

National Institutes of Health (NIH), Office of Disease Prevention

NIH Pathways to Prevention Workshop: The Role of Opioids in the Treatment of Chronic Pain

Program Book

September 29–30, 2014

William H. Natcher Conference Center
National Institutes of Health
Bethesda, Maryland



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#P2PChronicPain

Co-Sponsored by

NIH Office of Disease Prevention
NIH Pain Consortium
National Institute on Drug Abuse
National Institute of Neurological Disorders and Stroke



National Institutes of Health

Dear Workshop Attendees:

It is with great pleasure that I welcome you to the National Institutes of Health (NIH) Pathways to Prevention Workshop: The Role of Opioids in the Treatment of Chronic Pain. The Office of Disease Prevention (ODP) is pleased to co-sponsor this event with the National Institute on Drug Abuse (NIDA), the National Institute of Neurological Disorders and Stroke (NINDS), and the NIH Pain Consortium. I would like to thank Dr. Nora D. Volkow, Director of NIDA, and Dr. Story C. Landis, Director of NINDS, for their leadership in this endeavor and extend a special thank you to Dr. David A. Thomas, Deputy Director of NIDA's Division of Clinical Neurosciences and Behavioral Research, and Dr. Wendy Smith, Director for Research Development and Outreach in the Office of Behavioral and Social Sciences Research, who led the day-to-day development of the workshop alongside ODP staff. The goal of the Pathways to Prevention program is to host workshops that identify research gaps in a selected scientific area, identify methodological and scientific weaknesses in that scientific area, suggest research needs, and move the field forward through an unbiased, evidence-based assessment.

The ODP provides leadership for the development, coordination, and implementation of activities across the NIH and with other public and private partners to increase the scope, support, public health impact, and dissemination of health promotion and disease prevention research. This workshop is just one example of how the ODP promotes methodologically sound research to reduce the incidence of disease and increase healthy years of life. The workshop is designed to be interactive, so we encourage you to share your insights during audience discussion sessions about:

- Long-term effectiveness of opioids for treating chronic pain
- Potential risks of opioid treatment in various patient populations
- Effects of different opioid management strategies on outcomes related to addiction, abuse, misuse, pain, and quality of life
- Effectiveness of risk mitigation strategies for opioid treatment
- Future research needs and priorities to improve the treatment of pain with opioids.

We will also be accepting public comments on the panel's draft report, which will be posted on the ODP website in early October for a two-week period.

It is an exciting time for the ODP as we have begun implementing our first Strategic Plan for Fiscal Years 2014–2018. The plan was developed with input from a variety of stakeholders, and includes activities to strengthen existing programs and develop new initiatives to advance the prevention research agenda at the NIH and improve public health. The ODP Strategic Plan is available for download on the ODP website.

On behalf of the NIH and the ODP, thank you in advance for your contributions. We look forward to an informative and engaging workshop.

Sincerely,

David M. Murray, Ph.D.
Associate Director for Prevention
Director, Office of Disease Prevention
Division of Program Coordination, Planning, and Strategic Initiatives
Office of the Director
National Institutes of Health

Dear Colleagues,

I am pleased to join Dr. Murray and the National Institutes of Health (NIH) Office of Disease Prevention (ODP) in welcoming you to this workshop on the role of opioids in the treatment of chronic pain. We recognize that chronic pain is a significant health problem for the nation and for individuals who suffer from it. It is a complex disorder and its management often involves multiple interventions, including opioid analgesics. These prescription drugs may be an important component of a patient's pain treatment plan, but the significant increase in opioid prescriptions over the past 20 years has contributed to the diversion of these drugs for inappropriate and risky use.

The NIH Pain Consortium has joined with ODP in support of this workshop. The NIH Pain Consortium is composed of representatives from 25 of the NIH Institutes, Centers, and Offices. It was established to enhance pain research and promote collaboration among researchers across the many NIH Institutes and Centers that have programs and activities addressing pain. The Consortium's member institutes support and conduct research across a broad range of disciplines, including development of better treatments for pain, as well as approaches to address drug abuse and addiction. There is an urgent need to examine the current data and to identify gaps in our knowledge of how opioids affect chronic pain, the associated risks, and the best clinical practices for their use in people with chronic pain. Although challenging, your efforts over the next few days will provide direction to move towards filling our knowledge gaps and a foundation to inform clinical practice.

On behalf of the NIH Pain Consortium, I thank you for your dedication and valuable contributions, and look forward to the outcomes of the workshop.

Sincerely,

Story Landis, Ph.D.
Director, NINDS
Chair, NIH Pain Consortium

Dear Colleagues:

It is my pleasure to welcome you all to the National Institutes of Health Pathways to Prevention Workshop, entitled “*The Role of Opioids in the Treatment of Chronic Pain.*” I would like to thank the NIH Office of Disease Prevention (ODP) for taking on this important topic at the request of the NIH Pain Consortium. Our Nation is facing two major health crises related to opioid prescribing.

First, the IOM estimated in 2011 that 100 million Americans are suffering from chronic pain. Opioids are increasingly being used for the treatment of chronic pain, but there is not a consensus on when they should be used. Often opioids are overprescribed, increasing overdoses, dependence and diversion. However, opioids also are sometimes not prescribed when they are needed, leaving patients to suffer unnecessarily.

Second, the number of prescriptions for opioids has nearly quadrupled in the past 20 years. Unfortunately, this increase has fueled another major health crisis: the prescription opioid abuse epidemic. The rate of deaths from overdoses of prescription opioids in the United States more than quadrupled between 1999 and 2010. Rates of emergency department visits and substance-abuse treatment admissions related to prescription opioids have also increased markedly.

One purpose of this conference is to critically examine the scientific evidence and draw unbiased conclusions about the clinical situations when opioids should or should not be used to most effectively treat people in pain. This information should inform best practice for pain, with or without opioid research priorities.

I would like to thank the members of the Pain Consortium, our Federal partners, and members of the private sector that have worked diligently over the past 2 years to make this meeting a reality. I would like to specially acknowledge the efforts of Dr. Richard Denisco from NIDA, who originally proposed that the NIH Pain Consortium participate in the development of this meeting. Sadly Richard passed away earlier this year, but his efforts live on and this conference will attest to this.

My greatest appreciation for your participation.

Sincerely,

Nora D. Volkow, M.D.
Director

About the Workshop

Chronic pain is a major public health problem, which is estimated to affect more than 100 million people in the United States and about 20–30% of the population worldwide. The prevalence of persistent pain is expected to rise in the near future as the incidence of associated diseases (including diabetes, obesity, cardiovascular disorders, arthritis, and cancer) increases in the aging U.S. population.

Opioids are powerful analgesics that are commonly used and found to be effective for many types of pain. However, opioids can produce significant side effects, including constipation, nausea, mental clouding, and respiratory depression, which can sometimes lead to death.

In addition, long-term opioid use can also result in physical dependence, making it difficult to discontinue use even when the original cause of pain is no longer present. Furthermore, there is mounting evidence that long-term opioid use for pain can actually produce a chronic pain state, whereby patients find themselves in a vicious cycle in which opioids are used to treat pain caused by previous opioid use.

Data from the Centers for Disease Control and Prevention indicate that the prescribing of opioids by clinicians has increased threefold in the last 20 years, contributing to the problem of prescription opioid abuse.¹ Today, the number of people who die from prescription opioids exceeds the number of those who die from heroin and cocaine, combined.

Health care providers are in a difficult position when treating moderate to severe chronic pain; opioid treatments may lessen the pain, but may also cause harm to patients. In addition, there has not been adequate testing of opioids in terms of what types of pain they best treat, in what populations of people, and in what manner of administration. With insufficient data, and often inadequate training, many clinicians prescribe too much opioid treatment when lesser amounts of opioids or non-opioids would be effective. Alternatively, some health care providers avoid prescribing opioids altogether for fear of side effects and potential addiction, causing some patients to suffer needlessly.

The 2014 National Institutes of Health (NIH) Pathways to Prevention Workshop on The Role of Opioids in the Treatment of Chronic Pain will seek to clarify:

- Long-term effectiveness of opioids for treating chronic pain
- Potential risks of opioid treatment in various patient populations
- Effects of different opioid management strategies on outcomes related to addiction, abuse, misuse, pain, and quality of life
- Effectiveness of risk mitigation strategies for opioid treatment
- Future research needs and priorities to improve the treatment of pain with opioids.

The workshop is co-sponsored by the NIH Office of Disease Prevention (ODP), the NIH Pain Consortium, the National Institute on Drug Abuse, and the National Institute of Neurological Disorders and Stroke.

Initial planning for each Pathways to Prevention Workshop is coordinated by a Working Group that nominates panelists and speakers, and develops and finalizes questions that frame the workshop. After finalizing the questions, an evidence report is prepared by an Evidence-based Practice Center through a contract with the Agency for Healthcare Research and Quality. During the 1½-day workshop, invited experts discuss the body of evidence, and attendees have opportunities to provide comments during open discussion periods. After weighing evidence from the evidence report, expert presentations, and public comments, an unbiased, independent panel will prepare a draft report that identifies research gaps and future research priorities. The draft report is posted on the ODP website, and public comments are accepted for two weeks. The final report is then released approximately two weeks later.

¹Centers for Disease Control and Prevention, National Center for Health Statistics. Underlying Cause of Death 2000–2010 on CDC WONDER Online Database. Extracted February 11, 2013.

