



NCIPC Board of Scientific Counselors

January 7, 2016

National Center for Injury Prevention and Control
Centers for Disease Control and Prevention
Atlanta, Georgia



Table of Contents

Call to Order/ Roll Call / Welcome / Approval of last Meeting Minutes.....	3
Where We Are in the Guideline Process and Where We Need to Go.....	4
Prescribing Opioids for Chronic Pain (Guideline):	6
Background and Guideline Process	6
Discussion Points.....	9
Guideline: A CDC and HHS Priority	12
Discussion: Background and Guideline Process	13
Request for Establishment of the Opioid Guideline Workgroup	14
Discussion and Vote	31
Conclusion and Adjourn	34
Certification.....	35
Attachment A: Meeting Attendance	36

**DEPARTMENT OF HEALTH AND HUMAN SERVICES
PUBLIC HEALTH SERVICE
Centers for Disease Control and Prevention (CDC)
National Center for Injury Prevention and Control (NCIPC)**

BOARD OF SCIENTIFIC COUNSELORS (BSC)

Seventeenth Meeting: January 7, 2016

Via Teleconference

Summary Proceedings

The seventeenth meeting of the National Center for Injury Control and Prevention (NCIPC) Board of Scientific Counselors (BSC) took place via teleconference on Thursday, January 7, 2016. The BSC met in open session in accordance with the Privacy Act and the Federal Advisory Committee Act (FACA). Dr. Stephen Hargarten served as chair.

Call to Order/ Roll Call / Welcome / Approval of last Meeting Minutes

Stephen Hargarten, MD, MPH
Professor and Chair
Department of Emergency Medicine
Medical College of Wisconsin
Chair, National Center for Injury Prevention and Control Board of Scientific Counselors

Arlene Greenspan, DrPH, MPH, PT
Associate Director for Science
National Center for Injury Prevention and Control
Centers for Disease Control and Prevention

Dr. Stephen Hargarten called the seventeenth meeting of the NCIPC BSC to order at 9:03 a.m. on January 7, 2016. **Dr. Arlene Greenspan** conducted the official roll call of BSC voting members and *ex officio* federal liaison members. A quorum was present and was maintained throughout the meeting. The meeting attendance is appended to this document as Attachment A.

Dr. Greenspan then reviewed housekeeping items. She noted that meeting minutes were being taken and that the meeting was being audio recorded for archival purposes and to ensure accurate transcript of the meeting notes. Meeting minutes will be part of the official record and will be posted on the CDC website: www.cdc.gov/MASO. BSC members were asked to email Ms. Andrea Davis and Dr. Greenspan at the conclusion of the meeting to confirm their attendance.

Dr. Hargarten thanked the participants for taking time for this important meeting. He asked if anyone had questions or comments regarding the minutes from the sixteenth BSC meeting, convened July 15-16, 2015. Hearing none, he entertained a motion to approve the minutes.

Motion: July 15-16, BSC Meeting Minutes

Dr. Angela Mickalide moved to approve the minutes of the July 15-16, 2015 NCIPC BSC meeting. **Dr. Samuel Forjough** seconded the motion. The motion carried unanimously with no abstentions.

Where We Are in the Guideline Process and Where We Need to Go

Debra Houry, MD, MPH
Director
National Center for Injury Prevention and Control
Centers for Disease Control and Prevention

Dr. Debra Houry welcomed the attendees and thanked them for their willingness to participate in the meeting and for their active engagement on the BSC. She welcomed the newest members of the BSC and the new federal partners adding to the robust and diverse group. The BSC has asked to become more involved in NCIPC's work. The July 2015 BSC meeting featured a valuable conversation regarding NCIPC's research agenda. She emphasized that the January 7th meeting represented the most important guidance asked of the BSC to date.

Chronic pain is a public health concern in the US. At the same time, the US is in the midst of a prescription opioid overdose epidemic. In her career as a physician, Dr. Houry has seen many patients who, after injury or trauma, are in acute pain and need immediate relief and treatment. She has also seen patients with chronic illness and ongoing pain who need care and relief, and patients after an overdose of opioid pain medications or heroin. She has also been the one to inform families of the loss of a loved one. She recognized that many BSC members, CDC staff, and members of the public participating on the call had their own stories regarding these issues. She expressed appreciation for those stories and the stories from patients, families, and providers.

There has been an increase of 300% in prescription opioid medication sales since 1999. In fact, in 2012, there were 259 million prescriptions for opioid pain medications. That is enough for every American adult to have a bottle of pills. CDC's *Vitalsigns*TM published in the summer of 2015 indicated that people addicted to these pain medications are 40 times more likely to be addicted to heroin. In the meantime, it is estimated that more than two million people are dependent on opioid pain relievers. Data published last month in the *Morbidity and Mortality Weekly Report (MMWR)* revealed that in 2014, over 28,000 people died from drug overdose involving an opioid, including prescription opioids as well as illicit drugs.

We can, and we must, do better. People deserve safer and more effective pain management, and providers need guidance in these areas. However, existing guideline vary in their specific recommendations and the evidence used to inform the recommendations is a few years old. Further, in the past few years, more evidence has been published about the risks of opioids. CDC has published guideline on other topics, such as sexually transmitted infections (STIs) and HIV pre-exposure prophylaxis (PrEP). Given the worsening problem of opioid overdose in the US and CDC's focus on primary prevention, which aligns with safer prescribing, NCIPC undertook the task of developing a guideline for primary care providers for management of opioids and chronic pain.

Reducing this epidemic is a major priority not only for NCIPC, but also for CDC. CDC Director Dr. Tom Frieden identified the reduction of opioid deaths as one of CDC's main priorities for

2015 and 2016. US Department of Health and Human Services (HHS) Secretary Burwell has made addressing opioid abuse, dependence, and overdose a priority for the department. Work is underway within HHS on this important issue. One area of focus in the Secretary's initiative is informing opioid prescribing practices.

An essential part of the strategy is to reduce opioid overdose by preventing misuse, abuse, and overdose by encouraging safer prescribing of these medications. Primary care physicians prescribe approximately half of opioid pain medications and report having insufficient training for opioid prescribing. The development of prescribing guideline for primary care physicians will provide much-needed guidance to improve provider knowledge, change clinical practices, and benefit patient health. In addition to helping primary care providers offer safer and more effective care for patients with chronic pain and helping to reduce adverse outcomes from these drugs, the development of guideline for prescribing opioids for chronic pain will serve to improve clinical decision-making and improve communication between providers and patients regarding the risks and benefits of prescription opioids.

Starting opioids is a decision that should be weighed carefully by both the physician and the patient. Discussions on expected outcomes and reassessments are important to include. One of NCIPC's main research priorities in the next three to five years is evaluating the adoption, implementation, and impact of clinical practices guideline.

CDC followed a rigorous process using the best, most recent scientific evidence to develop the draft guideline. CDC performed an extensive review of more than 130 of the most relevant and recent scientific studies about the effectiveness and risks of opioids and other pain treatments. CDC consulted over a dozen of the top experts in the US in opioid prescribing, addiction, substance use disorder treatment, and pain management. CDC received more than 1500 comments on the guideline before the formal public comment period. This feedback came from physicians, pharmacists, other healthcare providers, professional organizations, pain advocacy organizations, state and local health departments, and patients. CDC scientists found this input helpful in producing the draft guideline.

Given the lives lost and impacted by these issues every day, there is an acute sense of urgency to issue guidance quickly. In order to be responsive to feedback from partners to provide additional opportunities to engage, CDC posted the draft guideline in the *Federal Register* to provide a public comment opportunity. The public comment period will be open until January 13, 2016. To date, more than 1900 comments have been received from the public, and more continue to be submitted. CDC will continue to compile these comments as they are received and will make them available to the proposed workgroup and the parent BSC.

Some concerns have been expressed about the process. A great deal of work has already been done, but NCIPC wants to ensure that there will be no concern about the final guideline when they are released. As part of the response, NCIPC proposes the establishment of a workgroup under the NCIPC BSC to review the guideline and feedback that has been received from stakeholders, peer reviewers, and importantly, the public. This workgroup must include diverse perspectives of experts, stakeholders, and consumers invested in reversing this epidemic and must also be cognizant of the important need for safe and effective pain management. The intent is for the workgroup to produce a report and discuss it at the next BSC meeting for their consideration. The BSC will then make recommendations to CDC regarding the proposed guideline.

These guideline will be an important and essential step for reversing the prescription drug epidemic. NCIPC looks forward to further discussions and thoughtful guidance in working together to reduce opioid dependence, overdose, and death.

Prescribing Opioids for Chronic Pain (Guideline): Background and Guideline Process

Tamara Haegerich, PhD
Deputy Associate Director for Science
Division of Unintentional Injury Prevention
National Center for Injury Prevention and Control
Centers for Disease Control and Prevention

Dr. Tamara Haegerich introduced herself and noted that she was one of the authors of the draft guideline. She provided an overview of the development of the draft CDC Guideline for Prescribing Opioids for Chronic Pain.

Based on the public health burden and the opportunities that a guideline can offer for improving clinical practice, NCIPC decided to develop a guideline with the purpose of:

- Supporting informed clinical decision-making;
- Helping providers offer safer, more effective care for patients with chronic pain;
- Helping to reduce misuse, abuse, and overdose from opioids; and
- Encouraging improved communication between providers and patients about the risks and benefits of opioid therapy.

The primary audience of this guideline is primary care providers, such as family physicians and internists. The primary care provider audience was selected as a focus audience because approximately 50% of opioid medications dispensed are accounted for by prescriptions from primary care providers. Further, primary care providers report receiving insufficient training in opioid prescribing. They also report significant concerns about medication misuse and addiction.

The guideline is focused on providers treating patients 18 years or older with chronic pain. Chronic pain is defined as lasting three or more months, or past the time of normal tissue healing. Further, the guideline focuses on outpatient settings and settings outside active cancer treatment, palliative care, and end-of-life care. These exclusions are due to the unique therapeutic goals, ethical considerations, opportunities for medical supervision, and the balance of risks and benefits with opioid therapy in these care settings.

In creating the draft guideline, CDC followed standards for rigorous and transparent guideline development, such as those issued by the Institute of Medicine (IOM). The guideline:

- Is based on a systematic review of the evidence;
- Has been developed with input from knowledgeable, multidisciplinary experts;
- Has considered important patient subgroups and preferences;
- Is based on an explicit, transparent process that minimizes bias; and
- Has included ratings of the quality of the evidence and the strength of the recommendations.

CDC intends to revise the guideline when new evidence warrants. NCIPC used the Grading of Recommendations Assessment, Development and Evaluation (GRADE) method to develop the draft guideline. This method has been used by approximately 100 organizations, including CDC, in guideline development efforts. The current guideline utilizes the adaptation and terminology used by the Advisory Committee on Immunization Practices (ACIP). GRADE specifies the systematic review of scientific evidence and offers a transparent approach to grading quality (type) of evidence and strength (category) of recommendation.

For the systematic review, NCIPC updated a 2014 Agency for Healthcare Research and Quality (AHRQ)-sponsored systematic review on the effectiveness of long-term opioid therapy for chronic pain management. The key questions addressed in this review included:

- Effectiveness of long-term opioid therapy
- Harms and adverse events
- Effectiveness of methods for initiation, titration, and dosing
- Accuracy of risk prediction instruments and effectiveness of risk mitigation strategies
- Effects of prescribing for acute pain on long-term use (Note that this final area was an addition to the additional scope of the AHRQ review for the purpose of the current guideline.)

