

Testimony of

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Before the

U. S. Senate
Special Committee on Aging
Opioid Use Among Seniors – Issues and Emerging Trends

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Good afternoon Chairman Collins, Ranking Member McCaskill and members of the Committee.

I am Dr. Sean Mackey, Chief of the Division of Pain Medicine and the Redlich Professor of Anesthesiology, Perioperative and Pain Medicine, Neurosciences and Neurology at Stanford University. I am also the former President of the American Academy of Pain Medicine. I served on the Institute of Medicine's Committee on Relieving Pain in America: A Blueprint for Transforming Prevention, Care, Education and Research. I also recently served as Co-Chair of the Oversight Committee for the National Institutes of Health Task Force to develop The National Pain Strategy.

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

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

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

- a.** Acting through the NIH, the IOM Committee on Pain that I chaired along with Dr. Noreen Clark, Myron Wegman Distinguished University Professor and Director of the Center for Managing Chronic Disease at the University of Michigan, as co-chair, was charged to address the current state of the science regarding pain research, care and education and to specifically:
 - i. Review and quantify the public health significance of pain, including the adequacy of assessment, diagnosis, treatment and management of acute and chronic pain in the US.
 - ii. Identify barriers to appropriate pain care and strategies to review them.
 - iii. Identify demographic groups and special populations and what needs to be done to address their needs.
 - iv. Identify what scientific tools and technologies are available, what strategies can enhance the training of pain researchers, and what interdisciplinary research is necessary in the short, and long term to advance research and improve diagnosis, care and management
 - v. Discuss opportunities for public-private partnerships in support of pain research, care and education

- b.** Our committee included 19 members with a wide range of expertise in the broad biopsychosocial aspects of pain – including the ethical, legal, clinical and public health perspectives, along with traditional and complementary medicine began its work in late November 2010. We completed our work over a seven-month period, thanks to the incredible support from the IOM and especially Adrienne Smith Butler, and submitted our report to the Congress and the NIH in June 2011.
 - i. Reviewed the literature
 - ii. Held public meetings and workshops
 - iii. Received testimony and comments from more than 2000 Americans.
 - iv. Commissioned a review on pain’s economic burden
 - v. We concluded that relieving acute and chronic pain is a significant overlooked problem in the US.

Our committee first established a number of underlying principles to help guide our work. Among them are:

- a.** Pain management is a moral imperative.
- b.** Chronic pain can be a disease in itself.
- c.** There is value in comprehensive treatment that includes interdisciplinary approaches, with a wider use of existing knowledge and a focus on prevention.
- d.** We recognized the conundrum of opioids and that this requires balance and additional review but were specifically directed that this topic was not part of the charge of our committee.
- e.** We recognized the importance of collaboration of patients and clinicians – in education, management and prevention and that there is a value to a public health approach – to education and management.
 - i. While we recognize that our focus was on the public health implications of pain, we understood that it is the individual human impact of chronic pain that underscores why this is such an important issue for our families, patients, communities and nation. I offer just a couple of comments from the more than 2000 that we received:
 - *From and advocate:* Treating a pain patient can be like fixing a car with four flat tires. You cannot just inflate one tire and expect a good result. You must work on all four.
 - *From a physician with chronic pain:* Pain management and physical rehabilitation was never addressed in my medical school curriculum nor in my family practice residency. My disability could have been avoided or lessened with timely treatment, and I could still be the provider instead of the patient.
 - *From a clinical pharmacy specialist:* We cannot successfully treat the complexity of pain without treating the whole patient. Insurance companies will pay for useless, expensive procedures and surgeries but won’t pay for simple cognitive-behavioral therapy and physical rehab therapy.
 - *From a patient with chronic pain:* I have a master’s degree in clinical social work. I have a well-documented illness that

explains the cause of my pain. But when my pain flares up and I go to the ER, I'll put on the hospital gown and lose my social status and my identity. I'll become a blank slate for the doctors to project their own biases and prejudices onto.