Financial Disclosures

The National Institutes of Health, Centers for Disease Control and Prevention, our planners, and our presenters wish to disclose that they have no financial interests or other relationships with the manufacturers of commercial products, suppliers of commercial services, or commercial supporters, with the exception of the following:

Name	Organization	Nature of Conflict of Interest AND Mechanism to Resolve*
Speakers		
Clauw, Daniel J.	Abbott, AstraZeneca, Cerephex, Eli Lilly and Company, Forest, Iroko, Jazz, Johnson and Johnson, Merck, Nuvo, Pfizer, Purdue, Theravance, Tonix, UCB	Honorarium and research grant. Resolved through a discussion.
Compton, Wilson M.	General Electric, Inc., Pfizer, Inc., 3M Corporation	Stock ownership. Resolved through a discussion.
Cruciani, Ricardo A.	Ameritox, Covidien, Depomed, ENDO, Grupo Ferrer	Honorarium. Resolved through a discussion.
Katz, Nathaniel P.	Analgesic Solutions, Alkermes, Astellas Pharma World Wide, AstraZeneca, Avanir Pharmaceuticals, Inc., Bayer, Biogen, Cephalon, Inc., Collegium Pharmaceutical, Inc., Concert Pharmaceuticals, Inc., ContraVir Pharmaceuticals, Inc., Covidien, Ltd., DePuy, DURECT Corporation, Eli Lilly and Company, Fidia, Flexion Therapeutics, Glenmark Pharmaceuticals Ltd., Grünenthal Group Worldwide, GW Pharmaceuticals, IL Pharma, Inc., Inflexxion, iX Biopharma Ltd., Janssen Pharmaceuticals, Inc., Mallinckrodt Pharmaceuticals, Mesoblast Ltd., Metys Pharmaceuticals, Nektar, NeurAxon, Novartis, Opioid Hyperalgesia Consortium, Organogenesis, Inc., Pfizer, Phosphagenics Limited, Purdue Pharma L.P., SG Cowen, Sun Pharmaceutical Industries Ltd., TARIS Biomedical, Inc., Teva Pharmaceutical Industries Ltd., Vertex Pharmaceuticals, Inc., Zogenix, Inc.	Salary, research grants, stock ownership or options, royalties, consultancy and advisory boards, patents, licenses or licensing fees, and consultations with investment analysts. Resolved through a discussion.

Name	Organization	Nature of Conflict of Interest AND Mechanism to Resolve*
Speakers (continued)		
Passik, Steven D.	Millennium Laboratories	Salary. Resolved through a discussion.
Portenoy, Russell K.	Pfizer Foundation	Research grant. Resolved through a discussion.
Walsh, Sharon	Astra Zeneca, Camurus, Eli Lilly and Company, Novartis, PCM, Pfizer, Scientific, Sun Pharmaceutical Industries Ltd.	Honorarium. Resolved through a discussion.
Working Group		
Von Korff, Michael	Pfizer, Inc.	Research grant. Resolved through a discussion.

*All other planners, speakers, and panelists signed statements that they have no financial or other conflicts of interest pertaining to the topic under consideration.

There is no commercial support for this activity.

Presentations will not include any discussion of the unlabeled use of a product or a product under investigational use with the exception of presentations by Dr. Clauw, Dr. Coffin, and Dr. Cruciani. Dr. Clauw will be discussing classes of drugs that work for pain due to differing underlying mechanisms. Dr. Coffin's presentation may include a discussion of naloxone administered intranasally, a route not yet approved by the U.S. Food and Drug Administration. Dr. Cruciani may discuss off-label use of certain opioids in his presentation on strategies to maximize opioid therapy.

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Agenda

Monday, September 29, 2014

- 8:30 a.m. **Welcome**
Nora D. Volkow, M.D.
Director
National Institute on Drug Abuse
National Institutes of Health
- 8:45 a.m. **Opening Remarks**
Story C. Landis, Ph.D.
Director
National Institute of Neurological Disorders and Stroke
National Institutes of Health
- 9:00 a.m. **Charge to the Panel**
David M. Murray, Ph.D.
Associate Director for Prevention
Director
Office of Disease Prevention
Division of Program Coordination, Planning, and Strategic Initiatives
Office of the Director
National Institutes of Health
- 9:10 a.m. **Workshop Overview and Panel Activities**
David B. Reuben, M.D.
Chief
Division of Geriatrics
Director
Multicampus Program in Geriatric Medicine and Gerontology
Professor of Medicine
Division of Geriatrics
David Geffen School of Medicine at the University of California,
Los Angeles
- 9:20 a.m. **Overview of Topic**
David A. Thomas, Ph.D.
Deputy Director
Division of Clinical Neurosciences and Behavioral Research
National Institute on Drug Abuse
National Institutes of Health
- 9:40 a.m. **The Folly of Trying To Speak for the 100 Million Americans**
Myra Christopher, L.H.D. (Hon.)
Kathleen M. Foley Chair for Pain and Palliative Care
Center for Practical Bioethics

Attendees will be responsible for meals and/or light refreshments on their own, at their own expense. The government and/or government contractors are not involved in facilitating the provision of food and/or light refreshments.

Monday, September 29, 2014 (continued)

10:00 a.m. **Clinician Perspective**
David J. Tauben, M.D.
Clinical Associate Professor
Department of Medicine
Chief (Interim)
Division of Pain Medicine
Medical Director
Center for Pain Relief
University of Washington

I. What is the long-term effectiveness of opioids?

10:20 a.m. **Evidence-based Practice Center I: Overview of Systematic Review Methodology and What Is the Long-Term Effectiveness of Opioids?**
Roger Chou, M.D., FACP
Director
Pacific Northwest Evidence-based Practice Center
Professor of Medicine
Department of Medical Informatics & Clinical Epidemiology
Oregon Health & Science University

10:50 a.m. **What Is the Long-Term Effectiveness of Opioids: Interpretation of Evidence**
Jane C. Ballantyne, M.D.
Professor, Retired
Department of Anesthesiology and Pain Medicine
University of Washington

11:10 a.m. **Understanding the Data: Efficacy, Effectiveness, and Generalizability**
Russell K. Portenoy, M.D.
Chief Medical Officer
Metropolitan Jewish Health System (MHJS) Hospice and Palliative Care
Director
MJHS Institute for Innovation in Palliative Care
Professor of Neurology
Albert Einstein College of Medicine

11:30 a.m. **Break**

11:50 a.m. **Predicting Individual Differences in Opioid Analgesic Effectiveness**
Stephen Bruehl, Ph.D.
Professor
Department of Anesthesiology
Vanderbilt University School of Medicine

Monday, September 29, 2014 (continued)

- 12:10 p.m. **Are Opioids Preferentially Effective in Treating Different Underlying Mechanisms of Chronic Pain?**
Daniel J. Clauw, M.D.
Professor of Anesthesiology, Medicine, and Psychiatry
Director
Chronic Pain and Fatigue Research Center
University of Michigan Medical Center
- 12:30 p.m. **Lunch (to be provided at the expense of the attendee)**
- 1:30 p.m. **Discussion**

II. What are the safety and harms of opioids in patients with chronic pain?

- 2:20 p.m. **Evidence-based Practice Center II: What Are the Safety and Harms of Opioids in Patients With Chronic Pain?**
Judith Turner, Ph.D.
Professor
Department of Psychiatry and Behavioral Sciences
University of Washington
- 2:40 p.m. **Adverse Drug Reactions With Opioid Analgesic Use in Older Adults**
Joseph T. Hanlon, Pharm.D., M.S.
Professor
Division of Geriatrics/Gerontology
Department of Medicine
University of Pittsburgh School of Medicine
- 3:00 p.m. **Prescription Opioids and Substance Use Disorder**
Edward C. Covington, M.D.
Director
Neurological Center for Pain
Cleveland Clinic
- 3:20 p.m. **Risks of Opioid Therapy**
Nathaniel P. Katz, M.D., M.S.
President and Chief Executive Officer
Analgesic Solutions
Adjunct Assistant Professor of Anesthesia
Tufts University School of Medicine

Monday, September 29, 2014 (continued)

- 3:40 p.m. **Public Health Impact**
Jane C. Maxwell, Ph.D.
Senior Research Scientist
Addiction Research Institute
The University of Texas at Austin School of Social Work
- 4:00 p.m. **Discussion**
- 5:00 p.m. **Adjourn**

Tuesday, September 30, 2014

III. What are the effects of different opioid management strategies?

- 8:30 a.m. **Evidence-based Practice Center Presentation III: What Are the Effects of Different Opioid Management Strategies?**
Roger Chou, M.D., FACP
Director
Pacific Northwest Evidence-based Practice Center
Professor of Medicine
Department of Medical Informatics & Clinical Epidemiology
Oregon Health & Science University
- 8:50 a.m. **Selected Strategies To Optimize Opioid Therapy and Decrease Risk of Abuse: State of the Evidence**
Ricardo A. Cruciani, M.D., Ph.D.
Director
Center for Comprehensive Pain Management and Palliative Care
Capital Institute for Neuroscience
Capital Health Medical Center
- 9:10 a.m. **Effectiveness of Treatment Strategies for Managing Patients With Addiction to Prescription Opioids on Outcomes Related to Addiction, Abuse, Misuse, Pain, Function, and Quality of Life**
Steven D. Passik, Ph.D.
Vice President
Clinical Research and Advocacy
Millennium Research Institute
Millennium Laboratories
- 9:30 a.m. **Impact of Pharmacokinetics and Pharmacodynamics: Relevance to Abuse and Addiction and Risks in Treatment**
Sharon Walsh, Ph.D.
Professor of Behavioral Sciences, Psychiatry, Pharmacology, and
Pharmaceutical Science
Director
Center on Drug and Alcohol Research
University of Kentucky College of Medicine
- 9:50 a.m. **Discussion**

Tuesday, September 30, 2014 (*continued*)

IV. What is the effectiveness of risk mitigation strategies for opioid treatment?

- 10:30 a.m. **Evidence-based Practice Center IV: What Is the Effectiveness of Risk Mitigation Strategies for Opioid Treatment?**
Judith Turner, Ph.D.
Professor
Department of Psychiatry and Behavioral Sciences
University of Washington
- 10:50 a.m. **Risk Mitigation by Way of Naloxone**
Phillip O. Coffin, M.D., M.I.A.
Director of Substance Use Research
HIV Prevention Section
San Francisco Department of Public Health
- 11:10 a.m. **Opioid Risk Mitigation and Adherence Monitoring in Practice**
Erin E. Krebs, M.D., M.P.H.
Core Investigator
Center for Chronic Disease Outcomes Research
Medical Director
Women Veterans Comprehensive Health Center
Minneapolis Veterans Administration
Associate Professor
Department of Medicine
University of Minnesota
- 11:30 a.m. **Prescription Opioid Misuse and Addiction: A National Priority**
Wilson M. Compton, M.D., M.P.E.
Deputy Director
National Institute on Drug Abuse
National Institutes of Health
- 11:50 a.m. **Discussion**
- 12:30 p.m. **Break**