After updating the systematic review and addressing the additional clinical question, NCIPC categorized the type, or quality, of the evidence. The evidence was rated based on the type of studies that generated the findings, consistent with the ACIP translation of the GRADE method:

- Type 1 evidence is generally considered high-quality and consists of precise and consistent findings from well-conducted randomized controlled trials (RCTs), or an overwhelming number of high-quality observational studies.
- Type 2 evidence consists of findings from RCTs with limitations, or strong observational studies.
- Type 3 evidence consists of findings from RCTs with notable limitations, or observational studies.
- Type 4 evidence is generally considered very low-quality and consists of findings from RCTs with major limitations, observational studies with notable limitations, or clinical observations and experience.

The GRADE method was then utilized to translate the clinical evidence derived from the key questions into recommendations. To support this work, NCIPC conducted a supplemental contextual evidence review that obtained additional information from the epidemiologic literature on the benefits and harms of opioid therapy; provider and patient values and preferences related to opioid therapy; and economic information about the associated costs.

In addition, because pain management consists of practices beyond opioid therapy, NCIPC conducted a rapid evidence review of the effectiveness of alternative treatments.

Based on all of this information, CDC drafted recommendation statements. In accordance with the GRADE process, the statements were developed based on the quality of the evidence associated with specific clinical practices while weighing benefits and harms, values and preferences, and cost. The magnitude of benefits related to harms and uncertainty regarding this tradeoff impact the strength of a recommendation.

Each recommendation statement is assigned a category to indicate its strength. The labels are also used by ACIP:

- Category A recommendations are considered strong recommendations and apply to all patients. Most patients should receive the recommended course of action.
- Category B recommendations are considered weak recommendations and require individual decision-making. Providers should help patients arrive at a decision consistent with their values and preferences and specific clinical situations.

When there is greater certainty that the advantages of a specific recommendation outweigh the disadvantages, based on the evidence and other factors, a Category A recommendation is made. When there is greater uncertainty regarding the advantages and disadvantages of a recommendation, or the magnitude of benefits relative to harms is relatively small, a Category B recommendation is made. The type of evidence that supports each recommendation statement is provided. There is not a direct correspondence between the type of clinical evidence and the category of the recommendation, given the additional considerations regarding benefits and harms, values and preferences, and cost.

The draft guideline development process consisted of several additional steps after CDC conducted the literature reviews and developed draft recommendations. A group of experts was recruited to review the evidence summaries and provide individual consultation on the draft recommendation statements. This Core Expert Group was convened in June 2015. The group included subject matter experts (SMEs), representatives of primary care professional societies and state agencies, and an expert in guideline development methodology. The experts underwent a rigorous conflict of interest screening process to ensure that the risk of bias associated with their interests and activities was minimal. For transparency purposes, relevant interests that did not pose a conflict were disclosed prior to the group's meeting and in draft documents.

After the consultation with the core experts, CDC drafted the full guideline, including:

- Background and scope
- Methods
- Evidence reviews
- Recommendation statements

The draft guideline was also distributed to a range of federal partners for review. HHS operational divisions reviewed the guideline through the agency clearance process, and all divisions concurred. The recommendations within the guideline were presented during two constituent engagement webinars in September 2015. Input was received from constituents, including providers and patients. In addition to the webinars, over 1200 constituent comments were received on the draft guideline. The guideline was also peer-reviewed by three independent experts in the field. The reviewers were provided with a summary of the constituent comments.

CDC summarized the feedback from the stakeholder reviewers, constituents, and peer reviewers. CDC then revised the guideline based on the feedback and summarized the ways that the revisions responded to the feedback. To ensure that anyone who would like to comment on the guideline has the opportunity to do so, the draft was posted in the *Federal Register*. It was filed for official public comment on December 11, 2015 and was available for viewing on December 14, 2015. The comment period remains open for 30 days.

The next stage of the process is BSC engagement. BSC members have received a full copy of the draft guideline, which includes a discussion of the following:

- Background, rationale, and audience
- Development methods
- Clinical evidence review
- Contextual evidence review
- Recommendation statements

The recommendations fall into the following three areas of consideration:

- When to initiate or continue opioids, with a specific focus on the selection of opioid therapy, non-pharmacologic therapy, or non-opioid pharmacologic therapies, and assessing the risks and benefits of such therapies;
- Opioid selection, dosage, duration, follow-up, and discontinuation; and
- Assessing risks and harms of opioid use, with a specific focus on prescription drug monitoring programs (PDMPs), use of urine drug testing, considerations for concurrent use with benzodiazepines, and arranging treatment for opioid use disorder.

Discussion Points

Dr. Hargarten opened the floor for discussion from the BSC and *ex officio* members.

Dr. Sherry Lynn Hamby noted that literature that did not address non-chronic pain was excluded from the literature review. She asked if expanding the literature review to include non-chronic pain might have informed the recommendations.

Dr. Haegerich said that the clinical evidence review was focused on the effectiveness of long-term opioid therapy for chronic pain, as the guideline are intended to inform decision-making about chronic pain. The review included outcomes of one year or longer. Previous evidence reviews are referenced in the guideline that considered the effectiveness of opioid therapy in the short-term, but these reviews were not part of the systematic review. The draft guideline

includes additional information about the benefits and harms of opioids in the contextual evidence review that incorporate shorter timelines, as it is known that harms can occur before the one-year mark. The search criteria were loosened to allow for studies with shorter timelines for the contextual evidence to inform translating clinical evidence into the recommendations.

Dr. Hamby commended NCIPC for the significant effort and thought that have gone into drafting these guideline. She was further impressed with the amount of feedback that NCIPC sought from a variety of constituencies, stakeholders, and experts in the field. The guideline will be translated into document for general practitioners and other front-line providers. In general, she has been impressed with these documents released by CDC. She wondered whether some practitioners may seek more specific guidance, particularly regarding measurement and screening associated with risk of harm as well as of improvements in pain and function. She asked whether the state of the field is such that practitioners could be directed to specific screeners or assessment tools that could be realistically implemented into primary care settings and other settings, not only pain management settings.

Regarding the assessment of pain and function, **Dr. Haegerich** said that the guideline refers to the “pain, enjoyment, general activity” (PEG) scale and how to use this instrument to look for improvement. The translation documents can include information about the PEG and how to use it. NCIPC is considering the content of the translation tools, even though the guideline process is not yet complete. In addition, the guideline refers to concerns about the specificity of the risk assessment instruments and their ability to predict risk accurately. The guideline describes general factors that providers should consider in prescribing that can increase risk and how to calculate the benefits and harms of opioid therapy considering those risk factors. NCIPC envisions a translation document focusing on how to assess benefits, harms, and potential risks, highlighting key risk factors and how to talk to patients about them. The information will be provided in an easy-to-use algorithm or checklist for use at the point-of-care. Additional translation documents will address urine testing and PDMPs and how to use them.

Dr. Houry added that NCIPC looks to partners and stakeholders to collaborate on dissemination products. CDC distills the science, but the partners who apply it in the field are crucial. Checklists can be useful tools to help providers engage in conversations with patients and to ensure that patients are included in determining when to initiate opioids and how to reassess the treatment. NCIPC welcomes comments from the BSC, the public, and partners in how to disseminate these materials.

Dr. Hamby said that in the field of violence, there has been a great deal of discussion about the limitations of assessments and interventions. Until there is a realistic alternative that can be integrated into research and practice, these discussions are not likely to progress. She is based on rural Appalachia where there are limited health services and access to pain management clinics is poor. Incorporating assessments and screening into the structure and script of a primary care or emergency department context will be essential for the recommendations to be used on a widespread basis. Regarding urine testing, she asked whether the guideline imply that patients seeing primary care physicians for acute conditions should be tested before receiving pain medication.

Dr. Houry clarified that the guideline are focused on chronic pain.

Dr. Deborah Dowell agreed and said that the urine drug testing recommendation applies specifically to chronic pain.

Dr. Houry said that for acute or chronic pain, the goal is to foster a collaborative effort between patients and physicians to have conversations. Even for acute pain, opioid prescription is a time to talk about the risks and benefits of opioid treatment.

Dr. Haegerich said that it is important to think about translating this information for use at point-of-care for different providers that have different capacity, as well as different kinds of health systems. NCIPC has been thinking about how to imbed the recommendations into the health system itself in addition to guiding individual providers.

Dr. Joan Marie Duwve said that in Indiana, a toolkit is available for chronic, non-terminal pain, called "First, Do No Harm." It has not been formally evaluated, but physicians have supported the toolkit as a framework for seeing patients. The toolkit has algorithms for starting opioids, monitoring opioids, and weaning patients off of opioids who are not benefiting from them. Physicians who have not been trained in these areas can follow a flow sheet. It addresses PDMPs and urine monitoring. There was a challenge to a portion of the urine drug monitoring aspect of the toolkit from the American Civil Liberties Union (ACLU). Universal urine drug monitoring presented a violation of the right not to have unusual search and seizure. The state changed the code so that patients who receive this testing must fall under one of 18 medical indications. Dr. Duwve indicated that she would share the toolkit with NCIPC.

Dr. Wilson Compton congratulated NCIPC on the progress on guideline development as well as the rigorous approach. Partner organizations, including the National Institutes of Health (NIH), can help in implementing the guideline. NIH is interested in studies to understand how guideline are implemented and whether they have the desired effect on practice outcomes.

Dr. Houry said that NCIPC would welcome that collaboration.

Dr. Holly Hedegaard asked whether there is an intent for professional organizations to endorse the guideline. The force of these organizations could be brought to bear on the acceptance and use of the guideline.

Dr. Houry replied that such endorsement is in their plans. Some organizations have endorsed the guideline through the public comment process, while other organizations have internal processes that can take one year. The endorsement of the guideline will be part of the dissemination and translation period. Organizations can also endorse the guideline through the publication of commentaries in their journals.

Dr. Thomas Feucht observed that assembling large bodies of evidence is a Herculean task. He was interested in the balance of the standards of rigor of the evaluation and outcomes studies and the contextual studies. He asked how NCIPC feels about the ways that the two types of research are incorporated into the guideline. There is some art to compiling information from rigorous studies and contextual information.

Dr. Haegerich said that the GRADE method is particularly helpful in this area, as the method is clear about research questions, search criteria, eligibility criteria for studies, and the quality of evidence assigned to them. The readers of the recommendations can therefore clearly understand the evidence that supports them. The contextual review allows for the inclusion of information that is not in the direct clinical sphere, but that is important for clinical decision-making and that helps interpret and apply clinical evidence. She agreed that there is an art to the task of interpretation, but GRADE helps articulate the clinical and contextual evidence. The rationale statements for the recommendations identify specific clinical evidence and contextual

evidence and how they were combined to justify the recommendation. Structuring the guideline in this manner is transparent, which was NCIPC's goal with the process. There is a limited evidence base, and transparency was a critical element of the guideline development process.

Guideline: A CDC and HHS Priority

Thomas R. Frieden, MD
Director
Centers for Disease Control and Prevention

Dr. Thomas Frieden apologized for not attending the meeting in person and thanked the group for their participation. He reiterated the seriousness of the problem of prescription opioid overdose and emphasized the importance of the BSC's input to NCIPC and to CDC. Using the best available science to finalize guideline for primary care physicians regarding the treatment of chronic pain is extremely important, and the BSC's input is valuable in this process.