An overarching conclusion from our report on Alleviating Pain in America is that to reduce the impact of pain and the resultant suffering will require of cultural transformation in how pain is perceived and judged both by people with pain and by the health care providers who help care for them. The overarching goal of this transformation should be gaining a better understanding of pain of all types and improving efforts to prevent, assess and treat pain. The Committee's report offers a blueprint for achieving this transformation that included 16 recommendations that addressed:

- a. Public health challenges
- b. Pain care and management
- c. Education of patients, communities and providers
- d. Research

To help establish priorities, the IOM Committee recommended that four of its 16 recommendations be implemented by the end of 2012 and that the remaining twelve recommendations be completed before the end of 2015 and then be maintained on an ongoing basis. These are as follows:

- a. *Immediate – Complete by the end of 2012*
 - i. The Secretary of HHS should create a comprehensive population-level strategy for pain prevention, treatment, management and research
 - Coordinate efforts across public and private sector
 - Include agenda for developing research
 - Improve pain assessment and management programs
 - Improve ongoing efforts to enhance public awareness of pain.This should involve multiple federal, state and private sector entities – including the NIH, FDA, CDC, AHRQ, HRSA, CMS, DoD, VA, professional societies and others
 - ii. The Secretary of HHS along with other federal, state and private sector entities should develop strategies for reducing barriers to the care of pain – focusing in particular on populations disproportionately affected by and undertreated for pain, including the elderly.
 - iii. Through CMS, the VA, DoD, health care providers, insurers and others - support collaboration between pain specialists and primary care clinicians, including referral to pain specialists when appropriate.
 - Given the prevalence of chronic pain, it is not realistic or desirable to relegate pain management to pain specialists alone. There are fewer than 4000 such specialists in the US, with limited geographic coverage. Ideally primary care physicians would coordinate pain management, but such a change cannot be achieved without significant improvements in education and

training. Moreover payment systems must be restructured to allow primary care physicians to spend more time with patients with chronic pain and deliver care more effectively. Given the increasing demands on primary care physicians, it would be unfair to add expectations without providing opportunities for education and payment for counseling patients. Similar issues and constraints apply to nurses, psychologists, physical and occupational therapists, pharmacists, and practitioners of complementary and alternative medicine.

- iv. The Director of the NIH should designate a lead institute at the National Institutes of Health that is responsible for moving pain research forward. That has been accomplished with Dr. Walter Koroshetz, Director of National Institute of Neurological Disorders and Stroke taking the lead. They have also formed the Federal Pain Research Strategy to developed a strategic plan for pain research across federal agencies. The NIH was also directed to increase the support for and scope of the Pain Consortium. These efforts should involve pain advocacy and awareness organizations and should foster public private partnerships.

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

i. Public Health

- Improve the collection and reporting of data on pain

ii. Care

- Promote and enable self-management of pain
- Provide educational opportunities in pain assessment and treatment in primary care
- Revise reimbursement policies to foster coordinate and evidence-based pain care.
- Provide consistent and complete pain assessments

iii. Education

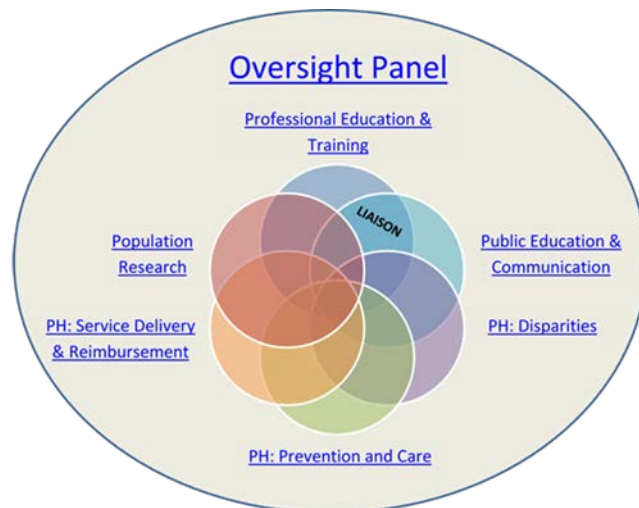
- Expand and redesign education programs to transform the understanding of pain
- Improve curriculum and education for health care professionals
- Increase the number of health professionals with advanced expertise in pain care

iv. Research

- Improves the process for developing new agents for pain control
- Increase support for interdisciplinary research in pain
- Increase the conduct of longitudinal research in pain
- Increase the training of pain researchers.

In response to IOM Recommendation 2-2, the Assistant Secretary for Health directed the NIH Interagency Pain Research Coordinating Committee (IPRCC) to oversee creation of The National Pain Strategy (NPS). Dr. Linda Porter (Director of Pain Policy, NINDS) and I assembled an Oversight Panel which created six Working Groups that aligned with the IOM recommendations —population research, prevention and care, disparities, service delivery and

reimbursement, professional education and training, and public awareness and communication. The working groups comprised 80 experts from a broad array of relevant public and private organizations, including health care providers, insurers, and people with pain and their advocates.