Tuesday, September 30, 2014 (continued)

- 12:50 p.m. **Roundtable Discussion on Opioids in the Real World**
Wendy B. Smith, Ph.D., M.A., BCB, Moderator
Senior Scientific Advisor for Research Development and Outreach
Office of Behavioral and Social Sciences Research
Office of the Director
National Institutes of Health
- Daniel J. Clauw, M.D., Panelist*
Professor of Anesthesiology, Medicine, and Psychiatry
Director
Chronic Pain and Fatigue Research Center
University of Michigan Medical Center
- Ricardo A. Cruciani, M.D., Ph.D., Panelist*
Director
Center for Comprehensive Pain Management and Palliative Care
Capital Institute for Neuroscience
Capital Health Medical Center
- Tracy W. Gaudet, M.D., Panelist*
Director
Office of Patient Centered Care and Cultural Transformation
Veterans Health Administration
U.S. Department of Veterans Affairs
- 1:30 p.m. **Workshop Wrap-Up/Next Steps**
- 1:40 p.m. **Adjourn**

Speaker Biographies and Presentation Summaries

Opening Session

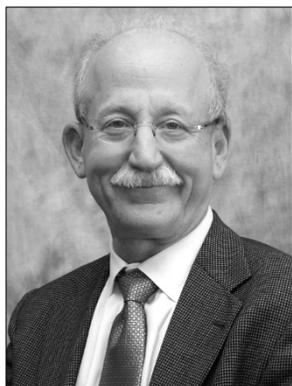


Myra Christopher, L.H.D. (Hon.), is the Kathleen M. Foley Chair in Pain and Palliative Care at the Center for Practical Bioethics. Prior to December 2011, Ms. Christopher was President and Chief Executive Officer of the Center for Practical Bioethics since its inception in 1984. From 1998 to 2003, Ms. Christopher served in the Robert Wood Johnson Foundation's National Program Office for Community-State Partnerships to Improve End-of-Life Care, which was housed at the Center. She is currently the Principal Investigator on the Pain Action Initiative: A National Strategy and was a Pain Study Committee Member with the Institute of Medicine panel, which released its report *Relieving Pain in America: A Blueprint for Transforming Prevention, Care, Education, and Research* in June 2011. She is currently

a member of the National Institutes of Health's Interagency Pain Research Coordinating Committee and its National Pain Strategy Oversight Committee. Ms. Christopher serves as a public member of a number of boards including the American Academy of Family Physicians Foundation, the Coalition for Physician Accountability, and the Coalition To Transform Advanced Illness. She is a past member of a number of editorial and advisory boards including the American Association of Critical Care Nurses Certification Corporation, the *American Journal of Bioethics*, and the American Bar Association's Commission on Law and Aging. She has served on many local and regional boards and advisory committees, including the Kansas Board of Healing Arts, the Federation of State Medical Boards, Kansas University's School of Nursing, and the Kansas Commission on the Future of Healthcare. She has received many awards for her work in bioethics, palliative care, and chronic pain including the American Academy of Pain Medicine's Patient Advocacy Award, the American Academy of Pain Management's "Head Heart Award," and the American Academy of Hospice and Palliative Medicine President's Award. Ms. Christopher holds a bachelor's degree in philosophy from the University of Kansas–Missouri City and received an honorary doctorate from National University of Health Sciences in Chicago in December 2011.

The Folly of Trying To Speak for the 100 Million Americans. Chronic pain is a major public health issue that affects at least 100 million Americans. It is clearly folly for one person to attempt to speak for 100 million Americans; however, this presentation will try to point out the humanistic costs juxtaposing two critically important public health issues—chronic pain and addiction. To address the needs of those whose lives are often destroyed by chronic pain, the Institute of Medicine's (IOM) report, *Relieving Pain in America: A Blueprint for Transforming Prevention, Care, Education, and Research*, called for a "cultural transformation in the way pain is perceived, judged, and treated." One of the report's recommendations was to shift from a biomedical to a biopsychosocial model of care and one that addresses the individual's needs, goals, and values. Such an approach might include prescription medications, nerve blocks, steroid injections, chiropractic care, behavioral health, diet and nutrition counseling, acupuncture, and other treatments. The juxtaposition of chronic pain against another significant public health issue, addiction—more specifically, the abuse of prescription pain medications—and causally connecting them has, unintendedly, made the lives of many who live with chronic pain a living nightmare. Efforts to reduce the abuse of prescription pain medications have made it increasingly difficult for many chronic pain patients to access treatment they need, including, but not limited to, medications that many of them deem "life-saving."

Furthermore, today they are frequently seen as a threat to those who care for them and are often characterized by those in the healing professions as “drug seekers” and “fired” from medical practices. Some have described chronic pain patients as the “collateral damage” in the War Against Drugs and the battle between these two public health issues for resources and attention. The solution to this dilemma was supposed to be “balanced pain policy.” It is challenging, however, to argue that there is anything balanced about efforts to address these two important public health issues. The abuse of prescription pain medications is the headline; it is the focus of policy efforts at both the state and federal levels—not the undertreatment of chronic pain. One of the guiding principles that underpinned the IOM report was that there “is a moral imperative to treat chronic pain” and that this imperative imposes an ethical “responsibility and duty on those in the healing professions” to do so. To turn our backs on the pain and suffering of 100 million Americans is morally unconscionable, and to deny them care out of concern for those who struggle to live with addiction is wrong. Good ethics start with good facts; it is time to clarify both the risks and benefits of opioid use in the treatment of chronic pain and the incidence of iatrogenic addiction. It is also time to address the undertreatment of chronic pain in America and to correct the harm that has been done to those who live with chronic pain.



David J. Tauben, M.D., is Chief of the University of Washington (UW) Division of Pain Medicine, Medical Director of the UW Center for Pain Relief, and Director of Medical Student and Resident Education in Pain Medicine. He is jointly appointed in the Department of Medicine and Anesthesiology and Department of Pain Medicine, and board certified in both internal medicine and pain medicine. Dr. Tauben is Medical Director of UWTelePain, a tele-video-conferencing program, providing innovative pain education and consultative support to Northwest regional primary care providers. He serves as Principal Investigator for UW’s National Institutes of Health Pain Consortium Center of Excellence for Pain Education, leading curriculum development to increase pain proficiency for interprofessional primary care providers. Dr. Tauben is a founding member of Washington State Agency Medical Directors’ panel of medical experts developing opioid prescription guidelines for the state. He has served as a clinical and content expert for regulatory and legislative bodies involved in public policy regarding pain medicine practice and standards. He served as an expert for several Centers for Disease Control and Prevention clinical outreach programs advising primary care providers on how to prescribe opioids for chronic non-cancer pain. He is annually recognized by his peers as a recipient of regional awards in the care of pain patients and brings decades of best practices for medication management of acute and chronic pain.

Clinician Perspective. The clinician’s perspective while prescribing chronic opioid therapy (COT) for chronic pain is formed initially by inadequate pain curricula for most health professionals delivering primary and specialty care throughout training years. Challenges of complex multidimensional pain assessment in high-volume clinical settings are daunting, hampered without readily accessible tools for measuring and tracking treatment outcomes and adherence during COT. Clinicians also need timely access to pain experts who best match provider discipline to carefully identified patient needs. Heavy reliance on opioids, without strong evidence of benefit and higher than expected risks and costs, have left many clinicians struggling with their own or inherited panels of patients doing poorly on high-dose opioids who resist dose taper. Regular adherence monitoring can foster distrustful and unsatisfying patient-provider interactions. Clinicians also fear potentially severe disciplinary punishment in an ever-changing regulatory environment. Many solutions are

available now or in development. All include access to adequate curricula in pregraduate and graduate professional education; evidence-based guidelines and patient self-management tools recommending best practice COT including non-opioid alternatives; validated, integrated, and streamlined pain assessment and tracking tools; enough time and support to correctly manage COT; and ready access to collaborative and coordinated multidisciplinary interprofessional pain-trained experts.

Evidence-based Practice Center



Roger Chou, M.D., FACP, is a Professor in the Department of Medicine and Department of Medical Informatics & Clinical Epidemiology at Oregon Health & Science University (OHSU) School of Medicine, and Staff Physician in the Internal Medicine Clinic at OHSU. He has served as Director of the Pacific Northwest Evidence-based Practice Center since 2012. He has conducted systematic reviews in a number of areas, including chronic pain and musculoskeletal conditions, screening and prevention, diagnostic testing, and prognosis. He has served as Director of the American Pain Society clinical guidelines program, is the GRADE (Grading of Recommendations Assessment, Development, and Evaluation) methodologist for the World Health Organization's Division of Reproductive Health, is a member of the Cochrane Back Review Editorial Board, and is Co-Chair of the National Quality Forum Musculoskeletal Standing Committee.

Evidence-based Practice Center: Dr. Chou will first present an overview of the key questions and methods used in the Evidence-based Practice Center's systematic evidence report, *The Effectiveness and Risks of Long-Term Opioid Treatment of Chronic Pain*. He will summarize the study inclusion criteria and review process. He will also summarize the evidence on the long-term effectiveness and comparative effectiveness of opioids for long-term outcomes related to pain, function, and quality of life, as well as the evidence on the comparative effectiveness of different opioid regimen and dosing strategies for outcomes related to pain, function, and quality of life, and risks of overdose, addiction, abuse, or misuse.