Opioid abuse and overdose is epidemic in the US. Overdose deaths from prescription opioids quadrupled from 1999 to 2013. In addition, prescription opioids are fueling an increase in heroin use and overdose. Heroin overdose death rates have tripled since 2010. Sadly, rates of opioid overdose deaths, including both licit and illicit drugs, continued to increase significantly from 2013 to 2014.

Addressing the prescription drug overdose epidemic is one of CDC's top priorities. Over-prescription of opiates for pain is the key driver of this epidemic. CDC believes that the epidemic can be reversed. Key areas include improving prescribing for both pain and addiction. There are definite and often fatal risks associated with prescription opiates, including addiction and deaths. Their benefits for chronic pain are largely unproven and uncertain. There is also the potential to reduce harm by increasing the use of naloxone and medication-assisted treatment (MAT) with methadone, buprenorphine, and naltrexone.

These guideline will be an important tool to improve clinical decision-making and to reduce inappropriate opioid prescribing. It is very important to get this right. Although ideal evidence is not available, this cannot wait. It is crucial to use the best available science and evidence and to gather feedback from a diverse group of experts, stakeholders, and patients to provide guideline that will support patients with pain, support their physicians, and minimize harm.

Dr. Frieden said he looked forward to reviewing the BSC's input and others' input as the guideline are finalized. He thanked the group for their participation in the process and for their valuable time.

Discussion Points

Dr. Houry thanked Dr. Frieden for his personal leadership and support on this issue, and for participating in the meeting. She said that she and NCIPC personally appreciate his leadership and guidance.

Dr. Hargarten thanked Dr. Frieden on behalf of the NCIPC BSC. The BSC values his leadership and takes this work very seriously.

Discussion: Background and Guideline Process

Stephen Hargarten, MD, MPH
Professor and Chair
Department of Emergency Medicine
Medical College of Wisconsin
Chair, National Center for Injury Prevention and Control Board of Scientific Counselors

Dr. Hargarten noted that the official agenda reserved time for discussion of the background and guideline process. The BSC had already shared constructive questions and comments on these issues. During this session, he invited the BSC members to share additional comments.

Discussion Points

Dr. Traci Green asked about the process of the clinical evidence review, noting that the review was carried out to include publications through April 2015. She asked about plans to update the literature review through the end of 2015.

Dr. Haegerich replied that there are no current plans to update the literature review.

Dr. Maria Testa perceived a “guideline” to be a recommendation that is not binding. She asked about the impact of CDC guideline.

Dr. Haegerich confirmed that CDC guideline are recommendations, not regulations, policies, or laws. CDC hopes that practitioners will adopt the guideline in their clinical practices, but there are no legal requirements associated with them.

Dr. Testa observed that insurance companies tend to utilize these guideline, as many of the comments from the public and physicians on the draft guideline expressed concerns regarding the potential lack of insurance coverage for actions that do not meet the guideline.

Dr. Haegerich said that in general, insurance companies consider a range of clinical guideline and other information in the literature. For instance, they consider quality improvement initiatives and quality metrics from other federal agencies. CDC has not made direct comments or recommendations related to insurance coverage in the draft guideline.

Dr. Houry emphasized that the guideline are intended to guide conversations between physicians and patients and are not statutory or regulatory. Partners and stakeholders, including insurance companies, will be important as CDC works on elements of the recommendations such as non-opioid treatments.

Request for Establishment of the Opioid Guideline Workgroup

Amy Peeples, MPA
Deputy Director
National Center for Injury Prevention and Control
Centers for Disease Control and Prevention

Ms. Amy Peeples shared NCIPC's thinking regarding the establishment and composition of a Prescribing Opioids for Chronic Pain Workgroup, or Opioid Guideline Workgroup. CDC values stakeholder and public engagement in a transparent, scientifically rigorous guideline development process.

NCIPC requested that the BSC form a workgroup to review the draft guideline and comments received, and present observations about the guideline to the BSC. A copy of the draft charge was provided to the BSC, which would be to:

- Review the quality of the clinical and contextual evidence reviews
- Review each of the recommendation statements and accompanying rationale
- Consider for each recommendation:
 - The quality of the evidence supporting the recommendation (i.e., the accuracy of the evidence quality rating)
 - The balance of benefits and risks associated with the recommendation; that is, the degree to which the benefit of issuing the recommendation outweighs the harms
 - The values and preferences of providers and patients related to the recommendation; that is, the degree to which there is variability or uncertainty in values and preferences
 - The cost feasibility of the recommendation; that is, the degree to which implementation is feasible for health systems and patients financially
 - The category designation of the recommendation; that is, whether Category A or Category B is justified. Category A recommendations apply to all patients; Category B recommendations require individual decision-making where different choices will be appropriate for different patients so that providers must help patients arrive at a decision consistent with patient values and preferences and specific clinical situations
- Provide a summary report of observations associated with the charge related to the Proposed 2016 Guideline for Prescribing Opioids for Chronic Pain, including points of agreement and disagreement (the final deliverable of the workgroup)

NCIPC recommended that the workgroup be comprised of 10 members and convene approximately 4 times. In seeking a balance of perspectives, NCIPC identified audiences directly affected by the guideline, audiences that would be directly involved with implementing or integrating into current practice, and audiences qualified to provide representation of a specific discipline or expertise as they align with the charge of the workgroup. The perspectives that the workgroup should include the following:

- Primary care, specifically family practice and internal medicine: these providers are the primary audience of the guideline
- Pain medicine: a discipline referred to for consultation in the guideline
- Public health: this sector issues guideline for prescribing and monitors injuries and deaths associated with prescription drugs
- Patients
- Behavioral health: patients with chronic pain can also have behavioral health conditions; behavioral pain management approaches are included in the guideline, and behavioral health specialists are referred to for consultation
- Substance abuse treatment: these providers treat patients with prescription opioid dependence and are referenced in the guideline
- Pharmacy: pharmacists dispense opioid prescriptions and are involved in the prescription drug monitoring reporting that is referenced in the guideline
- Research methods, public health research, and clinical research: these perspectives are important because a systematic review of public health and clinical research was used to inform the recommendations in the guideline, and CDC used the GRADE methodology

Two of the proposed individuals for the workgroup were on the initial Core Expert Group, and two participated on the Stakeholder Review Group. In addition, HHS requires that two members from the BSC parent committee participate in the workgroup and that one of these individuals serve as Chair.

The professional credentials and potential conflicts of interests have been carefully reviewed to minimize any undue influence on the part of the proposed workgroup members. Specifically, possible professional and personal interests were reviewed for the following:

- An existing professional obligation that effectively requires the individual to publicly defend a previously-established position within the last year on an issue that is relevant to the functions to be performed in this workgroup activity; this item could be related to controlled substances
- Having provided expert opinion or testimony within the last year, such as part of a regulatory, legislative, or judicial process, related to opioid pain relievers or associated products

- Having held an office or other position within the last year, paid or unpaid, representing interests related to opioid pain relievers or associated products
- Holding, or having a member of the immediate family holding, financial, equity, or proprietary interest in, or receiving research support from, an organization whose product or product concept is involved in the deliberation of the workgroup; competing with a product or product concept being discussed by this work group; would substantially benefit from research emphasis in a defined area (Possible conflicts could include employment; held investments such as stock, partnership, joint venture, or board membership; or consultation with an organization that was associated with opioid pain relievers or associated products, all within the last year)
- Having obtained research support such as grants, honoraria, collaborations, sponsorships, payment for manuscript development, speaker's bureau, or non-monetary support for more than \$1000 from such an organization in the last year
- Having obtained another form of financial support, such as travel, accommodations, or gifts from such an organization in the last year

No significant conflict of interest concerns were identified for the proposed members of the workgroup. Interests that might be considered to pose minimal risk were disclosed and were provided to the BSC for transparency purposes in the advance materials. These disclosures will also be included in any resulting reports associated with workgroup activities. In some instances, recusal from the discussion of specific topics is recommended due to disclosure of specific, minimal risk, interests.

The individuals being proposed and with their disclosed interests are delineated in the following table:

NAME	AREA(S) OF EXPERTISE	BIOGRAPHY	DISCLOSED INTERESTS
Erin Krebs, MD, MPH	Internal Medicine; Research	Dr. Krebs is the Medical Director of the Women Veterans Comprehensive Health Center, Core Investigator of the Center for Chronic Disease Outcomes Research, and Associate Professor at the University of Minnesota. Dr. Krebs is board-certified and practices internal medicine at the US Department of Veterans Affairs (VA). Her research interests include chronic pain management, opioid effectiveness and safety, and pain assessment.	Dr. Krebs discloses that she served on the CDC Opioid Prescribing Guideline Core Expert 1 Group.
Mitchell H. Katz, MD	Internal Medicine; Health Services	Dr. Katz is the Director of the Los Angeles County Department of Health Services, the second-largest health system in the nation. Previously, he was the Director of Health for the City and County of San Francisco for 13 years. Prior to becoming the Director in San Francisco, he served the Department in a number of positions, including Director of the AIDS Office and Director of the Emergency Medical Services Agency.	No interest to disclose.

NAME	AREA(S) OF EXPERTISE	BIOGRAPHY	DISCLOSED INTERESTS
Mark Wallace, MD	Pain Medicine	Dr. Wallace is the Chair, Division of Pain Medicine in the Department of Anesthesiology at the UC San Diego School of Medicine. He is a board-certified anesthesiologist who specializes in multi-modal pain management and practices at the UC San Diego Medical Center. Dr. Wallace is also a co-chair of the Public Health Service Delivery and Reimbursement workgroup of the HHS National Pain Strategy.	Dr. Wallace discloses that he served on a Kempharma advisory panel for an abuse-deterrent hydrocodone to treat acute postoperative pain. Dr. Wallace would be recused from any discussion related to abuse-deterrent drugs.
Gregory Terman, MD, PhD	Pain Medicine; Research	Dr. Terman is Professor and Director of Pain Medicine Research in the Department of Anesthesiology and Pain Medicine at the University of Washington Medical Center, where he practices. His research has focused on effects on the central nervous system as a result of long-term exposure to prescription opioids.	Dr. Terman discloses that he serves as the President of the American Pain Society.
Katherine Galluzzi, DO	Pain Medicine/ Palliative Care, Osteopathic Medicine, Geriatrics	Dr. Galluzzi is a Family Physician and is Professor and Chair of the Department of Geriatrics at Philadelphia College of Osteopathic Medicine. She has published on diverse topics, including management of neuropathic pain; management of opioid-induced constipation; and elders' preferences in patient-physician communication. She is certified as a Diplomate of the American Board of Hospice and Palliative Medicine and serves as a member of the steering committee of PAINS.	No interest to disclose.
Christina Porucznik, PhD, MSPH	Public Health; Research	Dr. Porucznik is an Associate Professor of Family and Preventive Medicine in the University of Utah School of Medicine. She was a co-investigator on the evaluation of the Utah clinical guideline on prescribing opioids.	Dr. Porucznik discloses that she served on the CDC Opioid Prescribing I Guideline Core Expert Group.
Penney Cowan	Patient Perspective	Ms. Cowan is the CEO of the American Chronic Pain Association (ACPA), and is a person who has lived with chronic pain. She was appointed to the Interagency Pain Research Coordinating Committee of the NIH.	No interest to disclose.
Chinazo Cunningham, MD, MS	Substance Use Disorder Treatment; Internal Medicine; Research	Dr. Cunningham is the Associate Chief of the Division of General Internal Medicine at Albert Einstein College of Medicine; the founding Director of the General Internal Medicine Fellowship Program; and the Director of Diversity Affairs within the Department of Medicine. Her research has focused on improving access to care; utilization of health care services; and health outcomes for marginalized populations, including drug users; HIV-infected individuals; and the unstably housed.	Dr. Cunningham discloses that her husband is employed by Quest Diagnostics. Dr. Cunningham would be recused from any discussion related to urine drug testing.

