ACTTION blueprint for evidence-based clinical trial design for chronic pain pharmacotherapy was published in the Journal of Pain in 2011. Dr. Rappaport highlighted some of the challenges in analgesic drug development involving animal models and failure in preclinical studies and explained the rationale behind the initiative focus on clinical trial design. He also mentioned the advantages of bringing in stakeholders from both the public and private sectors to address these challenges and the critical importance in identifying appropriate people to coordinate the effort. The FDA has provided seed funding for the project which plans to seek further funding from private sources. Dr. Robert Dworkin at the University of Rochester is currently directing the

ACTTION initiative and FDA recently awarded additional grant-type funding. Dr. Rappaport closed by describing a number of current ACTTION activities, upcoming meetings, and future initiative opportunities in research, education, and treatment.

Dr. Landis opened the discussion by enquiring about foundations supporting the FDA similar to the Foundation for NIH as well as current ACTTION efforts in developing biomarkers for pain. Dr. Rappaport informed the committee that a foundation for FDA is under development and there is currently one active ACTTION program for pain biomarkers. An IMMPACT consensus meeting on the role of biomarkers and related measures in improving analgesic drug development is scheduled for June 2012.

Dr. Smith enquired about differences between the ACTTION initiative and current NIH-supported research programs such as the Orofacial Pain: Prospective Evaluation and Risk Assessment (OPPERA) and Multidisciplinary Approach to the Study of Chronic Pelvic Pain (MAPP) initiatives. Dr. Kusiak explained that the OPPERA initiative is a cooperative agreement between the University of North Carolina and the National Institute of Dental and Craniofacial Research studying biological, behavioral, and psychological risk factors for the onset of temporomandibular joint disorders. Dr. Mackey mentioned that the primary goal of the MAPP consortium is to collect phenotypic and genotypic data to understand mechanisms underlying chronic pelvic pain. The committee agreed that current projects under OPPERA, MAPP, and ACTTION provide a strong research foundation for building future cost-effective and inclusive research projects that reduce duplication. Dr. Smith emphasized that an important focus area is the transition from acute to chronic pain across diseases with common underlying pathways.

Ms. Vargas asked what percentage of pain research focuses on developing drug abuse deterrents versus analgesic treatments for patients and the ethics of patients taking drug abuse deterrent formulations. Dr. Rappaport responded that the ACTTION initiative does study the area of drug abuse deterrence and that this is an area of high interest among various stakeholders including the private sector. Dr. Thomas and he cited examples of products that were not approved by the FDA because of adverse effects in patients. Dr. Dubner commented that the interdisciplinary nature of the committee would allow it to address cross-cutting issues concerning overlapping chronic pain conditions. In closing, Dr. Landis mentioned that an inventory of federal pain activities may be useful in addressing some of the discussed issues.

### **Establishing a Framework for Analysis of the Federal Pain Research Portfolio**

Agency for Healthcare Research and Quality (AHRQ)

*Dr. Richard Ricciardi, PhD, NP, Health Scientist, Center for Primary Care, Prevention, and Clinical Partnerships, Agency for Healthcare Research and Quality*

Dr. Ricciardi highlighted the AHRQ mission and focus on improving health care outcomes, improving efficiency in transforming research into practice, facilitating wider access to healthcare, and promoting safety and quality of healthcare for all Americans. Among AHRQ's six research portfolio areas, pain research is mainly focused on comparative effectiveness research. Dr. Ricciardi noted that AHRQ's operational funding request for FY2013 was approximately \$409 million with \$345 million for the evaluation service fund, \$62 million for

the outcome research fund, and \$12 million for the prevention and public health fund. Similar to other federal agencies, AHRQ utilizes investigator-initiated research grants and research contracts, and in particular, systematic evidence reviews using the Effective Healthcare Program, to support pain research. Future mechanisms may include targeted research grants for rapid cycle research conducted through Practice Based Research Networks (PBRNs) and contracts similar to the Accelerating Change and Transformation in Organizations and Networks (ACTION II) initiative. Finally, Dr. Ricciardi highlighted a number of research networks, centers, and projects that can be utilized to disseminate research findings.