Judith Turner, Ph.D., received a Ph.D. in clinical psychology from the University of California, Los Angeles, then completed postdoctoral training in pain and geriatrics at the University of Washington (UW). Since 1980, she has served on the faculty at the UW School of Medicine, where she is Professor in the Department of Psychiatry and Behavioral Sciences and Department of Rehabilitation Medicine, and Adjunct Professor in the Department of Anesthesiology and Pain Medicine. She is Co-Director of Behavioral Health Services at the UW Medicine Center for Pain Relief, where she works clinically with patients with chronic pain. Dr. Turner's research interests include clinical trials of medical, surgical, and psychosocial interventions for chronic pain; prediction of pain outcomes; prevention of chronic disability among injured workers; and safety and effectiveness of long-term opioid therapy for chronic pain. She has published over 190 peer-reviewed articles related to chronic pain studies and is internationally recognized for this research (e.g., Wilbert E. Fordyce Clinical Investigator Award from the American Pain Society for contributions to clinical pain research, International Society for the Study of the Lumbar Spine prize for clinical pain research). She is currently Secretary, and in October 2014 will become President-Elect, of the International Association for the Study of Pain.

Evidence-based Practice Center: Dr. Turner will present results from the Evidence-based Practice Center's systematic evidence report, *The Effectiveness and Risks of Long-term Opioid Treatment of Chronic Pain*, on risks of long-term opioid therapy for harms and adverse events, including opioid abuse, addiction, overdose, and other harms (e.g., gastrointestinal-related harms, falls, fractures, motor vehicle accidents, endocrinological harms, infections, cardiovascular events, cognitive harms, psychological harms). She will also present the evidence on risk assessment and risk mitigation strategies. She will summarize evidence on the accuracy of opioid risk prediction instruments; effectiveness of use of risk prediction instruments and use of various risk mitigation strategies (including opioid management plans, patient education, urine drug screening, and use of prescription drug monitoring program data) for outcomes related to overdose, addiction, abuse, or misuse; and comparative effectiveness of treatment strategies for managing patients with addiction to prescription opioids for outcomes related to overdose, abuse, misuse, pain, function, and quality of life.

Question I. What is the long-term effectiveness of opioids?



Jane C. Ballantyne, M.D., received her medical degree from the Royal Free Hospital School of Medicine in London, England. She trained in anesthesia at the John Radcliffe Hospital, Oxford, England, before moving to the Massachusetts General Hospital (MGH), Harvard University, Boston in 1990. She became Chief of the Division of Pain Medicine at MGH in 1999. She moved to the University of Washington (UW) in 2011 as UW Medicine Professor of Education and Research. Her research is focused on the development of opioid management tools utilizing electronic outcomes assessment and rapid learning methodology. She has editorial roles in several leading journals and textbooks, and is a widely published author.

What Is the Long-Term Effectiveness of Opioids: Interpretation

of Evidence. Trials are normally conducted for periods of weeks or months but not beyond. While trials confirm the effectiveness of opioids administered over relatively short periods, we are left with less reliable evidence when it comes to assessing opioid effectiveness over longer periods (e.g., years). This presentation will examine existing evidence, as well as evidence gaps, in assessing long-term effectiveness of opioids.



Russell K. Portenoy, M.D., is Chief Medical Officer of Metropolitan Jewish Health System (MJHS) Hospice and Palliative Care and Director of the MJHS Institute for Innovation in Palliative Care. He is a Professor of Neurology at the Albert Einstein College of Medicine. Prior to joining MJHS, Dr. Portenoy was founding Chairman of the Department of Pain Medicine and Palliative Care and the Gerald J. Friedman Chair in Pain Medicine and Palliative Care at Beth Israel Medical Center, New York. Dr. Portenoy is Past President of the American Academy of Hospice and Palliative Medicine and Past President of the American Pain Society. He previously chaired the American Board of Hospice and Palliative Medicine. He is a recipient of the Lifetime Achievement Award and the National Leadership

Award of the American Academy of Hospice and Palliative Medicine, has received both the Wilbert Fordyce Award for Lifetime Excellence in Clinical Investigation and the Distinguished Service Award from the American Pain Society, and was given the Founder's Award by the American Academy of Pain Medicine. Dr. Portenoy has been Editor-in-Chief of the *Journal of Pain and Symptom Management* for more than two decades, Co-Editor of the *Oxford Textbook of Palliative Medicine*, and is Editor for the palliative care section of *The Oncologist*. He has written, co-authored, or edited 21 books and more than 525 papers and book chapters on topics in pain and symptom management, opioid pharmacotherapy, and palliative care.

Understanding the Data: Efficacy, Effectiveness, and Generalizability. The clinical context provided by current “best practices” contextualizes the effort to interpret the extant evidence related to the long-term effectiveness of opioid therapy. There is an international consensus among specialists in palliative care that opioid therapy is first-line therapy for moderate or severe pain related to active cancer and other advanced illnesses. In contrast, there is an emerging consensus among specialists in pain medicine that opioid therapy should be reserved for a small segment of the population with other types of pain, specifically those for whom other approaches have a more

unfavorable assessment of risk and benefit, and a low likelihood of opioid-related functional decline or serious adverse effects. This divergence in clinical practices underscores both the limitations of the current evidence and the complexity of chronic pain and its associated medical and psychiatric co-morbidities. Systematic reviews have repeatedly revealed a lack of data related to efficacy beyond several months or effectiveness for any period of time for *both* chronic cancer pain and chronic pain unrelated to cancer. There are no adequate studies that either support or refute the hypothesis, which is reasonably derived from the clinical experience of specialists in palliative care and in pain medicine, that long-term opioid therapy is beneficial in some subpopulations with chronic pain and harmful in others. The research needed to address this hypothesis must be broad, including qualitative studies, epidemiologic studies, large prospective cohort studies, and clinical trials in carefully defined subgroups.



Stephen Bruehl, Ph.D., is a Professor of Anesthesiology at Vanderbilt University School of Medicine. He received his Ph.D. in clinical psychology in 1994 from the University of Kentucky, where he also learned to use opioid blockade methodology to explore opioid system function. Throughout his career, Dr. Bruehl has conducted research focused on understanding the mechanisms of and factors influencing chronic pain, with a particular focus on endogenous opioid systems. He has published more than 110 peer-reviewed articles regarding both acute and chronic pain, and he has been Principal Investigator on five pain-related research grants funded by the National Institutes of Health. He is an Associate Editor of the journal *Pain* and the *Journal of Behavioral Medicine*, and is also Research Director for an effort sponsored jointly by the U.S. Food and Drug Administration, the American Pain Society, and industry to develop a data-driven chronic pain diagnostic taxonomy for the major chronic pain disorders. Dr. Bruehl's recent research has been in the area of personalized pain medicine. He is currently Co-Principal Investigator on a National Institute on Drug Abuse-funded project examining predictors of opioid analgesic responses and the role of endogenous opioid mechanisms in those predictive effects.

Predicting Individual Differences in Opioid Analgesic Effectiveness. Opioid analgesics used in chronic pain management have both risks and benefits that may vary from one individual to the next. The ability to optimize the risk/benefit ratio for a given patient benefits from understanding the predictors of, and ideally the mechanisms underlying, variability in responses to opioid analgesics. This talk will provide a brief overview of the literature regarding several classes of possible opioid response predictors, including genetic, demographic, psychological, receptor- and neurotransmitter-related, and pain phenotypes. Recent mechanism-focused research will be summarized documenting that endogenous opioid system status is a determinant of analgesic responses to opioid medications. Results indicating that evoked pain sensitivity predicts opioid analgesic efficacy in part via endogenous opioid mechanisms will be described. Limitations in the literature regarding prediction of opioid analgesic responses will be discussed, including limited replication, a dearth of studies in chronic pain patients, and the absence of studies predicting responses to chronic opioid use. Overall, there do not yet appear to be well-established predictors of opioid analgesic responses, and those predictors with the strongest supporting data exhibit relatively small effect sizes. Fundamental problems with relying upon traditional randomized controlled trials to address opioid response prediction issues will be highlighted, and future research directions will be suggested.



Daniel J. Clauw, M.D., is a Professor of Anesthesiology, Medicine, and Psychiatry. He attended undergraduate and medical school at the University of Michigan, and then did his internal medicine residency and rheumatology fellowships at Georgetown University, where he eventually held roles including Chief of Rheumatology and Vice Chair of Medicine. He moved back to Michigan in 2002, bringing with him one of the leading pain research groups. This group has helped identify prominent central nervous system contributions to a number of chronic pain disorders, as well as the most effective pharmacological and non-pharmacological treatments for chronic pain. Dr. Clauw was also the first Principal Investigator of the University of Michigan Clinical and Translational Science Award and Associate Dean for Clinical and Translational Research, and founding director of the Michigan Institute for Clinical and Health Research. Although he stepped down from these latter roles in 2009 to rededicate himself to pain research, he remains very active in institutional clinical research training programs and is a very active and recognized mentor of clinical and translational researchers.

Are Opioids Preferentially Effective in Treating Different Underlying Mechanisms of Chronic Pain? Most practitioners have historically considered most chronic pain to be largely from peripheral nociceptive input (i.e., damage or inflammation). When considering the involvement of the central nervous system (CNS) in pain, most focus on psychological factors such as mood disorders or catastrophizing. We now understand that non-psychological CNS factors can markedly increase (sensitization) or decrease pain sensitivity. The CNS is now thought of as “setting the volume control” or gain on pain processing. Centralized pain or central sensitization can be identified in most individuals with conditions such as fibromyalgia, irritable bowel, tension headache, and temporomandibular joint disorder, and in subsets (typically at least 20–30%) of individuals with other chronic pain states such as rheumatoid arthritis, systemic lupus erythematosus, low back pain, and osteoarthritis. Thus, all chronic pain states may be “mixed” pain states with variable peripheral and central contributions in different individuals with the same clinical label. Emerging data suggest that opioids might be more effective in treating nociceptive rather than centralized pain. In fact, some evidence even suggests that endogenous opioid systems might contribute to the pathogenesis of centralized pain states, and that opioids might even make these conditions worse. Moving forward in both clinical trials and clinical practice, we need to better phenotype chronic pain patients so as to differentiate underlying pain mechanisms that may underlie differential responsiveness to treatments.

Question II. What are the safety and harms of opioids in patients with chronic pain?