NAME	AREA(S) OF EXPERTISE	BIOGRAPHY	DISCLOSED INTERESTS
Anne Burns, RPh	Pharmacy	Anne Burns is Vice President of Professional Affairs at the American Pharmacists Association.	Dr. Burns discloses that she participated in a congressional briefing on the pharmacist's role of furnishing Naloxone. In addition, she discloses that she participates on the National Advisory Board for the Prescription Drug Abuse and Heroin Summit.
Traci Green, PhD, MSC	Research	Dr. Green is an Associate Professor of Emergency Medicine and Epidemiology, Brown University	No interest to disclose.

Drs. Porucznik and Green serve as NCIPC BSC members. NCIPC proposed that Dr. Porucznik serve as the workgroup chair.

Discussion Points

Dr. Hargarten thanked Ms. Peeples for the summary and commented on the diversity of content expertise represented on the proposed workgroup. The clinical specialties represented and the interests and expertise across the spectrum of public health, research, patient perspective, the VA system, and the associations that are involved in these issues make for a good and diverse group. He opened the floor for comments and questions from the BSC regarding the proposed workgroup, particularly with respect to whether a content area might be missing from the group.

Ms. Peeples added that comments and questions pertaining to the charge of the workgroup would also be helpful for NCIPC.

Dr. Gerry Gioia asked whether the literature review had identified issues related to adolescents and their associated risk factors or contribution to the opioid problem. If there is potential for adolescents to have increased risk, representation from adolescent medicine might enhance the group.

Dr. Haegerich noted that the scope of the guideline is for the treatment of patients who are 18 years of age or older, so the evidence review and recommendation statements do not have a specific focus on pediatric populations.

Dr. Shelly Timmons asked whether the group includes content expertise on surgical treatments for chronic pain. She specifically referred to neurosurgical procedures and functional neurosurgery, such as dorsal column stimulation and intrathecal narcotic pain pumps. If there is not enough expertise in this area on the group, expert opinion could be solicited in that regard.

Dr. Dowell noted that the anesthesiologist on the workgroup, Dr. Wallace, has expertise in that area.

Dr. Houry said that Dr. Terman still sees patients regularly and could have expertise in this area. In addition, Dr. Galluzzi is an osteopath who focuses on neuropathic pain.

Dr. Robert Johnson, a pediatric and adolescent specialist, thought that the workgroup may still need expertise in adolescent medicine. The problem of opioid abuse is most displayed in adults, but it frequently begins in the latter stages of pediatrics. An approach with young adults may be different from an approach with mature adults and the geriatric population. Someone with this expertise may not need to be on the workgroup, but they could seek input.

Ms. Peeples said that workgroup members have the option to call upon SMEs in a consultative manner in particular or topics arise for which the group does not have adequate representation.

Dr. Hargarten asked whether the workgroup would have an opportunity to consider additional, potentially relevant research findings that have been published since April 2015.

Dr. Haegerich said that at this time, additional literature review is not planned. The workgroup can debate and discuss whether an update is needed and appropriate.

Dr. Houry said that the guideline refer to the need for more research. It will likely be several years before sufficient robust evidence is built from rigorous RCTs to influence significant changes to the evidence review. The workgroup may choose to discuss this issue during its first meeting.

Dr. Duwve suggested incorporating obstetric expertise, given the significant population of women of childbearing age who suffer from chronic pain as well as the propensity of obstetricians to prescribe opioids, given the limitations on other nonsteroidal anti-inflammatory drug (NSAID) pain relievers.

Ms. Peeples said that specific expertise in obstetrics is not reflected in the membership of the workgroup, but a consultant could provide additional advice and input. In developing the draft guideline, NCIPC worked carefully with the National Center for Birth Defects and Developmental Disabilities (NCBDDD), which has a close relationship with the obstetric community.

Dr. Dowell added that the stakeholder review group that was involved in the guideline development process included representation from the American College of Obstetrics and Gynecology (ACOG).

Ms. Dawn Castillo suggested that the workgroup consider seeking consultation from the workers' compensation community.

In response to a question from **Dr. Angela Mickalide**, **Ms. Peeples** clarified that the workgroup serves under the parent committee of the BSC. As such, the workgroup's proposed deliverable is a report summary that will be presented to the BSC during a public meeting.

Dr. Duwve noted that one of the workgroup's charges is to consider cost feasibility. She wondered if this aspect of the charge would be tasked to the entire workgroup or whether an individual on the group has specific expertise in that domain. While the realm of insurance coverage is beyond the scope of the guideline, it would be negligent not to have those discussions in light of the focus on cost feasibility.

Ms. Peeples said that in the draft guideline, cost feasibility is defined as "the degree to which implementation is feasible within health systems and patients' finances."

Dr. Haegerich indicated that Roger Chou, the methodologist who assisted with the guideline development, will be available as a consultant to the workgroup to help with interpretation of the GRADE method and other questions. He has expertise in applying the GRADE method to cost considerations and in cost-effectiveness studies.

Dr. Compton inquired about the timeline for the workgroup to complete its report.

Ms. Peeples replied that NCIPC hopes to move as quickly as possible, given the urgent nature of the issue. The release of a *Federal Register* notice of the next public BSC meeting is expected in the coming days. The workgroup chair will plan to present the workgroup summary report to the BSC during that meeting, and the BSC will have the opportunity to discuss it and deliberate on it before making a formal recommendation to CDC.

Ms. Peeples summarized that the BSC had recommended that the workgroup seek input from additional areas of expertise, including: surgical treatment of chronic pain, adolescent expertise, obstetrics and gynecology, and workers' compensation.

Dr. Hargarten agreed and commented that the surgical treatment of chronic pain may be an alternative to opioid treatment and may not be germane to the scope of the guideline.

Ms. Castillo noted that occupational medicine falls within the purview of a primary care provider. Expertise in occupational medicine / workers' compensation will be helpful.

Dr. Hargarten noted that many of the individuals proposed for the workgroup are trained in pain medicine. They likely have contact with a variety of patients, including those with occupational-related injuries as well as others.

Dr. Green suggested consulting an individual with expertise in addiction psychiatry as well, given the guideline that are related to MAT, especially benzodiazepines.

Dr. Dowell pointed out that the workgroup does not include an addiction psychiatrist per se, but Dr. Cunningham has experience in addiction medicine and has published on MAT.

Public Comment Period

Given that the meeting was ahead of the published agenda, **Dr. Greenspan** suggested opening the lines for public comment early and allowing a longer period for comment. She suggested ending the public comment period at 12:15 p.m. to allow the BSC time for discussion and voting on the formation of the workgroup.

Dr. Hargarten agreed and reminded participants that public comments were limited to two minutes per person. He explained that the goal of the session was to gather input on the workgroup charge as well as on missing areas of expertise, some of which had already been raised by the BSC. The input from the public will inform the BSC's recommendations and vote.

Dr. Greenspan emphasized that in order to maximize the time that the public had to comment, specific questions would not be answered during this session. However, all comments would be taken into consideration during the discussion at the end of the meeting.

The line was opened for public comment at 11:14 a.m.

Dr. Christopher Shahar
Health First Family Care Center

Dr. Christopher Shahar practices at a Federally Qualified Health Center (FQHC) in Southeastern Massachusetts. The overdose epidemic in the region has attracted attention from the governor and the department of health, to the extent that there has been a general call and orders for equipping Emergency Medical Services (EMS) providers with naloxone. In compliance and cooperation with guideline, standing orders are being developed with local pharmacies for prescription of naloxone for those with opioid medication. Given the FQHC population, with its large prevalence of complex patients, mental health co-morbidity, and general deficiency in available mental health and addiction services, he asked whether there might be an emphasis on the handling of opioid prescribing and its interface with buprenorphine naloxone in this type of setting and/or service population.

Terry Smith
Individual

Mr. Terry Smith is a chronic pain patient who has had 21 neurological surgeries and procedures. He echoed his appreciation for the work completed so far. He respectfully disagreed with Dr. Frieden's statement that there is no evidence of the benefit of opioids for those who suffer. Opioids are the only thing that have helped him with the chronic pain that he has lived with for 15 years, in times when his pain level is "off the chart." His pain is currently managed by a local pain management group. Each month, a urine sample and a five-page questionnaire are required by the group. The group also counts his pills, and they will end their treatment of him if the count is inaccurate. He is by no means addicted to the opioids. A nurse practitioner recently told him that it was a good thing that other patients aren't as serious about their pain management, or else they would not have a job. Opioids are one tool in his tool chest. Medication is another tool. Opioids work for him, but they are not perfect. He expressed concern that the discussions are focused on opioid reduction, where a larger perspective is needed on a cure for pain and establishment of a "pain society." Instead of focusing on one simple aspect of pain, broader work needs to be done.

William Dowery
US Citizen

Mr. William Dowery said that the medical community needs guidance from CDC regarding opioid prescribing. There is an epidemic of addiction and overdose. Guidance on duration of opioid use is also required. Excessive quantities are frequently prescribed for acute pain, even when fewer than three days of medicine would have been sufficient. Dosing guidance is also required, as high doses increase the risk of overdose, deaths, and other adverse effects. He recalled that two years ago, when his wisdom tooth was pulled, he asked the dentist about pain from the procedure. Before he pulled the tooth or knowing whether Mr. Dowery would be in pain, the dentist said that he would prescribe Percoset®. Mr. Dowery asked why the dentist would not prescribe ibuprofen and have a discussion about further measures if he was still experiencing pain. The dentist's "go-to" response was to prescribe the opioid. Mr. Dowery has attended multiple funerals of people who have been lost to this epidemic. He urged that these guideline be approved as soon as possible to reduce the amount of addiction and overdose deaths.

Dr. Greenspan respectfully reminded the public speakers that verbal comments should only be shared related to the formation of the Opioid Guideline Workgroup. There will be opportunities to provide comments on the guideline themselves at a subsequent BSC meeting. The date and time of that meeting will be published in the *Federal Register* in the next few days. The public comment period on the draft guideline will be open until January 13, 2016.

Kristen Ogden
Families for Intractable Pain Relief

Ms. Kristen Ogden is a patient advocate and the co-leader of a new group, Families for Intractable Pain Relief. Her husband is a long-term, intractable pain patient. She expressed concern that the needs and requirements of intractable pain patients many not be adequately represented in the nominees for the workgroup. Intractable pain patients are the population of chronic pain patients for whom all standard therapies have already failed. Many people have failed non-opioid care and non-pharmacological therapies. These people rely on opioid medication to have a good quality of life. Despite the lack of high-quality evidence, which is preferred, opioid medicine use in the long-term can be very effective. Her husband is 65 years old and has been on high doses of opioid pain medication for the last five years, which have been the best five years of his adult life. He has gained significant quality of life and functionality without any increase in his required dose. Therefore, to address a significant gap in the viewpoints represented in the development of these guideline, she suggested including a clinician with many years of hands-on experience treating this difficult population of patients who require opioids, at times at higher doses than referenced in the draft guideline, to maintain a good quality of life.