The discussion session focused on the Practice Based Research Networks (PBRNs) and how they may be utilized for pain research and dissemination along with networks supported by the Centers for Medical Services (CMS) and HRSA. Dr. Green led a discussion about the science of inclusion, services to rural or underserved populations, and selecting the best strategy to address known barriers. Ms. Liller commented that differences in short-term versus long-term pain treatment strategies should be considered.

Centers for Disease Control and Prevention (CDC)

*Dr. Charles Helmick III, MD, Senior Medical Epidemiologist, National Center for Chronic Disease Prevention and Health Promotion, Centers for Disease Control and Prevention*

Dr. Helmick underscored CDC's focus on prevention efforts from a complete population perspective. The agency's pain portfolio primarily focuses on implementing evidence-based interventions for arthritis and other rheumatic conditions as well as promoting patient education for self-management of pain conditions. Other areas of focus include oral pain including existing disparities and access to services, as well as prescription drug overdose deaths due to opiates. CDC employs surveillance systems such as the behavioral and national surveys to monitor and collect burden of disease data and funds efforts to imbed evidence-based interventions in sustainable systems. The agency also supports pilot studies to identify and implement effective intervention strategies as well as health communications efforts tailored for different ethnic groups. Dr. Helmick highlighted partnerships with state-level governments and non-governmental organizations for implementing interventions and disseminating information. Finally, Dr. Helmick mentioned a major effort at the Department of Health and Human Services focusing on multiple chronic conditions as well as the 2012 IOM report on chronic illness entitled *Living Well with Chronic Illness: A Call for Public Health Action*, which highlights the severe quality of life problems associated with chronic diseases.

Dr. Green opened the post-presentation discussion by stressing the need for increased awareness of pain research and care in general and advocating for an effort to leverage current federal support of health disorders and diseases areas such as obesity and cancer to promote pain initiatives. Dr. Mackey asked about coordination among the federal agencies such as the CDC and NIH and current public private partnerships in pain research and heard about example collaborative projects between the CDC and NIH involving arthritis, epilepsy, and deep brain stimulation for Parkinson's disease. Dr. Ricciardi mentioned a federal interagency coordination committee at AHRQ focusing on primary care coordination and patient self-management that could benefit from CDC's participation. Ms. Tockarshewsky discussed leveraging and building on the foundation laid for diseases such as diabetes which often lead to painful conditions such

as diabetic neuropathy. Dr. Briggs highlighted another model of cooperation between CDC and NIH where NIH utilizes survey information gathered by CDC and CDC surveys incorporate NIH funded research.

Department of Defense (DoD)

*Maj. Gen. Richard Thomas, MD, DDS, Commanding General, Western Region Medical Command, Department of Defense*

Maj. Gen. Thomas from the US Army Medical Command highlighted a 2010 report entitled *Providing a Standardized DoD and VHA Vision and Approach to Pain Management to Optimize Care for Warriors and Their Families* released by a Joint DoD-VHA Pain Management Task Force. Recommendations from the report include a focus on wounded military personnel and their families and promote synchronization between pain education and intervention efforts, availability of tools and infrastructure to advance research in pain management, and establishing evidence-based best practices for acute and chronic pain care. Maj. Gen. Thomas pointed out similarities to recommendations from the IOM pain report and advocated for a national strategy to target pain. He next discussed areas of focus within the DoD pain research portfolio including efficacy of battlefield regional anesthesia, battlefield pain outcomes and their co-morbidity with post-traumatic stress disorder and traumatic brain injury, as well as developing a novel pain scale. Groups involved in pain research at the DoD include the Medical Research and Material Command, the Battlefield Pain Management Research Group, and an intramural Defense and Veterans Center for Integrative Pain Management. Maj. Gen. Thomas mentioned a number of collaborative partnerships with other federal agencies including integrated pain management centers with the VA, non-governmental organizations, and academia. Finally, he and Col. Chester Buckenmaier presented an informational video on the Patient Assessment and Outcomes Registry (PASTOR) - a NIH/DoD collaborative patient outcomes registry project adapting decision-making tools from the NIH-supported Patient Reported Outcomes Measurement Information System (PROMIS) project for DoD use. The video presentation was followed by a discussion about the role of the family in pain management.