Joseph T. Hanlon, Pharm.D., M.S., is a tenured Professor of Medicine and the Co-Director of the Geriatric Pharmaceutical Outcomes and Geroinformatics Research and Training Program in the School of Medicine at the University of Pittsburgh. Dr. Hanlon also has secondary faculty appointments in Pharmacy and Epidemiology and is a Health Scientist with the Center for Health Equity Research and Promotion and with the Geriatric Research Education and Clinical Center at the U.S. Department of Veterans Affairs Pittsburgh Healthcare System. He has been an active and continuously funded clinical pharmacist researcher since 1987 in the areas of pharmaco-epidemiology and health services interventions to improve drug therapy for older adults. One of his research focus areas is examining central nervous system medication use including opioids and geriatric syndromes, and he is widely published on these topics. He has also frequently given invited talks on the topic of analgesic use in older adults and has been asked to serve on various National Institutes of Health/U.S. Food and Drug Administration research and safety programs concerning analgesics in older adults.

Adverse Drug Reactions With Opioid Analgesic Use in Older Adults. This talk will focus on factors that put older adults at risk for opioid adverse effects. This will include a focus on age-related changes in opioid pharmacokinetics, pharmacodynamics, drug interactions, and risk of geriatric syndromes (i.e., cognitive impairment/delirium, falls/fractures) and other opioid adverse effects.



Edward C. Covington, M.D., was trained in psychiatry at the Mayo Clinic. He is certified by the American Board of Psychiatry and Neurology in psychiatry with added qualifications in pain management and addiction medicine. He is also certified by the American Board of Pain Medicine. He founded the Chronic Pain Rehabilitation Program at Cleveland Clinic in 1979 and has served as its Director since that time. It was selected last year as a Center of Excellence by the American Pain Society. He developed a hospital pain consultation service for the diagnosis and management of problematic acute, chronic, and malignant pain. In 2008, he founded the Neurological Center for Pain in the Neurological Institute at Cleveland Clinic. He has published articles and chapters on subjects related to the psychology, physiology, and pharmacology of chronic pain and on its interface with addictive disorders. He is a member of the Editorial Review Board for *Pain Medicine* and an *ad hoc* reviewer for *Pain*, *The Journal of Pain*, and the *Clinical Journal of Pain*. He lectures nationally and internationally on subjects related to chronic pain. He recently completed four years of service on the U.S. Food and Drug Administration's Anesthetic and Analgesic Drug Products Advisory Committee. He has been active in medical organizations and served as President of the Ohio Psychiatric Association and the American Academy of Pain Medicine. He served for 10 years as Secretary of the American Board of Pain Medicine and for 30 years on the Board of Directors of the American Chronic Pain Association.

Prescription Opioids and Substance Use Disorder. Increased opioid prescribing over the last 25 years has been paralleled by an increase in opioid addiction, overdose deaths, and, recently, an epidemic of heroin addiction. While evidence suggests that creation of addiction by opioid

prescribing is uncommon, a sizable minority of patients receiving chronic opioid analgesia suffers from co-morbid addiction. This presentation will attempt to reconcile these seemingly contradictory findings, dissect the varying trajectories of opioid addiction, describe ways to detect addiction in pain patients, and suggest strategies for mitigating the problem.



Nathaniel P. Katz, M.D., M.S., is President and Chief Executive Officer of Analgesic Solutions, a research, education, and consulting firm exclusively focused on pain therapeutics. Dr. Katz is also Adjunct Assistant Professor of Anesthesia at Tufts University School of Medicine. After completing his neurology residency at Tufts-New England Medical Center, he entered a pain management fellowship in the Department of Anesthesia at Brigham & Women's Hospital in 1990 and was later appointed staff neurologist in the Pain Management Center. Dr. Katz subsequently founded the Pain and Symptom Management Program at Dana-Farber Cancer Institute and the Pain Trials Center (a clinical analgesics research unit) at Brigham & Women's Hospital. He remained director of both until 2001. From 2000 to 2004, Dr. Katz served as Chair of the Advisory Committee, Anesthesia, Critical Care, and Addiction Products Division, U.S. Food and Drug Administration, during which time he completed an M.S. in biostatistics at Columbia University. Dr. Katz is active in shaping public policy to reduce prescription opioid fraud and abuse, having served as a consultant to the Office of National Drug Control Policy and other government agencies. Dr. Katz's interests include clinical research methods, analgesic clinical trials, opioids for chronic pain, opioids and addiction, neuropathic pain, cancer pain, and new methods for advancing prescription monitoring. He has completed numerous clinical trials of treatments for pain, both industry initiated and investigator initiated, involving pharmaceuticals, non-pharmaceutical analgesics, and devices, and has also conducted studies related to opioids, pain, and addiction. He is an active member of the Initiative on Methods, Measurement, and Pain Assessment in Clinical Trials (IMMPACT) and has been a co-author on several IMMPACT guidelines. Dr. Katz has over 60 publications in peer-reviewed journals and has made numerous presentations at scientific congresses. He has served as an Associate Editor at the *Clinical Journal of Pain* and Associate Editor (Pain) for the *Encyclopedia of Neurological Sciences*, and has overseen many local and national educational programs on pain management.

Risks of Opioid Therapy. To optimize the risk-benefit balance of opioids, we need to mitigate the risks, which requires knowing what the risks are. In this presentation, Dr. Katz will cover the risks of opioids outside direct addiction-related disorders. The most common serious complication of long-term opioid use is opioid-induced androgen deficiency (OPIAD), which is primarily manifested as decreased libido, infertility, menstrual irregularities, and possibly increased pain sensitivity. Opioids are also associated with falls and fractures, which are in part related to OPIAD, since androgen deficiency also leads to osteoporosis. The opioids are associated with a long list of "nuisance" side effects, such as nausea, vomiting, dizziness, constipation, and sweating; unfortunately, these side effects are more than a nuisance and cause significant morbidity and perhaps mortality. Tolerance and hyperalgesia, while not adverse events per se, may limit efficacy and drive dose escalation. Finally, several risks related to abuse deserve mention: neonatal withdrawal syndrome, accidental ingestion in children, and suicide-related events using opioids.



Jane C. Maxwell, Ph.D., is a Senior Research Scientist at the Addiction Research Institute at the University of Texas at Austin. She has been a member of the Substance Abuse and Mental Health Services National Advisory Council, a consultant to the U.S. Food and Drug Administration's Center for Drug Evaluation and Research, a Fulbright Senior Specialist, a member of the National Institute on Drug Abuse's (NIDA) Community Epidemiology Work Group, and an Adjunct Professor at the Centre for Accident Research and Road Safety–Queensland. She has been an investigator on grants from NIDA to study patterns of methamphetamine use in the central Texas area and routes of administration of heroin, and is now Principal Investigator on a grant from the National Institute on Alcoholism and Alcohol Abuse to study factors in recidivism for impaired driving offenders who have been in substance abuse treatment. Her research specialties include trends and patterns of substance abuse nationally and internationally, with special interest in methadone mortality; the U.S.-Mexico border; patterns of use and abuse of methamphetamine, party and synthetic drugs, heroin, and prescription drugs; the relationship of substance abuse and traffic safety; and the relationship of substance abuse and HIV/AIDS and other sexually transmitted diseases.

Public Health Impact. This paper will discuss the economic costs of opioids and draw together the latest available data, including survey findings, poison control center calls, emergency department and substance abuse treatment admissions, death data, forensic data, and data on the manufacture and distribution of scheduled drugs. This update will not only consider current trends, but also changes in patterns of use and the impact of initiatives to deter the distribution and use of opioid drugs. Of special importance is to understand the recent changes in patterns of use and the impact of opioid use and abuse in the creation of new high-risk groups in need of special care.

Question III. What are the effects of different opioid management strategies?



Ricardo A. Cruciani, M.D., Ph.D., is Director of the Center for Pain Medicine and Palliative Care at Capital Health Medical Center, Hopewell, New Jersey. Prior to this position, he was Vice Chairman, Director of the Pain Division, and Director of the Center for Non-Invasive Brain Stimulation of New York, Department of Pain Medicine and Palliative Care, Beth Israel Medical Center, and Professor of Clinical Neurology and Clinical Anesthesiology at AECOM, also in New York. He has a Ph.D. in pharmacology (*summa cum laude*) and was an Associate Researcher at the National Institutes of Health (NIH) where he trained in opioid pharmacology and neurophysiology. He trained in neurology and psychiatry at Weill College of Medicine and in pain management at Memorial Sloan

Kettering Cancer Center. His main research interests are opioid pharmacology, neuropathic pain, and brain stimulation. He has over 100 publications including articles in peer-reviewed journals, book chapters, and editorials. He has been a keynote speaker and lecturer at over 100 international and national meetings; he also served as a member of the Scientific Committee and Board of Directors of the American Pain Society and of the U.S. Environmental Protection Agency, for which he is now President Elect. He is co-editor of several books and is on the Editorial Board of the *Journal of Pain and Symptom Management*. He has been a reviewer for numerous journals and study sections at the NIH, where he was also a grantee.

Selected Strategies To Optimize Opioid Therapy and Decrease Risk of Abuse: State of the Evidence. In this presentation, Dr. Cruciani will discuss the state of the evidence of strategies developed through the years to maximize the efficacy of opioid therapy and decrease risk. One of the strategies that has been in use for a long time is the combination of a long-acting opioid formulation with a short-acting formulation to achieve 24-hour coverage of pain (long acting), while allowing extra medication to treat pain exacerbation (short acting). Another popular strategy within the opioid field is the concept of opioid rotation. This strategy was developed as a tool to achieve analgesic efficacy when tolerance or unacceptable side effects to an opioid develop. The conversion from one opioid to another might be challenging to those not accustomed to prescribing opioids on a regular basis because of the difference in potency and efficacy, and incomplete development of cross-tolerance that varies from opioid to opioid. To assist with these opioid rotations, researchers developed “equianalgesic tables.” These tables, while advocated by many, have been recently questioned by some investigators and suggested to be the cause of accidental overdose in some cases. More recently, the focus of attention drifted from access to therapy to decreasing the risk of abuse and diversion. In this context, abuse-deterrent opioid formulations were developed. While some practitioners suggest that opioid prescribing should be done only in the form of abuse-deterrent formulations, others argue that the evidence is not strong enough to make that recommendation.