Kim Miller
Fight for Florida Pain Care Action Network

Ms. Kim Miller has been a pain patient for many years. Her regimen of maintenance dosage of opioids does not have to be increased. She did not feel that the committee represents people who are on a maintenance dosage of opioids who have maintained a better quality of life as a result of the opioid treatment. These patients pass their drug tests and pill counts, and they have monthly reports to show that they are not “doctor shopping.” They are doing just fine despite official reports. She has been through all of the tests and therapy and has tried it all. She does not want to take opioids, but without them, she would sit on the couch and do nothing. She expressed her hope that the workgroup would include someone to represent this perspective, such as Dr. Forest Tennant, a PharmD, or Dr. Jeffrey Fudin.

Margaret Cogger
Individual Patient

Ms. Margaret Cogger asked whether the panel would include a person with experience with excruciating pain throughout their lives and who is on narcotics and does not abuse them. She was diagnosed with severe interstitial cystitis (IC) 16 years ago. At that time, she was a nurse, and she had to quit her job. She expressed her hope that someone like her, a patient, could participate on the panel.

**Sherry Harris
Individual**

Ms. Sherry Harris agreed. She has been a chronic pain patient since 2001. When the US Drug Enforcement Administration (DEA) changed the laws on what can be prescribed, her quality of life went from an 8 to a 2, and it has remained a 2. She has fibromyalgia, and there is no relief other than opioids. She has tried spinal blocks and physical therapy. She has no quality of life without medication and is afraid that she will end up with no life.

**Eric Collie Salla
PMTA Greenwoods Terminals**

Mr. Eric Collie Salla asked about opportunities for representatives from private industry, such as maritime transportation or the manufacturing sector to be considered for consultation to the workgroup or, at a minimum, to offer observations or opinions regarding day-to-day opioid use and its possible effects in the workplace; or whether such input will be assigned via the public comment venue.

**Ashley Walton
American Society of Anesthesiologists**

Ms. Ashley Walton asked about the process by which the proposed workgroup members were selected. She asked whether there would be a *Federal Register* comment period following the workgroup's report, and whether any outside expertise sought by the workgroup would be posted in the *Federal Register* and opened for nomination.

**Cammie Lavalle
RSD and Fibroid Advocacy**

Ms. Cammie Lavalle observed that the workgroup lacks representation from the rare disease community, which is concerning. She suggested seeking out the National Organization of Rare Disorders (NORD) for input or expert opinion, given the approximately 7000 rare diseases. She has a rare disorder known as Reflex Sympathetic Dystrophy (RSD)/Complex Regional Pain Syndrome (CRPS). Per the Mayo Clinic and the University of Minnesota, highly-respected medical facilities, her only option is opiate pain management. She was concerned that the workgroup should include persons with expertise in Ketamine, Calmare Pain Therapy Treatment[®], intravenous immunoglobulin (IVIG), or any of the alternative treatments that are being proposed prior to the use of opiate medication. She also wondered whether anyone on the panel is aware of what RSD/CRPS is.

**Sheryl Akopian
Individual**

Ms. Sheryl Akopian is a chronic pain patient. She is allergic to morphine and cannot take related medications. As stated by other commenters, when the laws lowered their dosages, her life has gone downhill. Regarding the workgroup, she expressed hope that a number of chronic pain patients would be included, as well as representatives from the police or judges. These efforts seem to be targeted at chronic pain patients who do not abuse their medications, and who have to have their medications. The discussions have not addressed abusers, the addicted, or criminals who are stealing. The President is releasing these criminals from jail early, so heroin will be back on the street sooner than it should be. Taking away a legitimate

pain patient's medication is harmful and is against the 8th Amendment. The stress of this issue is making pain patients' conditions worse. She said she hoped to hear more about what will be done about illegal drugs.

Lorinda Wood
Fight for Florida Pain Network

Ms. Lorinda Wood is a workers' compensation patient. She said she hoped that the workgroup would address this group of patients, who did not want to get hurt and did not want to be put in this position. She was in a boot cast for one year and in a cast for another six months, and the damage it did to her body was devastating. She is on the same dosage of pain medicine that she started with five years ago. She does not abuse it. She cannot function without help. The pain, stress, and quality of life "is killing us." These patients are not the problem in America. Workers' compensation needs to address and fix people quicker so that there might not be as many people in this situation.

Janet Colbert
STOPP Now

Ms. Janet Colbert is a neonatal nurse who cares for drug-addicted babies. She started the group Stop The Organized Pill Pushers Now (STOPP Now). The workgroup does not seem to include representation from an advocacy group that has witnessed the harm of opiates. This perspective could shed light on possible solutions, such as legislation. She lives in Broward County, Florida. This is the epicenter of this whole epidemic, which was created by the greed of physicians and drug companies. Legislation is needed. A possible group for representation could be Physicians for Responsible Opioid Prescribing (PROP). There are plenty of pills available for the people who need them, but the problem must be solved. The parents who lose children and the heroin addicts who started with an innocent pill from the drug companies should be considered.

Maureen Killian
Scared Straight Florida

Ms. Maureen Killian said the guideline being developed are a great start, but the acute pain problem must be addressed. Chronic pain begins as acute pain, which is the initiation of the opioid. We are past urgency in this matter. Physician communities should consider urgent action in co-prescribing naloxone with every opioid. This approach opens a conversation with the patient and physician, allowing the physician to rethink the prescription. It also provides for informed consent. She suggested that the workgroup consider that the state medical boards, which regulate medicine in each state, take too long. Urgency is needed. There can be no more accidental overdoses in patients who were legally prescribed opioids. DEA licenses could mandate physician re-education and the PDMP. She was concerned that the public is under the impression that this epidemic is about abuse. Abuse is not the biggest problem. In fact, the biggest problem is taken-as-prescribed, narcotic dependency. This point is agreed-upon across chronic pain patients who become physically and psychologically dependent on the medications and then display aberrant behaviors. This language change is needed to educate the public that this is a taken-as-prescribed epidemic with abuse.

**Eryn Kahler
Individual**

Ms. Eryn Kahler is an intractable chronic pain patient. She has had chronic pain for 20 years and has only recently been given opioids to help her pain because she refused to be on medication. Her doctor told her that she would not be able to live or walk without limping and crawling. Her doctor forced her to go on opioids because everything she was given did nothing to touch the pain. Her doctor put her on a pain contract and did everything that should be done. She tried every other kind of medicine and treatment to try to help her for 20 years, as she has two rare chronic pain diseases that nothing can help or treat. She got these conditions as a young adult. She said that the fact that this group of people is not represented on the workgroup is gross negligence. Chronic pain patients are not abusing these drugs. They are a last resort for all of them.

**Michelle Harford
US Pain Foundation**

Ms. Michelle Harford said that there is a true epidemic in the US of drug abuse and related deaths. There is also an epidemic of chronic pain sufferers for many different reasons, such as an accident or a disease that sets in. She has several conditions herself and is very concerned not only about the epidemic of drug abuse, but also the epidemic of chronic pain. It is stressful to observe. There needs to be more education on mental health, especially with people who are prone to addiction and are set up in families for addiction, as well as families who are set up for chronic illness. Both sides of the story are valid and need to be addressed. There must be a happy medium. It does not have to be a “dogfight” between addiction and chronic pain sufferers. Adults and children are suffering from addiction and from chronic pain. People with chronic pain should not be treated as if they are automatically going to be addicts.

**Kenneth McKenna
Chronic Pain Patient**

Mr. Kenneth McKenna lives in Florida. He is a veteran and a chronic pain patient. He understands all of the concerns and the complicated, wide scope of the issues. There have been pill mills in Florida, with addicts to support them. The VA hospitals are now being affected, and veterans are suffering and scared. He said he hoped that the guideline would not force desperate people into desperate measures. He asked that they be considered when making these guideline. He said he hoped that the guideline would help the situation and do what they should do.

**Mary Mills
Individual**

Ms. Mary Mills was recently diagnosed with CRPS. It is getting worse as time progresses. She has found that the only way to have quality of life is with an opioid pain patch. She cannot move without it. She is concerned that these guideline will affect how her insurance perceives this situation. She recognized that CDC stated that the guideline should not affect insurance, which takes other factors into account, but insurance ignores many of those other factors. Based on her own research, she disagreed with the comment that there is no evidence of opiates helping patients with chronic pain. She suggested that there should be at least one or two patients on the workgroup.

**Howard Techau
Individual**

Mr. Howard Techau has been a chronic pain sufferer for over four and a half years. It does not seem like patients, especially rare disease patients, are well-represented on the workgroup. He recommended adding individuals from the Pain Association, the US Pain Foundation, or any of the foundations that support fibromyalgia or RSD. People are needed to give the perspective of the patients' lives on a daily basis.

**Patricia Bruckenthal
Pain Action Alliance to Implement the National Pain Strategy**

Ms. Patricia Bruckenthal represents the Pain Action Alliance to Implement the National Pain Strategy (PAINS) and also is the past president of the American Society for Pain Management Nursing® (ASPMN®). She is an Associate Professor at the Stony Brook School of Nursing and a Nurse Practitioner who has cared for patients with chronic pain for the past 25 years. The most important aspect to membership on the committee is that it should include the voices of patients who suffer with pain, and of the clinicians who care for them. The workgroup is focusing on prescribing opioids, but the CDC recommendations state that opioids should not be used as a first line of defense. As a practicing clinician, she is frustrated not to be able to provide services such as cognitive behavioral therapy, for which she is trained, due to reimbursement issues. Her patients and fellow practitioners are frustrated as well. It may be important to hear from insurance carriers that can help with the dual crisis that this country faces. She observed that the proposed workgroup members represent a broad scope, including patient advocates. She said she hoped that there would be a plan for workgroup members to reach out to other clinicians and persons in pain to collect their critical perspectives.

**Lynne Wilburn
Patient**

Ms. Lynne Wilburn has had RSD/CRPS for over 20 years. She had a career as a paralegal, but after an industrial accident, she has been on opioids for over 20 years. She cannot take other medications, and most of them had not been invented when she started needing them. She expressed concern at leaving levels at 100 mg patient. She is slightly tall and has a maintenance dose of over twice that amount. She does not understand how to set a level without taking an individual's metabolism, lifestyle, and tolerance of the drugs into account. All patients cannot be on the same dose and have an effective result. Insurance will not cover Ketamine. Many patients could be off of opioids if they had help getting Ketamine.

**Kelly Lloyd
Fight for Florida Pain and Care Action Network**

Ms. Kelly Lloyd said that there needs to be an opioid lifeline for intractable pain patients where no other modalities have worked. Sometimes, high doses of opioid medication may be required. A person needs to be included on the workgroup who speaks for these patients. She suggested Dr. Forest Tennant, a primary care physician and public health physician who has an intractable pain clinic in California. He has dedicated his practice to pain management and clinical studies for those for whom no other modalities have worked. She also suggested Dr. Jeffrey Fudin, a professor of pharmacy Diplomate to the American Academy of Pain Management and an Associate Professor of Pharmacy Practice at Western New England University College of Pharmacy. He has conducted extensive research on the effects of long-

term, high-dose opioid medications. This subset group of patients, for whom nothing else has worked and who have been on high and less-high doses of opioid medication, needs to be addressed within the workgroup.

Twinkle Zanfleet
Tower of Pain Foundation

Ms. Twinkle Zanfleet said that early intervention can minimize chronic pain from developing, even before it begins. As the workgroup is built, she said she hoped that they would not lose sight of both sides of the epidemic and the intractable pain patients.