Department of Veterans Affairs (VA)

*Dr. Audrey Kusiak, PhD, Portfolio Manager, Rehabilitation Research and Development Service, Office of Research Development, Department of Veterans Affairs*

Dr. Kusiak began by describing the VA's integrated health care system with 152 medical centers, 1400 clinics, and an intramural research program. She emphasized a focus on translational research at the VA and highlighted a number of pain programs including research centers studying interactions between pain associated with chronic disease and behavioral health factors as well as recovery of nervous systems function. The VA Office of Research and Development's new Pain Consortium is promoting public-private partnerships and translational research. The VA uses mechanisms similar to NIH mechanisms to support pain research as well as unique programs called service directed programs created and managed by program managers. Dr. Kusiak provided examples of existing partnerships with the Donahue Foundation and Mayday Fund and identified public-private partnerships as an area of interest and growth.

During the discussion period, Dr. Smith enquired about Health Services research and development and was informed that the VA has a health systems portfolio covering substance abuse and opioid prescription practices. Dr. Mackey asked whether there were ongoing pain research partnerships between the VA and the NIH. Dr Kusiak responded that the VA and NIH were collaborating on a number of clinical trials and the VA electronic healthcare record system provided opportunities for collaborations on longitudinal studies. In response to questions from Drs. Miaskowski and Green, Dr. Kusiak mentioned that the VA patient services branch supported a standardized training program for physicians as well as providing training and compensation to families and care providers and engaging them with telemedicine and social media.

#### Food and Drug Administration (FDA)

*Dr. Bob Rappaport, MD, Director, Division of Anesthesia and Analgesia Products, Center for Drug Evaluation and Research, Food and Drug Administration*

Dr. Rappaport described activities undertaken by the FDA Office of Surveillance and Epidemiology (OSE) to study adverse events due to opioids and other medications and the Office of New Drugs that funds projects of specific interest to the FDA. He listed various mechanisms used to fund projects including contracts, grants, and cooperative agreements and some of the advantages and disadvantages associated with each mechanism. He mentioned that appropriated funds can be useful for funding small studies of interest to the FDA and for starting public-private partnerships. Dr. Rappaport next highlighted examples of FDA partnerships in addition to the ACTION initiative. OSE studies are often conducted in partnership with other organizations and federal agencies including AHRQ and CMS. For instance, the SAFE USE initiative run in partnership with the National Council for Prescription Drug Programs and a number of patient and advocacy groups supports education and outreach for safe use of drugs. Dr. Rappaport ended his presentation by listing a number of pain and drug use related workshops supported by FDA in recent years. In 2009, FDA hosted workshops on the extrapolation of efficacy from one pain condition to another and on pediatric pain drug development. In 2012, FDA is supporting workshops on the efficacy of opiates for non-cancer chronic pain as well as on the use of naloxene as outpatient treatment for opioid overdose. Dr. Rappaport's presentation was followed by a brief discussion about FDA reports and workshops informing policy changes.