Steven D. Passik, Ph.D., joined Millennium Laboratories and Millennium Research Institute as Director of Clinical Addiction Research and Education and Principal Investigator after a 25-year academic and clinical career at Memorial Sloan Kettering Cancer Center, University of Kentucky, and Vanderbilt University, and was recently promoted to Vice President of Clinical Research and Advocacy. Dr. Passik is presently planning multiple projects in medication monitoring and pharmacogenetic testing and outcomes in addiction treatment. His research has focused on psychiatric aspects of cancer and cancer symptom management and the interface of pain management and addiction. He has served as editor and reviewer for multiple journals in pain and psycho-oncology. He has authored over 120 scholarly articles and has nearly 200 publications overall.

Effectiveness of Treatment Strategies for Managing Patients With Addiction to Prescription Opioids on Outcomes Related to Addiction, Abuse, Misuse, Pain, Function, and Quality of Life. In his lecture, Dr. Passik will discuss the clinical challenge of treating pain in people with addictions. He will discuss this issue from both the point of view of clinical observation, guidelines, and the small but growing empirical literature on the subject. Given the national crises of pain and prescription drug abuse, views have changed considerably on the propriety of opioid therapy in many pain subpopulations, not the least of which are those at highest risk for poor outcomes related to worsening or rekindling addiction. Is management with controlled substances completely contraindicated or is it beneficial when precautions are built in?



Sharon Walsh, Ph.D., is a Professor of Behavioral Science, Psychiatry, Pharmacology, and Pharmaceutical Sciences in the Colleges of Medicine and Pharmacy at the University of Kentucky. She is the Director of the Center on Drug and Alcohol Research. She earned her Ph.D. from Rutgers University in behavioral neuroscience and, after postdoctoral training, she joined the faculty at Johns Hopkins University School of Medicine where she remained for 13 years before leaving at the rank of Professor. Her clinical research focuses on pharmacological and behavioral issues in opioid abuse and dependence, including studies on the pharmacodynamic and pharmacokinetic characteristics of opioid dependence pharmacotherapies (i.e., buprenorphine, methadone, LAAM) and more recently on widely used opioid analgesics (i.e., oxycodone, hydrocodone, tramadol, morphine). She has published over 100 manuscripts and book chapters. Her honors include receiving the Presidential Early Career Award for Scientists and Engineers, the Joseph Cochin Young Investigator Award, and the Betty Ford Award, and serving as President of the College on Problems of Drug Dependence. She has served on review and advisory boards for the National Institute on Drug Abuse, National Institute on Alcoholism and Alcohol Abuse, U.S. Department of Veterans Affairs, National Institutes of Health, and American Society for Addiction Medicine, and presently serves as a special government appointee to the U.S. Food and Drug Administration.

Impact of Pharmacokinetics and Pharmacodynamics: Relevance to Abuse and Addiction and Risks in Treatment. Numerous synthetic and semisynthetic opioid products are marketed for the treatment of pain and the treatment of opioid addiction; unfortunately, many of these are now widely abused in the United States. Among these, there are critical differences in pharmacology that impact efficacy, safety, and abuse liability. While intrinsic activity, potency, and half-life are obvious key

pharmacological contributors, formulation properties also play a critical role in efficacy and safety. Specific issues related to immediate- versus extended-release products, route of administration, and unique risks associated with methadone will be discussed. The importance of pharmacodynamic and pharmacokinetic interactions with concomitant therapeutics will be explored with specific attention to pharmacokinetic interactions related to changes in CYP450 metabolism (enzyme induction or inhibition), absorption (slowed gastrointestinal transit), and efflux (P-glycoprotein effects). Serious risks associated with sedation and fatal overdose arise from the use of opioids in combination with sedatives, including benzodiazepines and alcohol; however, limited empirical data exist to inform clinical practice behaviors, and co-prescribing of benzodiazepines is common. Finally, development strategies for abuse-deterrent formulations aimed at reducing both abuse and safety risks will be discussed.

Question IV. What is the effectiveness of risk mitigation strategies for opioid treatment?



Phillip O. Coffin, M.D., M.I.A., is a Clinician Investigator at the San Francisco Department of Public Health and University of California, San Francisco. He is a board-certified internist and infectious disease clinician with active practices including inpatient and outpatient HIV and infectious disease care. As the Director of Substance Use Research at the San Francisco Department of Public Health, he oversees National Institutes of Health, Centers for Disease Control and Prevention, and foundation-supported pharmacologic and behavioral clinical trials, implementation science studies, mathematical modeling, and epidemiologic research addressing the health effects of substance use. Dr. Coffin's current active studies address pharmacotherapies for methamphetamine dependence, behavioral interventions and naloxone for opioid overdose prevention, and analyses of drug-related mortality.

Risk Mitigation by Way of Naloxone. Naloxone has been provided to illicit opioid users since the mid-1990s to prevent opioid overdose mortality and has been associated with impressive declines in community-level mortality. Increasingly, this intervention is being applied to patients prescribed opioid medications for pain management. This talk will discuss the data underlying these initiatives and the potential adjunctive benefits of naloxone to broader opioid safety initiatives.



Erin E. Krebs, M.D., M.P.H., is a core investigator at the Minneapolis U.S. Department of Veterans Affairs (VA) Center for Chronic Disease Outcomes Research and an Associate Professor of Medicine at the University of Minnesota. She was previously a Robert Wood Johnson Foundation Clinical Scholar at the University of North Carolina at Chapel Hill and completed a 5-year VA Research Career Development Award focused on the quality and safety of opioid prescribing in primary care. Her research focus is on pain management in primary care, benefits and harms of opioid analgesics for chronic pain, and pain assessment. She is currently leading a VA-funded randomized clinical trial comparing opioid versus non-opioid-prescribing strategies for long-term treatment of chronic back and osteoarthritis pain. In addition, Dr. Krebs is an active primary care physician and serves as Women's Health Medical Director for the Minneapolis VA Health Care System.

Opioid Risk Mitigation and Adherence Monitoring in Practice. Guidelines for opioid prescribing recommend a variety of patient selection and monitoring practices to reduce the risks of opioid therapy to both patients and the larger community. Recommended opioid management practices, such as risk stratification, urine drug testing, opioid treatment agreements, and frequent clinic visits, are intended to reduce harm related to prescription opioid use disorders, opioid misuse, and overdose, but data on their effectiveness are limited. Less research is available on the mitigation of other potential risks of long-term opioid therapy, such as sleep-disordered breathing and hypogonadism. Studies suggest that recommended opioid management practices have not been widely implemented in primary care and other general medical settings, where most opioids are prescribed. In primary care, barriers to implementing recommended practices include lack of

acceptance among prescribers and resource constraints. Few studies have examined best practices for implementation of opioid risk mitigation strategies.



Wilson M. Compton, M.D., M.P.E., is Deputy Director of the National Institute on Drug Abuse (NIDA) at the National Institutes of Health. Dr. Compton's responsibilities include working with the Director to provide scientific leadership of NIDA's entire research portfolio to improve the prevention and treatment of drug abuse and addiction. Previously, from 2002 until 2013, Dr. Compton served as Director of NIDA's Division of Epidemiology, Services and Prevention Research. Over his career, Dr. Compton has achieved multiple scientific accomplishments: he was selected to serve on the *Diagnostic and Statistical Manual of Mental Disorders, Fifth Edition*, Revision Task Force; is author of more than 130 articles and chapters including widely cited papers drawing attention to prescription drug abuse problems; and is an invited speaker at multiple high-impact venues, including multiple presentations to federal judges. Dr. Compton is a member of numerous professional organizations, including the Alpha Omega Alpha medical education honor society, and the recipient of multiple awards. In 2008, he received the American Psychiatric Association's Senior Scholar Health Services Research Award, in 2010 the American Psychopathological Association's Paul Hoch Award, in both 2012 and 2013 the U.S. Food and Drug Administration's Leveraging Collaboration Award, and in 2013 the U.S. Department of Health and Human Services Secretary's Award for Meritorious Service.

Prescription Opioid Misuse and Addiction: A National Priority. Increasing rates of opioid prescriptions have been associated with increasing rates of opioid treatment admissions to specialty care and, most concerning, with increased rates of opioid overdose fatalities. Analgesics are among the most common drugs first abused and are surprisingly commonly abused by teenagers. Rates of opioid prescriptions have nearly tripled in the past 20 years, as have treatment admissions for opioid addiction. Rates of prescription opioid overdose fatalities have increased nearly fourfold. Rates of heroin use have also increased since 2008, and the relationship of prescription opioids to heroin is complex. Prescription opioid use is a risk factor for subsequent heroin addiction, but only a small proportion of those who misuse prescription opioids shift to heroin. On the other hand, most initiators of heroin in the past 10 years report prior use of prescription opioids. Treatment for opioid addiction (both heroin and prescription opioid addiction) includes medication-assisted treatment with agonists (e.g., methadone), partial agonists (e.g., buprenorphine), and antagonists (e.g., naltrexone). Treatment has been shown to markedly improve outcomes, and recent work demonstrates an association of treatment expansion with reduced mortality. Overall, high rates of opioid prescribing appear to be an upstream driver of the high rates of opioid misuse, addiction, and mortality seen in recent years in the United States.