Cheryl Dwyer
Individual

Ms. Cheryl Dwyer said she hoped that a workgroup representative such as herself would be considered. She is the mother of an 18-year-old chronic pain patient who is being neglected. If she presented as an addict, she would receive more compassion and more medical help than she does as a chronic pain patients. Her doctors are afraid to prescribe medication to help her and have apologized to the family. She recently had her fifth spine surgery. It was confirmed that the epidural injections have caused her more harm, with lesions all over her spinal nerve, because the decision was “process over patient.” Her pain doctor gave her injections rather than helping her with a low dose of opiates that would have helped her spine. Doctors should not be afraid to prescribe. Ms. Dwyer’s daughter is not an addict. She is going to nursing school. She is grateful to have found a doctor who can help her and lessen her pain, although the pain will never go away.

Jan Chambers
National Fibromyalgia and Chronic Pain Association

Ms. Jan Chambers expressed her hope that the workgroup, which seems to be focused on the serious problems on both sides, will define terminology such as “dependence.” People with chronic conditions such as diabetes or multiple sclerosis depend on their effective medications. So do chronic pain patients. If those medications are opioids, then dependence on them is not an addiction. She also asked that the workgroup consider making recommendations for integrated treatments that also have low-quality evidence, since chronic pain is not going away and must be treated and cannot be ignored. An integrated treatment opportunity may allow for coverage by insurance companies, but they need to be accompanied by recommendations from an agency such as CDC. Patients who have failed the available non-opioid treatments need to have a strong voice in the guideline. They have been maligned, and the stigmatization toward them is rampant. The media feeds into this situation so that people who have chronic pain and their doctors have been afraid to speak up. There are not “plenty of pills” for patients. There are many barriers for them to overcome to have access to them when their doctors are willing to prescribe them. Doctors do need guideline and help. She said she looked forward to additional opportunities for public comment after the workgroup completes its work.

Judy Rummler
Steve Rummler Hope Foundation and Fed Up Coalition

Ms. Judy Rummler pointed out that one group of patients who can never be represented on the workgroup is the group of over 200,000 people whose voices have been silenced by this epidemic. They did not want to die, but most of them died as a result of over-prescribing of

opioids. It is wonderful that pain patients can participate and make comments, but the workgroup and CDC must consider those who have been lost to the epidemic as they write these guideline.

Oxana Pickeril
HealthyWomen.org

Dr. Oxana Pickeril serves as the Board Chair of HealthyWomen.org, a leading national health communication nonprofit that is focused on engaging women as healthcare decision-makers for themselves and their families. Comments from the BSC indicate that the recommendations may include improving communication with providers and consumers. She suggested that the impressive clinical expertise on the workgroup could be enhanced by the addition of a health communication professional. HealthyWomen.org can recommend specific names if needed.

Ginny Resaconske
Individual

Ms. Ginny Resaconske is a chronic pain patient of many years, since experiencing childhood trauma. She has been on the same dose of opiates for nearly 30 years. She has a board-certified pain doctor and is drug tested every month. Her drugs are locked up. She understands the need for something to be done, as she has been asked for her pain medication. People have tried to get her medication, and her husband picks up her medication at the pharmacy. While she appreciates the need for action, addicts have these behaviors, not chronic pain patients. She has tried every modality available for pain, and nothing has helped. She needs the opiates to maintain her sanity and to stay alive. It is important to be considerate of the many patients who are doing the right thing and are not problematic. She asked that the problem be about addiction and not about medical dependence.

Jennifer Drewsa
Arachnoiditis

Ms. Jennifer Drewsa is a chronic, intractable pain patient with arachnoiditis. She is a 41-year-old mother who previously refused opiates, but they give her a quality of life so that she can be a mother to her children. She suggested that more people other than doctors should be on the workgroup. The pain management specialist and anesthesiologist she sees is becoming afraid to prescribe what Ms. Drewsa needs to function, and it is not high-dose. She takes other forms of pain management. She had four spinal surgeries, one of which was thoracic and left her with epidural fibroids encasing the nerve root. Arachnoiditis progresses with more invasive procedures. Every time she has a surgery or an injection, she gets worse. She said she hoped to see more pain patients from different diseases that cause pain, and who need opiates for quality of life, represented.

Paula Lopez
National Pain Report

Ms. Paula Lopez agreed. She also sees a doctor for chronic pain. Before the doctor would treat the pain, a psychiatrist evaluation was required to make sure Ms. Lopez would not abuse. She understands both side of the issue, having lost two brothers and a sister to heroin overdose. They did not start on pain pills. Heroin addiction does not always start with pills. Without her doctor and the prescribed opioids, Ms. Lopez would not be able to function. She sympathizes with those who have lost a loved one because of opioids. She tried not to take

opioids because she was afraid she would start taking heroin. She asked that the workgroup include someone who understands addiction and abuse, as well as someone who understands doctors and pharmacists who are afraid to prescribe the medications or to fill the prescriptions. Patients with chronic pain are too ill to suffer.

Diane Gracely
Pain Advocates

Ms. Diane Gracely said that the goal of the CDC guideline is to reverse the prescription drug epidemic. This is inhumane to chronic pain patients, and the voices of chronic pain patients need to be heard by CDC and DEA. She is an Ambassador for the US Pain Foundation to advocate and help other chronic pain patients to fight for their human rights to opiate pain medication. By reversing the prescription drug epidemic, more patients will be pushed to the streets for drugs, causing more suicides. She would like to see members in the workgroup from foundations and organizations such as the Muscular Dystrophy Association (MDA), the Charcot-Marie-Tooth (CMT) Disease, and others. CDC is targeting opiates, which are legal drugs. The targets should be heroin, cocaine, and methamphetamines. Opiates are a last resort for pain patients, who have been through physical therapy, injections, and surgeries. The guideline are affecting their health insurance as well. Because of CDC and DEA, doctors and pharmacies are losing their licenses. Chronic pain patients are continually going through urine and blood tests to make sure they are not abusing or selling their medications. She has suffered with chronic pain for 46 years, having been diagnosed with CMT disease at age five. Her feet were reconstructed so that she could walk. She was hit by a drunk driver in April 2015 and suffers with chronic back and neck pain. The workgroup needs patients to be involved to hear their side.

Karen Year Gain
Cook County Health Department

Ms. Karen Year Gain has been a nurse for 36 years and a public health nurse for 28 years. She has been a chronic pain patient for 5 years, 4 months, and 10 days. Her pain came on overnight. In this work, opiate prescription drugs are called "the problem." However, nobody can say how much of the problem is heroin, versus illicitly acquired opiates, versus legally prescribed opiates. There are prescribable opiates that are legally prescribed, and there are those opiates that have been illegally acquired from diversion and from the black market, never having passed through the appropriate venues. All efforts focus on intended consequences, but there are unintended consequences. Chronic pain patients and the doctors who are willing to treat them holistically, including the possibility of opiates, could suffer as an unintended consequence. Doctors are afraid to deal with complex pain patients. They are being charged with crimes, and their lives are being ruined. She expressed hope that the workgroup would consider prescribable opiates versus what has been legally and illegally acquired. Pain patients should be represented. Opiates can work in the long-term, and dependence does not equal addiction.

Sandra McBee
Individual

Ms. Sandra McBee agreed that the workgroup should include patients. She received her first opiate prescription when she was eight years old. She has muscular dystrophy, rheumatoid arthritis, osteoarthritis, and several autoimmune disorders. A 120 mg dose does not help her. There was a time when she was not compliant, but she now has a doctor she likes and she no

longer takes another medication that caused hypermetabolism of the opiate. However, she has dropped out of school and she has other physical problems due to the 120 mg limit. She likened this situation to a quote from the movie *Good Will Hunting*, “Don’t suppose you know anything about love simply because you read Shakespeare.” Nobody has any business prescribing opiates unless they have taken them. In many of the overdoses, people are taking the opiates in combination with other medications and alcohol. Many of them are not overdoses, but suicides from not receiving sufficient pain care.

Gary Mendell
Shadowproof

Mr. Gary Mendell lost a son because of addiction to opiates. He thanked everyone on the call, CDC, and the workgroup for their work. As in any situation, some things are facts, and some things are opinions. Taking a step back and looking at “the big picture,” there are clear facts. The US has a current epidemic that is growing dramatically. There is no question that the epidemic is being driven by the over-prescribing of prescription pain medication. He has read every word of the draft guideline, which were well-written and well-prepared. The vast majority of comments made on this call today would not be affected by the current guideline as they have been drafted. The guideline do not take medication away from the many people who need and deserve it. Despite the number of comments on the call from patients who need pain medication, the guideline as drafted do not affect them. He strongly urged the workgroup to strengthen the first recommendation by listing chronic conditions for which opiates should be avoided. He strongly urged the workgroup not to revise the fifth recommendation related to dosage and not to revise the sixth recommendation related to duration of dosage. He also urged that the workgroup include the perspectives of parents who have lost children to the epidemic.

Denise Molohon
ASAP Chronitis Society for Awareness and Prevention

Ms. Denise Molohon said that some of the qualifications for participation on the workgroup may eliminate some of the country’s best experts in the field of opioid prescribing for severe chronic pain disease. These areas need to be addressed either with expert consultation or on the workgroup itself. One of the experts is Dr. Forest Tennant and the other is Dr. Jeffrey Fudin. Dr. Fudin is a leader in the technology for urine drug testing, which has been a significant issue for doctors in opioid prescribing. He has a great deal of knowledge in the science and technology software. Dr. Tennant offers expertise in many areas, one of which is often overlooked—genetic cytochrome P450 oxidoreductase deficiency. She said she hoped that Dr. Tennant would be consulted in that area. He has been appointed by two former presidents to serve in capacities offering his expertise in pain management and has consulted with the US Food and Drug Administration (FDA), DEA, the National Football League (NFL), and has authored over 300 scientific articles. In addition, the patient community should be represented to a greater degree on the workgroup. She said she appreciated that there is one proposed patient representative on the group and expressed her hope that more people, including patients and families, would be invited to consult the workgroup.

The public comment period closed at 12:19 p.m.

Discussion and Vote

Stephen Hargarten, MD, MPH
Professor and Chair
Department of Emergency Medicine
Medical College of Wisconsin
Chair, National Center for Injury Prevention and Control Board of Scientific Counselors

Dr. Hargarten expressed his gratitude to all callers for their comments and opened the floor for discussion from the BSC. He asked Ms. Peeples to begin the conversation by noting themes and patterns that emerged from the comments.

Discussion Points

Dr. Greenspan thanked everyone for their comments and appreciated the diversity of comments received.

Ms. Peeples added her thanks and appreciation for the personal stories shared by the public commenters, recognizing that they have extensive personal experiences and perspectives which are impactful to CDC. NCIPC appreciates the impact that pain has had on the commenters and their loved ones, and their passion regarding these issues. NCIPC appreciates that the commenters shared their insights and thoughts. CDC hopes that the guideline will increase clinician awareness and comfort regarding treating pain as effectively and safely as possible. NCIPC agrees that it is critical to have representation on the workgroup from a pain patient and family member. For this reason, Penny Cowan has been nominated to serve as a member of the workgroup. In addition, NCIPC feels that it is important to capture the perspectives of family members and caregivers. While medical history was not one of the elements required for disclosure in the conflict of interest forms, Ms. Peeples has permission from Ann Burns to share that her husband suffers from severe chronic pain. In addition to her professional credentials, she brings the perspective of a care provider.