#### National Institutes of Health (NIH)

*Dr. Martha Somerman, DDS, PhD, Director, National Institute of Dental and Craniofacial Research, National Institutes of Health*

Dr. Somerman presented NIH funding data showing a 30% increase from 2007 (\$277 million) to 2011 (\$386 million) in NIH support for chronic pain research. She also presented an estimated breakdown of NIH pain funding by research categories for 2008 – 2010, showing robust support for clinical and basic research (37% and 33%, respectively). Dr. Somerman highlighted a number of pain activities and initiatives supported by the NIH Pain Consortium, including the Annual Symposium, the new Centers of Excellence in Pain Education initiative, and the chronic low back pain working group. She announced the release of the National Vulvodynia Research Plan – an example of how NIH incorporates input from researchers, patients, and the public in developing a comprehensive research strategy on disease specific topics. She also mentioned

ongoing and new pain initiatives launched at NIH including the NIH Neuroscience Blueprint Grand Challenge on Pain, the NINDS Headache Common Data Elements project, and a number of pain workshops and conferences held in 2010-2011. Next, Dr. Somerman cited examples of recent scientific advances in basic, translational, and clinical pain research and described common funding mechanisms used by NIH to support pain research. Finally, Dr. Somerman described the Osteoarthritis Initiative – public-private partnership between NIH and the private industry to develop a research resource for evaluating osteoarthritis biomarkers. In the post-presentation period, Ms. Vargas enquired about pain studies in the context of healthy people as opposed to patients and was informed of ongoing studies such as the OPPERA study and other basic research projects studying underlying pain mechanisms not specific to diseases.

#### Overview of Federal Portfolio and Next Steps

*Dr. Story Landis, PhD, Director, National Institute of Neurological Disorders and Stroke, National Institutes of Health*

Dr. Landis provided a brief overview of the federal pain portfolio and led a discussion about next steps for the committee. Prior to the IPRCC inaugural meeting, a data call was sent to the federal members asking for science advances, a preliminary analysis of their pain portfolio, and a list of education, dissemination, and public-private partnership activities. Agencies analyzed their pain portfolios according to six research categories – basic, translational, clinical, comparative effectiveness, epidemiology, and health disparities. Based on this analysis, Dr. Landis highlighted some areas of research for potential collaboration and synergy among the federal agencies and invited input from the committee members.

Following Dr. Landis's presentation, committee members discussed an in-depth federal pain portfolio analysis. The consensus agreement was for NIH staff to devise categories that encompass the research activities of the IPRCC federal agencies for vetting by staff at the other member agencies, followed by review by a IPRCC working group, and finally by the full committee. Once the research categories are finalized, the member agencies will assign their research activities to the categories and the analysis will be provided to IPRCC members in advance of the next IPRCC meeting. The committee next discussed potential times and agenda items for the second IPRCC meeting and agreed to hold a meeting in Fall 2012 with interim conference calls to review progress. Members also discussed potential methods for soliciting pain research advances from the community.

#### **Discussion/Selection of IPRCC Chair**

*Dr. Paul Scott, PhD, Director, Office of Science Policy and Planning, National Institute of Neurological Disorders and Stroke, National Institutes of Health*

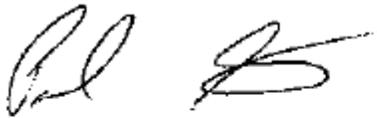
Nominations for the IPRCC chair were solicited from committee members ahead of the meeting and they were able to nominate other members or themselves at that time. Dr. Paul Scott, the Designated Federal Official for the IPRCC, tabulated the nominations and developed a ballot for voting at the IPRCC meeting. Voting proceeded as outlined in Robert's Rules of Order and pending approval from the NIH Director, Dr. Landis was named the IPRCC chair after receiving a clear majority of the votes.

### **Public Comment Period**

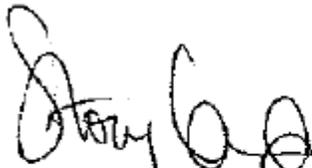
There were no oral public comments.

### **Adjournment**

The meeting was adjourned at 4:40 p.m.



Paul A. Scott, Ph.D.  
Director, Office of Science Policy and Planning, NINDS  
and  
Designated Federal Official, Interagency Pain Research Coordinating Committee



Story C. Landis, Ph.D.  
Director, NINDS  
and  
Chair, Interagency Pain Research Coordinating Committee