Roundtable Discussion on Opioids in the Real World

Moderator



Wendy B. Smith, Ph.D., M.A., BCB, serves as the Senior Scientific Advisor for Research Development and Outreach for the Office of Behavioral and Social Sciences Research (OBSSR) at the National Institutes of Health (NIH). In this position, she advises the NIH Associate Director for Behavioral and Social Sciences Research on programmatic and scientific issues related to behavioral and social sciences and interdisciplinary research, and public-private partnerships, and leads the development of new trans-NIH research initiatives from emerging research opportunities. She joined OBSSR from the Office of the NIH Director, Office of Science Policy where she served as the NIH Program Director for Clinical Research Partnerships. Prior to her roles within the Office of the NIH Director, she served as the inaugural Deputy Director of the National Cancer Institute's Office of Cancer Complementary and Alternative Medicine where she also created and directed the Research Development and Support Program. Dr. Smith earned her M.A. in the psychology of health and her Ph.D. in applied-experimental psychology, and is a licensed experimental psychologist and a nationally certified biofeedback therapist with advanced training in the use of hypnosis for pain. She left clinical practice to join the NIH in 1990 as a Research Psychologist in the intramural research program within the Neurobiology and Anesthesiology Branch, Pain Section at the National Institute for Dental and Craniofacial Research. She is a founding member of the NIH Pain Consortium and a senior member of numerous trans-NIH and trans-Agency scientific committees and working groups. Dr. Smith's publications include research on pain memory, psychophysics of pain perception, psychological aspects of pain, complementary and alternative medicine, and research methodologies. Dr. Smith has served on NIH special-emphasis review panels and on several editorial boards, including the *Journal of Alternative and Complementary Medicine*, *The Journal of the Society for Integrative Oncology*, *The Clinical Journal of Pain*, and the *Journal of Cancer Integrative Medicine*, and continues to publish on pain and symptom management, research methodologies, and complementary and alternative medicine.

Panelist



Daniel J. Clauw, M.D., is a Professor of Anesthesiology, Medicine, and Psychiatry. He attended undergraduate and medical school at the University of Michigan, and then did his internal medicine residency and rheumatology fellowships at Georgetown University, where he eventually held roles including Chief of Rheumatology and Vice Chair of Medicine. He moved back to Michigan in 2002, bringing with him one of the leading pain research groups. This group has helped identify prominent central nervous system contributions to a number of chronic pain disorders, as well as the most effective pharmacological and non-pharmacological treatments for chronic pain. Dr. Clauw was also the first Principal Investigator of the University of Michigan Clinical and Translational Science Award and Associate Dean for Clinical and Translational Research, and founding director of the Michigan Institute for Clinical and Health Research. Although he stepped down from these latter roles in

2009 to rededicate himself to pain research, he remains very active in institutional clinical research training programs and is a very active and recognized mentor of clinical and translational researchers.

Panelist



Ricardo A. Cruciani, M.D., Ph.D., is Director of the Center for Pain Medicine and Palliative Care at Capital Health Medical Center, Hopewell, New Jersey. Prior to this position, he was Vice Chairman, Director of the Pain Division, and Director of the Center for Non-Invasive Brain Stimulation of New York, Department of Pain Medicine and Palliative Care, Beth Israel Medical Center, and Professor of Clinical Neurology and Clinical Anesthesiology at AECOM, also in New York. He has a Ph.D. in pharmacology (*summa cum laude*) and was an Associate Researcher at the National Institutes of Health (NIH) where he trained in opioid pharmacology and neurophysiology. He trained in neurology and psychiatry at Weill College of Medicine and in pain management at Memorial Sloan Kettering Cancer Center. His main research interests are opioid pharmacology, neuropathic pain, and brain stimulation. He has over 100 publications including articles in peer-reviewed journals, book chapters, and editorials. He has been a keynote speaker and lecturer at over 100 international and national meetings; he also served as a member of the Scientific Committee and Board of Directors of the American Pain Society and of the U.S. Environmental Protection Agency, for which he is now President Elect. He is co-editor of several books and is on the Editorial Board of the *Journal of Pain and Symptom Management*. He has been a reviewer for numerous journals and study sections at the NIH, where he was also a grantee.

Panelist



Tracy W. Gaudet, M.D., became Director of the Veterans Health Administration (VHA) Office of Patient Centered Care and Cultural Transformation (OPCC&CT) in January 2011. Dr. Gaudet is responsible for creating a structure, employing and training staff, establishing Centers of Excellence, and guiding and supporting the transformation of every VHA network and health care facility to address the VHA's number one strategic priority, "to provide personalized, proactive, patient-driven health care to our veterans." VHA recognizes that the current medical model is not optimally designed to achieve this, and that to succeed it is necessary to rethink the fundamental construct of "health care." The OPCC&CT is charged with leading this transformation. She came to the VHA from Duke University Medical Center where she served as Executive Director of Duke Integrative Medicine, a position she held since 2001. She led Duke Integrative Medicine to the forefront of the field, co-founding the Consortium of Academic Health Centers for Integrative Medicine. Prior to her work at Duke University, Dr. Gaudet was the founding Executive Director of the University of Arizona Program in Integrative Medicine, helping to design the country's first comprehensive curriculum in this new field. Dr. Gaudet, a recognized leader in the transformation of health care, speaks nationally through both public and professional venues ranging from Institute of Medicine and Department of Defense events to "The Oprah Show." She has been featured in numerous national media, including the PBS special titled "The New Medicine" and was named by *Shape* magazine as one of 11 women

who shaped the medical world. Dr. Gaudet was recognized as one of the “Top 25 Women in Healthcare 2011” by *Modern Healthcare* and received the 2013 Bravewell Leadership Award. Dr. Gaudet is the author of *Consciously Female*, a book on integrative medicine and women’s health, and *Body, Soul, and Baby*. She received her B.A. and her M.D. from Duke University, and completed her residency in obstetrics and gynecology at the University of Texas in San Antonio. She is board certified in obstetrics and gynecology, and regularly teaches and writes for the American College of Obstetrics and Gynecology.

Working Group

Working group members provided their input at a meeting held August 28–29, 2013. The information provided here was accurate at the time of that meeting.

Chairpersons: **David A. Thomas, Ph.D.**
Deputy Director
Division of Clinical Neurosciences and Behavioral Research
National Institute on Drug Abuse
National Institutes of Health
Rockville, Maryland

Richard A. Denisco, M.D., Ph.D.
Services Research Branch
National Institute on Drug Abuse
National Institutes of Health
Rockville, Maryland

Caroline Acker, Ph.D.
Associate Professor and Head
Department of History
Carnegie Mellon University
Pittsburgh, Pennsylvania

Edward C. Covington, M.D.
Director
Neurological Center for Pain
Cleveland Clinic
Cleveland, Ohio

Jane C. Ballantyne, M.D.
Professor, Retired
Department of Anesthesiology and Pain
Medicine
University of Washington
Philadelphia, Pennsylvania

Jody Engel, M.A., R.D.
Director of Communications
Office of Disease Prevention
Division of Program Coordination, Planning,
and Strategic Initiatives
Office of the Director
National Institutes of Health
Bethesda, Maryland

Wen G. Chen, Ph.D.
Program Director
Sensory and Motor Disorders of Aging
Behavioral and Systems Neuroscience
Branch
Division of Neuroscience
National Institute on Aging
National Institutes of Health
Bethesda, Maryland

Roger B. Fillingim, Ph.D.
Professor
University of Florida College of Dentistry
Director
University of Florida Pain Research and
Intervention Center of Excellence
Gainesville, Florida

Roger Chou, M.D., FACP
Director
Pacific Evidence-based Practice Center
Associate Professor of Medicine and Medical
Informatics and Clinical Epidemiology
Oregon Health & Science University
Portland, Oregon

Joseph T. Hanlon, Pharm.D., M.S.
Professor of Medicine and Health Scientist
Division of Geriatric Medicine
University of Pittsburgh
Pittsburgh, Pennsylvania

Suchitra Iyer, Ph.D.
Health Scientist Administrator
Center for Outcomes and Evidence
Agency for Healthcare Research and Quality
Rockville, Maryland

Christopher M. Jones, Pharm.D., M.P.H.

Lieutenant Commander, U.S. Public Health Service
Team Lead
Prescription Drug Overdose Team
Division of Unintentional Injury Prevention
National Center for Injury Prevention and Control
Centers for Disease Control and Prevention
Chamblee, Georgia

Margaret Kotz, D.O.

Director
Addiction Recovery Services
Department of Psychiatry-Adult
University Hospitals Case Medical Center
Professor, Psychiatry
Professor, Anesthesiology
Case Western Reserve University School of Medicine
Cleveland, Ohio

Deborah Langer, M.P.H.

Senior Communications Advisor
Office of Disease Prevention
Division of Program Coordination, Planning, and Strategic Initiatives
Office of the Director
National Institutes of Health
Bethesda, Maryland

Elinore F. McCance-Katz, M.D., Ph.D.

Chief Medical Officer
Substance Abuse and Mental Health Services Administration
Rockville, Maryland

David M. Murray, Ph.D.

Associate Director for Prevention
Director
Office of Disease Prevention
Division of Program Coordination, Planning, and Strategic Initiatives
Office of the Director
National Institutes of Health
Bethesda, Maryland

Elizabeth Neilson, M.S.N., M.P.H.

Senior Communications Advisor
Office of Disease Prevention
Division of Program Coordination, Planning, and Strategic Initiatives
Office of the Director
National Institutes of Health
Bethesda, Maryland

Ann O'Mara, Ph.D., R.N., FAAN

Head
Palliative Care Research
Community Oncology and Prevention Trials Research Group
Division of Cancer Prevention
National Cancer Institute
National Institutes of Health
Bethesda, Maryland

Wilma Peterman Cross, M.S.

Deputy Director
Office of Disease Prevention
Division of Program Coordination, Planning, and Strategic Initiatives
Office of the Director
National Institutes of Health
Bethesda, Maryland

Bob A. Rappaport, M.D.

Director
Division of Anesthesia, Analgesia, and Addiction Products
Center for Drug Evaluation and Research
Food and Drug Administration
Silver Spring, Maryland

David B. Reuben, M.D.

Chief
Geriatric Division
Director
Multicampus Program in Geriatric Medicine and Gerontology
Professor of Medicine
Division of Geriatrics
David Geffen School of Medicine at the University of California, Los Angeles
Los Angeles, California

Wendy B. Smith, Ph.D., M.A., BCB

Director for Research Development and Outreach
Office of Behavioral and Social Sciences Research
Office of the Director
National Institutes of Health
Bethesda, Maryland

Judith Turner, Ph.D.

Professor
Department of Psychiatry and Behavioral Sciences
University of Washington
Seattle, Washington

Michael Von Korff, Sc.D.