Dr. Hargarten reflected on the theme in the comments pertaining to the need for the workgroup to include the perspective of a practicing clinician. Workgroup nominee Dr. Mark Wallace is an active clinician who manages chronic pain patients.

Ms. Peeples added that nominee Dr. Terman is also a practicing clinician. **Dr. Dowell** added that Drs. Krebs and Cunningham, both nominated to serve on the workgroup, are also practicing clinicians. **Dr. Houry** noted that Dr. Galuzzi is a practicing clinician as well. A total of five practicing clinicians in pain management are nominated for the workgroup.

Dr. Hargarten noted that several of the public comments emphasized the need to assure adequate representation of those who are actively involved in the prescriptions of opioids for chronic pain management and in managing patients with chronic pain. It appears that the theme is represented in the current proposed composition of the workgroup.

Dr. Hamby commented on the specific recommendations proposed during the public comment period for representation from various foundations that represent patients with different diseases. She said that the question of whether the needs of patients with different diagnoses are adequately represented with the number of patient advocates who are currently proposed for the workgroup should be considered. Another theme that emerged in the public comment period is the representation on the workgroup of the perspective of survivors—people who have overdosed. Reviewing the specific individuals who are recommended and their expertise would be a useful step.

Dr. Houry indicated that the individuals who were specifically recommended in the public comment period were among several of the names reviewed. After the robust conflict of interest process, conducted in accordance with CDC Management Analysis and Services Office (MASO) policy, NCIPC elected to nominate the presented individuals for the workgroup as representatives of pain medicine and other specialties. Regarding additional family members and pain foundations, those perspectives can be gathered through the public comment mechanism in addition to using them as consultants for the workgroup. More than 1900 public comments on the draft guideline have been received to date, and the comment period is not yet over. The amount of feedback is high, and the feedback and stories from different groups have been fantastic. The ACPA is represented on the proposed workgroup, and input from other foundations is welcome through the public comment process. NCIPC is assembling a list of consultants and experts who the workgroup can choose to tap into regarding specific issues, such as daily maintenance.

Ms. Peeples commented on another theme in the public comment—individuals who deal with intractable pain. NCIPC agrees that this perspective is important to bring to the discussion, and proposed workgroup member Dr. Wallace has expertise in this area.

Dr. Houry said that the list of potential consultants can include members of the Stakeholder Review Group, such as representatives from the American Academy of Pediatrics (AAP), ACOG, the American Society of Addiction Medicine (ASAM), and others. NCIPC will reach out to these organizations and other specialties suggested today to ensure that consultants are available for additional consultation, should the workgroup request it.

Dr. Hargarten noted that there were many public comments about including patient advocates on workgroup, but there is such a representative proposed for the workgroup. He wondered if this representation went unnoticed by the callers, or whether BSC believes that there should be another patient advocate in addition to the one who has been nominated. It seems reasonable to have a strong patient advocate on this workgroup. He asked the BSC whether they thought another was needed, or if the proposed composition seemed adequate.

Dr. Hamby recommended including another person who can represent the voice of the advocacy community and the patient community. In other CDC workgroups on which she has served, it is typical for as many as one-third to one-half of the members to represent advocacy groups. These individuals are not researchers or clinicians. Even though more of the callers to the public comment period were individuals who have been diagnosed with chronic pain ailments, representing the survivor community and the needs of people with addiction is also important. She asked whether any of the currently proposed nominees has expertise in these issues.

Ms. Peeples reminded the BSC that the proposed representatives of the workgroup were aligned with the charge of the workgroup. The proposed composition strikes a balance based on what the workgroup is being asked to do. This approach is one reason why a single person may represent multiple areas of expertise.

Dr. Johnson emphasized that the composition of workgroup should be appropriate for its charge. If the charge of the workgroup were more related to awareness and similar issues, then more representation from the advocacy community might be needed. It is important to remember that there will be opportunity to comment on the work of the workgroup in the future. The workgroup will consider the draft guideline and determine whether they are appropriate, given the workgroup's charge. The voices of patients and advocates are compelling and important, but those voices may need to be heard at a different point in the process as opposed to specifically at this juncture.

With no additional thoughts or comments from BSC members, **Dr. Hargarten** entertained a motion regarding the Opioid Guideline Workgroup.

Motion: Establishment of the Opioid Guideline Workgroup

Dr. Robert Johnson moved to approve the establishment of the Opioid Guideline Workgroup with the proposed composition as presented by NCIPC. **Dr. Shelly Timmons** seconded the motion.

Discussion Points

Dr. Hamby preferred to table the motion until the BSC meets in person and the recommendations that were made during this meeting could be reviewed by the committee creating the slate of workgroup members.

Dr. Johnson asked whether there would be an option to add members to the workgroup at a later time, or whether its membership would be closed after the BSC vote.

Dr. Hargarten answered that if the BSC voted to approve the current workgroup, it would be created with the proposed composition. The workgroup will have opportunities to make consultations and obtain additional input as described earlier.

Ms. Peeples suggested that a BSC member could modify the motion to move forward with the establishment of the workgroup, provided that CDC reaches out to the additional areas of expertise recommended to the workgroup to request consultation services.

Amended Motion: Establishment of the Opioid Guideline Workgroup

Dr. Shelly Timmons made a friendly amendment to the previous motion, adding that the BSC accepted the members of the workgroup as presented, but encouraged and requested that the workgroup solicit additional membership and outside expert consultants as needed in the future.

Dr. Houry clarified the difference between consultation and membership. Additional membership would change the constitution of the workgroup. Consultation would entail hearing the expertise of consultants from the different disciplines recommended, such as interventional

medicine, pediatrics, obstetrics and gynecology, persons who have lost a loved one to opioid overdose, and workers' compensation and occupational medicine.

Dr. Duvwe asked whether the amendment was requesting consultation, or encouraging the workgroup to request consultation. She favored including a request for consultation.

Dr. Hamby also favored including a request for consultation. She felt that the BSC should also include encouragement to add additional workgroup members as necessary.

Dr. Feucht pointed out that the proposed actions were different. One encouraged or required consultation, and the other encouraged or required membership.

Dr. Johnson clarified the amendment. Encouraging consultation with other groups and areas of expertise is appropriate; changing the composition of the workgroup is not appropriate. **Dr. Timmons** agreed with the clarification.

Amended Motion: Establishment of the Opioid Guideline Workgroup

The amended motion, moved by **Dr. Robert Johnson** and seconded by **Dr. Shelly Timmons**, was to establish the Opioid Guideline Workgroup with the composition as presented by NCIPC and to encourage outside input as appropriate. The motion carried with, 1 opposed.

Conclusion and Adjourn

Stephen Hargarten, MD, MPH
Professor and Chair
Department of Emergency Medicine
Medical College of Wisconsin
Chair, National Center for Injury Prevention and Control Board of Scientific Counselors

Dr. Hargarten thanked NCIPC for the opportunity for the BSC to provide input regarding the Opioid Guideline Workgroup. The BSC looks forward to hearing the workgroup's report.

Dr. Greenspan reminded BSC voting and *ex officio* members to send an email to confirm their attendance. She thanked Dr. Hargarten for chairing the meeting, and the BSC members and *ex officio* members for their participation. She thanked the members of the public who called in and participated in the meeting.

Motion: Meeting Adjourned

Dr. Robert Johnson moved to adjourn the seventeenth meeting of the NCIPC BSC. **Dr. Samuel Forjoh** seconded the motion. The meeting adjourned at 12:42 p.m.

Certification

I hereby certify that to the best of my knowledge, the foregoing minutes of the January 7, 2016 NCIPC BSC meeting are accurate and complete:

3/2/16
Date


Stephen Hargarten, MD, MPH
Chair, NCIPC BSC

DRAFT

**Attachment A: Meeting Attendance****BSC Members**

Joan Marie Duwve, M.D., M.P.H.
Associate Dean for Practice
Indiana University

Samuel Forjough, MD, MPH, DrPH, FGCP
Department of Family and Community Medicine
Texas A&M Health Science Center College of Medicine

Gerard Gioia, Ph.D
Chief, Division of Pediatric Neuropsychology
Children's National Medical Center

Sherry Lynne Hamby, PhD
Department of Psychology
Sewanee, The University of the South

Stephen Hargarten, MD, PhD
Professor and Chair
Department of Emergency Medicine
Medical College of Wisconsin

Robert L. Johnson, M.D.
Dean, University of Medicine and Dentistry
New Jersey Medical School

Angela D. Mickalide, PhD, MCHES
Executive Director
Emergency Medical Services for Children's National Resource Center
Children's National Medical Center

Sherry D. Molock, PhD
Associate Professor
Department of Psychology
The George Washington University

Christina A. Porucznik, PhD, MSPH
Assistant Professor
Department of Family and Preventive Medicine
University of Utah

Maria Testa, PhD
Senior Research Scientist
Research Institute on Addictions
University at Buffalo

Shelly D. Timmons, MD, PhD, FACS
Director of Neurotrauma
Department of Neurosurgery
Geisinger Medical Center

Ex-Officio

Melissa Brodowski, Ph.D., M.S.W., M.P.H.
Senior Policy Analyst
Administration for Children and Families

Iris Mabrey-Hernandez, M.D., M.P.H.
Medical Officer
Agency for Healthcare Research and Quality

Dawn Castillo, MPH
Director
Division of Safety Research
National Institute for Occupational Safety and Health

Elizabeth A. Edgerton, MD, MPH
Branch Chief
EMSC and Injury Prevention
Maternal and Child Health Bureau
Health Resources and Services Administration

Thomas E. Feucht, PhD
Executive Senior Science Advisor
National Institute of Justice

Holly Hedegaard, M.D., M.S.P.H.
Senior Service Fellow
National Center for Health Statistics

Jane L. Pearson, PhD
Associate Director for Preventive Interventions
Division of Services and Intervention Research
National Institute of Mental Health

Lyndon Joseph, Ph.D.
Health Scientist Administrator
National Institutes on Health
National Institute on Aging

Valerie Maholmes, Ph.D., C.A.S.
National Institutes on Health
National Institute of Child Health and Human Development

Wilson Compton, M.D., M.P.H.
Deputy Director
National Institutes on Health
National Institute on Drug Abuse

Jinhee Lee, PharmD
Senior Public Health Advisor
Substance Abuse and Mental Health Service Administration

Thomas Schroeder, M.S.
Director
U.S. Consumer Product Safety Commission

CDC Staff

Grant Baldwin, Ph.D., M.P.H.
Jeneita Bell, M.D., M.P.H.
Mark Biagioni, M.P.A.
Tamara Haegerich, Ph.D.
Jeffrey Herbst, B.A., Ph.D.
Debra Houry, M.D., M.P.H.
M. Chris Langub, Ph.D.
Kathy Meyer, M.B.A.
Amy Peebles, M.P.A.
Kathy Ramedei
David Sleet, Ph.D.
Mildred Williams-Johnson, Ph.D., D.A.B.T.
Joann Yoon, J.D.