The goal of The National Pain Strategy Task Force was to develop a strategic plan to transform pain prevention, care, and education in our country. The NPS was designed to be a “tactical report” with specific, meaningful, and measurable deliverables from each WG. Stakeholders were to be identified to implement the objectives. Additionally, short, intermediate and longer term goals and objectives were to be defined that can be executed and the results measured. Following deliberation by the 80 expert member group, the draft NPS report with 17 objectives was released for public commentary. We received many public comments with overwhelming support. The final version is pending release by the Secretary of HHS. Fundamental conclusions and implications drawn from the IOM report guided development of the National Pain Strategy, including:

- a. The public at large and people with pain, in particular, would benefit from a better understanding of pain and its treatment, in order to encourage timely care, improve medical management, and combat stigma.
- b. Increased scientific knowledge regarding the pathophysiology of pain has led to the conclusion that chronic pain can be a disease in itself that requires adequate treatment and a research commitment.
- c. Although pain is widespread in the population, data are lacking on the prevalence, onset, course, impact, and outcomes of most common chronic pain conditions. The greatest individual and societal benefit nevertheless would accrue from a focus on chronic pain.
- d. Every effort should be made to prevent illnesses and injuries that lead to pain, the progression of acute pain to a chronic condition, and the development of high-impact chronic pain.
- e. Significant improvements are needed in pain assessment techniques and practices to assure they are high-quality and comprehensive.
- f. Self-management programs can improve quality of life and is an important component of acute and chronic pain prevention and management.

- g. Chronic pain is a biopsychosocial condition that often requires integrated, multimodal, and interdisciplinary treatment, all components of which should be evidence-based.
- h. People with chronic pain need greater access to treatments that take into account their preferences and are in accord with best evidence on safety and effectiveness.
- i. New treatment approaches need to be developed that take into account individual differences that affect the onset of pain and response to treatment.
- j. Treatments that are ineffective, whose risks greatly exceed their benefits, or that may cause harm for certain subgroups need to be identified and their use curtailed or discontinued.
- k. Much of the responsibility for front-line pain care rests on primary care clinicians, who are not sufficiently trained in pain assessment and comprehensive, evidence-based treatment approaches.
- l. Greater collaboration is needed between primary care clinicians and pain specialists in different clinical disciplines and settings, including multispecialty pain clinics.
- m. Significant barriers to pain care exist, especially for populations disproportionately affected by and undertreated for pain, and need to be overcome.
- n. People with pain are too often stigmatized in the health care system and in society, which can lead to delayed diagnosis or misdiagnosis, bias in treatment, and decreased effectiveness of care.

The Framework and Objectives from each Working Group are presented below. Final language is pending edits and approval from the Secretary of HHS.

NPS Population Research Framework: The underlying framework of the Population Research WG was that understanding the significance of health problems in a population is a core public health responsibility. That we need to:

- a. Increase the precision of information about chronic pain prevalence overall, for specific types of pain, and in specific populations
- b. Develop capacity to collect electronically –information on treatments, their usage, costs, and effectiveness
- c. Enable tracking changes in pain prevalence, impact, and treatment over time, allowing evaluation of population-level interventions and identification of emerging needs

NPS Population Research WG Objectives:

- a. Objective 1: Estimate the prevalence of chronic pain and high-impact chronic pain overall and for anatomically defined pain conditions and for various population groups
- b. Objective 2: Refine and employ standardized electronic health care data methods to determine the extent to which people with common pain conditions, including those from vulnerable groups, receive various treatments and services, the costs of

these services, and the extent of use of treatments that best evidence suggests are underused, overused, effective, and ineffective.

- c. Objective 3: Develop a system of metrics for tracking changes in pain prevalence, impact, treatment, and costs over time that will enable assessment of progress, evaluation of the effectiveness of interventions at the population health level—such as public education or changes in public policy, payment, and care—and identification of emerging needs.