Senior Investigator
Group Health Research Institute
Group Health Cooperative
Seattle, Washington

Paris A. Watson

Senior Advisor
Office of Disease Prevention
Division of Program Coordination, Planning, and Strategic Initiatives
Office of the Director
National Institutes of Health
Bethesda, Maryland

Jessica Wu, Ph.D.

Health Scientist
Office of Disease Prevention
Division of Program Coordination, Planning, and Strategic Initiatives
Office of the Director
National Institutes of Health
Bethesda, Maryland

Panel

Panel Chairperson: **David B. Reuben, M.D.**
Chief
Division of Geriatrics
Director
Multicampus Program in Geriatric
Medicine and Gerontology
Professor of Medicine
Division of Geriatrics
David Geffen School of Medicine at the
University of California, Los Angeles
Los Angeles, California

Anika A.H. Alvanzo, M.D., M.S.
Assistant Professor of Medicine
Medical Director
Substance Use Disorders
Consultation Service
Johns Hopkins University School of Medicine
Baltimore, Maryland

Takamaru Ashikaga, Ph.D.
Director
Biometry Facility
University of Vermont College of Medicine
Burlington, Vermont

G. Anne Bogat, Ph.D.
Professor
Department of Psychology
Michigan State University
East Lansing, Michigan

Christopher M. Callahan, M.D.
Professor of Medicine
Cornelius and Yvonne Pettinga Professor
Indiana University (IU) School of Medicine
Director and Research Scientist
IU Center for Aging Research
Research Scientist
Regenstrief Institute, Inc.
Indianapolis, Indiana

Victoria Ruffing, R.N., CCRC
Director of Patient Education
Director of Nursing
Johns Hopkins Arthritis Center
Johns Hopkins University School of Medicine
Adjunct Faculty
Johns Hopkins University School of Nursing
Baltimore, Maryland

David C. Steffens, M.D., M.H.S.
Professor and Chair
Department of Psychiatry
University of Connecticut Health Center
Farmington, Connecticut

Speakers

Jane C. Ballantyne, M.D.

Professor, Retired
Department of Anesthesiology and
Pain Medicine
University of Washington
Philadelphia, Pennsylvania

Stephen Bruehl, Ph.D.

Professor
Department of Anesthesiology
Vanderbilt University School of Medicine
Nashville, Tennessee

Roger Chou, M.D., FACP

Director
Pacific Northwest Evidence-based
Practice Center
Professor of Medicine
Department of Medical Informatics & Clinical
Epidemiology
Oregon Health & Science University
Portland, Oregon

Myra Christopher, L.H.D. (Hon.)

Kathleen M. Foley Chair for Pain and
Palliative Care
Center for Practical Bioethics
Kansas City, Missouri

Daniel J. Clauw, M.D.

Professor of Anesthesiology, Medicine
and Psychiatry
Director
Chronic Pain and Fatigue Research Center
University of Michigan Medical Center
Ann Arbor, Michigan

Phillip O. Coffin, M.D., M.I.A.

Director of Substance Use Research
HIV Prevention Section
San Francisco Department of Public Health
San Francisco, California

Wilson M. Compton, M.D., M.P.E.

Deputy Director
National Institute on Drug Abuse
National Institutes of Health
Rockville, Maryland

Edward C. Covington, M.D.

Director
Neurological Center for Pain
Cleveland Clinic
Cleveland, Ohio

Ricardo A. Cruciani, M.D., Ph.D.

Director
Center for Comprehensive Pain Management
and Palliative Care
Capital Institute for Neuroscience
Capital Health Medical Center
Hopewell, New Jersey

Tracy W. Gaudet, M.D.

Director
Office of Patient Centered Care and Cultural
Transformation
Veterans Health Administration
U.S. Department of Veterans Affairs
Washington, DC

Joseph T. Hanlon, Pharm.D., M.S.

Professor
Division of Geriatrics/Gerontology
Department of Medicine
University of Pittsburgh School of Medicine
Pittsburgh, Pennsylvania

Nathaniel P. Katz, M.D., M.S.

President and Chief Executive Officer
Analgesic Solutions
Adjunct Assistant Professor of Anesthesia
Tufts University School of Medicine
Natick, Massachusetts

Erin E. Krebs, M.D., M.P.H.

Core Investigator
Center for Chronic Disease Outcomes
Research
Medical Director
Women Veterans Comprehensive
Health Center
Minneapolis Veterans Administration
Associate Professor
Department of Medicine
University of Minnesota
Minneapolis, Minnesota

Story C. Landis, Ph.D.

Director
National Institute of Neurological
Disorders and Stroke
National Institutes of Health
Bethesda, Maryland

Jane C. Maxwell, Ph.D.

Senior Research Scientist
Addiction Research Institute
The University of Texas at Austin School
of Social Work
Austin, Texas

David M. Murray, Ph.D.

Associate Director for Prevention
Director
Office of Disease Prevention
Division of Program Coordination, Planning,
and Strategic Initiatives
Office of the Director
National Institutes of Health
Bethesda, Maryland

Steven D. Passik, Ph.D.

Vice President
Clinical Research and Advocacy
Millennium Research Institute
Millennium Laboratories
San Diego, California

Russell K. Portenoy, M.D.

Chief Medical Officer
Metropolitan Jewish Health System (MJHS)
Hospice and Palliative Care
Director
MJHS Institute for Innovation in
Palliative Care
Professor of Neurology
Albert Einstein College of Medicine
New York, New York

David B. Reuben, M.D.

Chief
Division of Geriatrics
Director
Multicampus Program in Geriatric Medicine
and Gerontology
Professor of Medicine
Division of Geriatrics
David Geffen School of Medicine at the
University of California, Los Angeles
Los Angeles, California

Wendy B. Smith, Ph.D., M.A., BCB

Senior Scientific Advisor for Research
Development and Outreach
Office of Behavioral and Social
Sciences Research
Office of the Director
National Institutes of Health
Bethesda, Maryland

David J. Tauben, M.D.

Clinical Associate Professor
Department of Medicine
Chief (Interim)
Division of Pain Medicine
Medical Director
Center for Pain Relief
University of Washington
Seattle, Washington

David A. Thomas, Ph.D.

Deputy Director
Division of Clinical Neurosciences and
Behavioral Research
National Institute on Drug Abuse
National Institutes of Health
Rockville, Maryland

Judith Turner, Ph.D.

Professor
Department of Psychiatry and Behavioral
Sciences
University of Washington
Seattle, Washington

Nora D. Volkow, M.D.

Director
National Institute on Drug Abuse
National Institutes of Health
Rockville, Maryland

Sharon Walsh, Ph.D.

Professor of Behavioral Sciences,
Psychiatry, Pharmacology, and
Pharmaceutical Sciences
Director
Center on Drug and Alcohol Research
University of Kentucky College of Medicine
Lexington, Kentucky

Office of Disease Prevention Staff

David M. Murray, Ph.D.

Associate Director for Prevention
Director
Office of Disease Prevention
Division of Program Coordination, Planning,
and Strategic Initiatives
Office of the Director
National Institutes of Health
Bethesda, Maryland

Paris A. Watson

Senior Advisor
Office of Disease Prevention
Division of Program Coordination, Planning,
and Strategic Initiatives
Office of the Director
National Institutes of Health
Bethesda, Maryland

Deborah Langer, M.P.H.

Senior Communications Advisor
Office of Disease Prevention
Division of Program Coordination, Planning,
and Strategic Initiatives
Office of the Director
National Institutes of Health

Wilma Peterman Cross, M.S.

Deputy Director

Tanya J. Barnett

Program Specialist, Tobacco Regulatory
Science Program

Wanda Davis

Program Assistant

Jody S. Engel, M.A., R.D.

Director of Communications

Mary L. Garcia-Cazarin, Ph.D., M.S.

Scientific Advisor, Tobacco Regulatory
Science Program

John Gohagan, Ph.D.

Senior Scientific Officer

Patricia L. Mabry, Ph.D.

Senior Advisor for Disease Prevention

Rachel J. Mandal, M.Sc.

Senior Public Health Analyst, Tobacco
Regulatory Science Program

Helen I. Meissner, Ph.D., Sc.M.

Director, Tobacco Regulatory
Science Program

Elizabeth Neilson, Ph.D., M.P.H., M.S.N.

Senior Communications Advisor

Susanne Olkkola, M.Ed., M.P.A.

Senior Advisor

Barry Portnoy, Ph.D.

Senior Advisor for Disease Prevention

Denise Stredrick, Ph.D.

Health Science Policy Analyst

Jennifer Villani, Ph.D., M.P.H.

Health Science Policy Analyst

Kay Wanke, Ph.D., M.P.H.

Deputy Director, Tobacco Regulatory
Science Program

Jessica Wu, Ph.D.

Health Science Policy Analyst

Educational Planners

Melissa Barnett, M.S., CHES

Health Education Specialist
National Center for Immunization and
Respiratory Diseases
Centers for Disease Control and Prevention
Atlanta, Georgia

William M. Callaghan, M.D., M.P.H.

Chief
Maternal and Infant Health Branch
Division of Reproductive Health
National Center for Chronic Disease
Prevention and Health Promotion
Centers for Disease Control and Prevention
Atlanta, Georgia

Deborah Langer, M.P.H.

Senior Communications Advisor
Office of Disease Prevention
Division of Program Coordination, Planning,
and Strategic Initiatives
Office of the Director
National Institutes of Health
Bethesda, Maryland

Gloria Morrell, M.S., M.S.N., CIC

Nurse Planner
Division of Scientific Education and
Professional Development
Center for Surveillance, Epidemiology and
Laboratory Service
Centers for Disease Control and Prevention
Atlanta, Georgia

Elizabeth Neilson, Ph.D., M.P.H., M.S.N.

Senior Communications Advisor
Office of Disease Prevention
Division of Program Coordination, Planning,
and Strategic Initiatives
Office of the Director
National Institutes of Health
Bethesda, Maryland

Paris A. Watson

Senior Advisor
Office of Disease Prevention
Division of Program Coordination, Planning,
and Strategic Initiatives
Office of the Director
National Institutes of Health
Bethesda, Maryland