Stephanie Wallace – Cambridge Communications

Public Participants

Alix Scott	Tarlov Sysys
Amanda	Alliance for Patient Access National Coalition for Hospice & Palliative Care
Amy Melnick	Physicians for Responsible Opioid Prescribing
Andrew Kolodny	None
Angeline Boster	American Pharamist Association
Anissa Marzuki	Kaiser Permanente
Ann Kempiski	CDC
Anne Schuhart	The Carolinas Center
Annette Kaiser	Patient Advocate
Ashley Kingsley	

Ashley Walton	American Society of Anesthesiologist
Barbara Waitt	Personal
Barby Ingle	Power of Pain Foundation
Becky	Trust for Americas Health
Becky Payne	CDC
Beverly Rivero	US Pain Foundation
Blaire Kliner	Individual
Bob Mann	Cordant Health Solutions American Academy of Pain Management
Bob Twillman	Politico
Brett Norman	None
C Harper	RSD & Fibro Advocacy
Cammie Lavalle	Caption CO
Caption CO	Caption Colorado MD Heroin Awareness
Captionor	Advocates
Carin Millier	Life Support Group
Carl Aper	Pfizer
Carl Roland	Individual
Cassidy	NCIPC
Chakara Parkman	Myself
Charlene Seelye	Individual
Cheryl Dwyer	Oregon Health & Science University
Chow	CDC
Chris	Power of Pain Foundation
Christine	Healthfirst Family Care Center
Christoph Sahar	Not Applicable
Chronic Pain Patient	
Chrystal Weaver	
Ciana Yap	APHA
Cindy Steinberg	US Pain Foundation
Clare Rhodes	None
Colleen Weststrough	Participant
Courtney Lenard	CDC
Cristi Schwarcz	Centers for Disease Control
Dan Budnitz	CDC AZ Department of Health Services
Danielle Dandreaux	MA Hospital Assoc MHA
Dave Defossez	Advocate
David Crawford	The Commercial Fields
David Waters	Individual
Dawn	None
Dawn Laduca	

Debbie Bost	The Addict's Mom
Deborah Barnard	Disabled/Not Working.
Debra Bernard	No Organization
Dee Green	Sun
Deidre Cornwall	Pain Network
	Boston Healthcare for the
Denise Delas Nueces	Homeless
Denise Molohon	Individual
	ASAP Arachnoiditis Society
	for Awareness and
Denise Molohon	Prevention
Derek Flowren	Alliance for Patient Access
Dewpesh	GS
Diane Gracely	Pain Advocate
Don Teater	National Safety Council
Donna Corley	ASAP Social Media Page
Douglas Lynch	National Pain Report
Dr. Christophe Sahar	Health First Family Care
E Grant	none
E Green	N/A
Elizabeth Solhtalab	CDC
Elizabeth Wells	Grace Point Global
Elizabeth Zurick	CDC
Eric Tahon	FDA
Erica Fisher	Golan Harris
Erick Hawley-Saia	PMTA Greenwich Terminals
Erin Connolly	CDC
Erin Sykes	CDC
Eryn Kahler	Individual
Gabrielle Lane	CDC
Gary Mendell	Shatterproof
Gaya Myers	CDC
Ginger	N/A
Ginny Resaconske	Individual
Gladys Lewellen	CDC MASO
Golan	Golan
Heather Van Ness	Van Ness Communications
Helen Kingery	CDC
Helen Kuykendall	CDC
Hilary Eiring	CDC
Holly Meschko	Pain Patient Advocate
Howard Techau	Individual
James Cleary	New Coborn Cancer Center
Jamie Moore	Individual

Jan Chambers	National Fibromyalgia & Chronic
Jan Kirk	Patient
Jane Terry	NFC
Janet Colbert	STOPP Now
Jean	The MMA Montana Medical Association
Jean Branscum	MT Medical Association
Jean Hyatt	Sight for Florida Pain Care Action Network
Jeanette Chambers	National Pain Association
Jennifer Drewsa	Arachnoiditis
Jessica	UCEFF
Jessica	DCSS
Jessica White	HHS
Jessica White	US Department of Health & Human Services
Joanne O'Brien	Participant
Jodi	Power Pain Foundation
Joe	None
John Eadie	PDMP Center of Excellence
Jose Martinez	CT Attorney General's Office
Joseph Foster	CDC
Judy Rummler	Steve Rummler Hope Foundation / Fedup Coalition
Judy Toth	No Organization
Julian Hoffman	National Safety Counsel
Juliana Hoffman	National Safety Council
Kara Mathias	Pharmaceutical
Karen Seldhausen	Individual
Karen Year Gain	Krooks County Health Dept.
Kathleen Collins	Pfizer Inc.
Kathryn Foti	CDC
Kathy Harben	CDC
Kathy Hastings	Patient
Kathy Henry	Self
Katie Golden	Migraine.com
Keith Graysley	US Pain Foundation
Kelli	Teva
Kelly Dawson	CDC
Kelly L. Loyd	Fight for Florida Pain Care Action Network
Kenny McKenna	Chronic Pain Patient
Kerry Smith	Individual
Kim Miller	Fight for Florida Pain Care Action Network

Kristen	CDC Staff
Kristen Ogden	Families for Intractable Pain Relief
Kristin	CDC
Kristine Anderson	Pain Patients United
Larry Vondrasek	Individual
Lauren	HEPA
Lea McClantock	None
Lilia Zurkovsky	Peppa Pharmaceuticals
Linda Cassidy	AACN
Lindsay Gordon	Pernix
Lisa Doyle	Pain Matters
Lisa Kehrbert	
Lorinda Wood	Fight for Florida Pain Network
Lou Ann Thorsmess	Kaiser Permanente Northwest
Lyden Joseph	National Institute of Aging Ehlers Danlos Syndrome
Lynn Sanders	Network Cares Foundation
Lynn Wilburn	Patient Medicare Beneficiary Patient
Lynne Lieberman	Chronic Pain Patient
Lynne Wilburn	Patient
Marcia Stenson	Kurnicks Therapeutic
Margaret Coger	Individual - Patient
Margaret Vanamringe	Joint Commission
Marina Brodsky	Pfizer Inc.
Mario Mendoza	Pfizer
Mark Neil	National Association of Attorneys General
Mary	CDC
Mary Ellen Mynear	Office of KY Attorney General
Mary Mills	Individual
Matthew Grant	News
Maureen Killian	Scared Straight Florida
McCann	McCann
Melanie Reedy	Participant Fibromyalgia Association of MI
Melanie Reedy	MI
Melissa	NEXT
Melissa Mercado-Crespo	CDC
Melissa Story	Power of Pain Foundation
Member of the Public	Individual
Member of the Public	Individual
Member of the Public	Individual

Member of the Public	RSD CIPS
Michael	
Michele Roy	Egalet
Michelle	FDA
Michelle	National Pain Association
Michelle	None
Michelle Harford	US Pain Foundation
Michelle Parisa	Patient
Michelle Parisa	No Organization
Michelle Roy	Egalet
Michelle Rudovich	Attorney's General Office of KY
Michelle Wilson	CDC
Monte Ward	ACSM
Ms. Waters	CDC
Nathan Kopper	Mallin Croft Pharmaceuticals
Nick	Individual
Nicole Larson	Teva Pharmaceuticals
None	None
Norman Powell	DUIP
Oxana Pickeril	Healthywomen.org
Pam Fyffe	USDA
Pat	CDC
Pat Anson	Pain News Network
Pati Eng	Individual
Patricia Bruckenthal	Pain Action Alliance for Implementing a Nations Strategy
Paul	Corvallis Clinic
Paul Copland	Perdue
Paula Lopez	National Pain Report
Peg Ogea-Ginsburg	NE Dept. of Health & Human Services
Penny Poren	TEZA Pharmaceuticals
Rea Isaac	RSDSA /CDC
Rebecca Saley	Trust for America's Health
Rhonda Sciarra	Mallinckrodt
Rich Garcia	TX Support RSD/CRPS
Robin	Life Support Group
Robin Smith	Live Support Group
Rosie Bretthauer	CDC
Ruth Osinsky	BGR Group
Ryel Holder	Families for Intractable Pain Relief
Sam	Teva
Sandra McBee	Individual

Sandra Mofye	American Association of Colleges
Sara	McCann Health
Sarah	FDA
Sarah Code	Parker Management
Sarah Delgado	AACN
Scott Michaels	Pain Advocacy Group
Scott Michaels	None
Seth Kroop	CDC
Shambley Camp	CDC
Sherrie Harris	Individual
Sheryl Akopian	Individual
Stephanie	Hair & Treatment Centers
Stephanie Wallace	Cambridge Communication
Stephen Murphy	WebMD
Steve Wurzelbacher	NIOSH
Steven Bentsen	Beacon Health Options
Sue Peschin	Alliance for Aging Research
Susan	None
Susan	
Susan Award	ASAM
Susan Dixon	Individual
Taylor Turner	ABC News
Tess Benham	National Safety Council Arachnoiditis We Fight Together
Theodora Batistatos	Together
Tinsley Waters	CDC
Tootie Walker	Chronic Pain Patient
Twinkle Zanflet	Power of Pain Foundation
Vernique Wilson	CDC MASO Greater New Bedford Community Health Center
Victoria Pereira	Chicago Department of Public Health
Vineet Argarwal	
William Dougherty	US Citizen
William Smith	Private Citizen National Institutes on Drug Abuse
Wilson Compton	Abuse
Yolanda Williams	CDC Golin The American Pharmacist Association Golin No Organization CDC Not Speaking

Whiteford KY Paincare
Action Network
CDC
None
Partnership for a Drug Free
NJ
INCHD
Self
Families for Intractable Pain
Relief

Attachment B: Acronyms Used in this Document

Acronym	Expansion
AAP	American Academy of Pediatrics
ACIP	Advisory Committee on Immunization Practices
ACLU	American Civil Liberties Union
ACOG	American College of Obstetrics and Gynecology
ACPA	American Chronic Pain Association
AHRQ	Agency for Healthcare Research and Quality
ASAM	American Society of Addiction Medicine
ASPMN®	American Society for Pain Management Nursing®
BSC	Board of Scientific Counselors
CDC	Centers for Disease Control and Prevention
CEO	Chief Executive Officer
CMT	Charcot-Marie-Tooth
CRPS	Complex Regional Pain Syndrome
DEA	(United States) Drug Enforcement Administration
DOJ	(United States) Department of Justice
EMS	Emergency Medical Services
FACA	Federal Advisory Committee Act
FDA	(United States) Food and Drug Administration
FQHC	Federally Qualified Health Center
GRADE	Grading of Recommendations Assessment, Development and Evaluation
HHS	(United States Department of) Health and Human Services
IC	Interstitial Cystitis
IOM	Institute of Medicine
IVIG	Intravenous Immunoglobulin
MASO	Management Analysis and Services Office
MAT	Medication-Assisted Treatment
MDA	Muscular Dystrophy Association
<i>MMWR</i>	<i>Morbidity and Mortality Weekly Report</i>
NCBDDD	National Center for Birth Defects and Developmental Disabilities
NCIPC	National Center for Injury Prevention and Control
NFL	National Football League
NIH	National Institutes of Health
NORD	National Organization of Rare Disorders
NSAID	Nonsteroidal Anti-Inflammatory Drug
PAINS	Pain Action Alliance to Implement the National Pain Strategy
PDMP	Prescription Drug Monitoring Program
PEG	Pain, Enjoyment, General (Activity) (Scale)
PrEP	Pre-Exposure Prophylaxis
PROP	Physicians for Responsible Opioid Prescribing
RCT	Randomized Controlled Trial
RSD	Reflex Sympathetic Dystrophy
SME	Subject Matter Expert
STI	Sexually Transmitted Infection
STOPP Now	Stop The Organized Pill Pushers Now
VA	(United States Department of) Veterans Affairs