NPS Population Research WG follow up:

- a. The Population Research WG followed up the initial WG Objectives with the following project to operationalize (& Pilot Testing) a standardized definition of “High Impact Chronic Pain”. Furthermore, this WG has worked to identify four objectives for Healthy People 2020 to:
 - i. Decrease the prevalence of adults having high impact chronic pain
 - ii. Increase public awareness/knowledge of high impact chronic pain
 - iii. Increase self-management of high impact chronic pain
 - iv. Reduce impact of high impact chronic pain on family/significant others
- b. The Population WG under Dr. Michael Von Korff’s leadership with further leadership by Drs. Porter (NINDS) and Chad Helmick (CDC) developed four questions to be inserted into the National Health Interview Survey (NHIS) in 2016 and 2017.

NPS Disparities WG Framework:

- a. The Disparities WG noted that bias, negative attitudes and perceptions, and misconceptions about race, gender, ethnicity... even pain itself:
 - i. disproportionately affects vulnerable populations. Elderly patients in nursing homes were noted to be one of the vulnerable populations.
 - ii. creates stigma with unwillingness to report pain, participate in treatment decisions, or adhere to treatment
 - iii. negatively affect psychological state
 - iv. Insufficient knowledge of behavioral and biological mechanisms of pain, prevalence, treatment, and treatment response in vulnerable populations puts them at higher risk for pain and inadequate care

NPS Disparities WG Objectives:

- a. Objective 1: Reduce bias (implicit, conscious, and unconscious) and its impact on pain treatment by improving understanding of its effects and supporting strategies to overcome it.
- b. Objective 2: Improve access to high-quality pain services for vulnerable population groups.
- c. Objective 3: Facilitate communication among patients and health professionals.

- d. Objective 4: Improve the quality and quantity of data available to assess the impact of pain on higher-risk population groups, including data on group members' access to high-quality pain care and the costs of disparities in pain care.
- e. **Disparities WG Overall Intent** is to improve the quality of pain care and reduce barriers for all minority, vulnerable, stigmatized, and underserved populations at risk of pain and pain care disparities.

NPS Prevention and Care WG Framework:

- a. There is a great need to understand the factors that cause pain to become persistent and to develop and apply measures to prevent acute pain from transitioning to a chronic state.
- b. Existing knowledge should be used more effectively to prevent chronic pain
- c. People with pain should receive appropriate assessments and evidence-based care that is coordinated across providers and individualized.
- d. A robust research effort is needed to validate the effectiveness of pain prevention and management strategies already in use, and to develop new ones.

Prevention and Care WG Objectives:

- a. Objective 1: Characterize the benefits and costs of current prevention and treatment approaches.
 - i. A thorough benefit-to-cost analysis of current prevention and treatment approaches, including self-management methods and programs, should be performed to identify and create incentives for use of interventions having high benefit-to-cost ratios. Conversely, treatments with little absolute benefit or a low benefit-to-risk ratio should be identified through clinical studies and efforts made to dis-incentivize their use. In judging the benefit of many treatments, clinicians and payers should bear in mind that an individual may belong to a specific population group in which the treatment may be either more beneficial (or more risky) than in the population at large.
- b. Objective 2: Develop nation-wide pain self-management programs.
 - i. Despite evidence to support team-based, pain self-management programs for pain, their implementation has lagged, which represents an unmet opportunity to provide people with pain the appropriate skills, education, and resources to play an active role in managing their pain, which includes understanding when clinical consultation is needed. These programs should be integrated into the health care system to bolster their use and prevalence and to guide patients through the several levels of pain care. Goal setting (action planning), problem solving, decision making and psychosocial aspects of care should be included in the programs.
- c. Objective 3: Develop standardized, consistent, and comprehensive pain assessments and outcome measures across the continuum of pain.
 - ii. Pain assessment should be multifaceted and include self-report, as well as clinician examination. Assessment and outcomes measures should include

relevant pain, physical, psychological, and social domains of functioning that conform to the biopsychosocial model of pain, as well as patient-reported outcomes and patient-defined goals. Assessments and outcomes should be used for point of care decision-making by clinicians, longitudinal outcomes monitoring, estimations of value of alternative treatment approaches, and practice-based effectiveness studies.

NPS Service Reimbursement and Delivery Framework:

- a. There is a great need to understand the factors that cause pain to become persistent and to develop and apply measures to prevent acute pain from transitioning to a chronic state.
- b. Existing knowledge should be used more effectively to prevent chronic pain
- c. People with pain should receive appropriate assessments and evidence-based care that is coordinated across providers and individualized.
- d. A robust research effort is needed to validate the effectiveness of pain prevention and management strategies already in use, and to develop new ones.

NPS Service Reimbursement and Delivery Objectives:

- a. Objective 1: Define and evaluate integrated, multimodal, and interdisciplinary care for people with acute and chronic pain, and end of life pain, which begins with a comprehensive assessment, creates an integrated, coordinated, evidence-based care plan in accord with individual needs and preferences and patient-centered outcomes, and is supported by appropriate reimbursement incentives.
- b. Objective 2: Enhance the evidence base for pain care and integrate it into clinical practice through defined incentives and reimbursement strategies, to ensure that the delivery of treatments is based on the highest level of evidence, is population-based, and represents real-world experience.
- c. Objective 3: Tailor reimbursement to promote and incentivize high-quality, coordinated pain care through an integrated biopsychosocial approach that is cost-effective, comprehensive, and improves outcomes for people with pain.

NPS Professional Education and Training Framework:

- a. Many health professionals need greater skills to contribute to the cultural transformation in the perception and treatment of people with pain.
- b. Education of health professionals in the complex etiology, prevention, assessment, and treatment of pain is insufficient, in part because educators lack access to valid information about pain and pain care.
- c. Core competencies in pain care generally do not inform undergraduate curricula in health professions schools or in graduate training programs.
- d. Bias against people with chronic pain, exists in the medical community and can negatively affect patient care and reinforce pain stigma.

NPS Professional Education and Training Objectives:

- a. Objective 1: Develop, review, promulgate, and regularly update core competencies for pain care education and licensure and certification at the undergraduate and graduate levels.
- b. Objective 2: Develop a pain education portal that contains a comprehensive array of standardized materials to enhance available curricular and competency tools.
 - i. The portal will serve as a central, comprehensive source for pain education materials and will be monitored regularly and updated as new evidence-based guidelines and resources are available. The need for knowledge and skills that address how clinician empathy influences the effectiveness of care should be included in the available educational materials.

NPS Public Education WG Framework:

- a. Stigma and misperceptions about pain create barriers to treatment and make it difficult for people with chronic pain to live productively and with dignity.
- b. Public education is key to a cultural transformation in the understanding, care, and treatment of chronic pain.
- c. Evidence-based communications campaigns are needed to:
 - ii. increase public awareness of the pervasiveness and complexity of chronic pain and the importance of access to prompt and effective treatments
 - iii. change attitudes about people with chronic pain and some treatment options
 - iv. promote the value of pain self-management programs
 - v. foster coalitions -federal agencies, professional organizations, accreditation agencies, insurers, employers, foundations, patient advocate organizations- to participate and promote such campaigns
 - vi. provide patient education on the safe use of pain medications.

NPS Public Education WG Objectives:

- a. Objective 1: Develop and implement a national public awareness and information campaign about the impact and seriousness of chronic pain, in order to counter stigma and correct common misperceptions.
- b. Objective 2: Develop and implement a national educational campaign encouraging safe medication use, especially opioid use, among patients with pain.

The National Pain Strategy Vision:

- a. If the objectives of the National Pain Strategy are achieved, the nation would see a decrease in prevalence across the continuum of pain.....which would reduce the burden of pain for individuals, families, and society as a whole.
- b. Americans experiencing pain...would have access to a care system that meets their biopsychosocial needs and takes into account individual preferences, risks, and contexts.

- c. Americanswould recognize chronic pain as a complex disease and a threat to public health significant public resources would be invested in the areas of preventing pain, creating access to evidence-based and high-quality pain assessment and treatment services and improving self-management abilities among those with pain.individuals who live with chronic pain would be viewed and treated with compassion and respect.

These recommendations of the IOM and the objectives of the National Pain Strategy serve the goal of creating a comprehensive, population-level strategy for pain prevention, management and research. The scope of the problems in pain management is daunting, and the limitations in the knowledge and education of health care professional are glaring. The medical community must actively engage in the necessary cultural transformation to reduce the pain and suffering of Americans. Importantly the cultural and social transformation needed to alleviate pain in America will require the collaboration of the healthcare provider community with patients and their families who are suffering from pain, including their communities, professional societies and advocacy organizations as well as state and federal government. New public private partnerships and a broad concerted level that addresses pain as a public health initiative as well as an individual's source of suffering will be necessary if we are to make progress in alleviating pain. Successful implementation of these strategic objectives will create the cultural transformation in pain prevention, care, and education called for in the IOM Pain Report and needed by the American public.

I appreciate the opportunity to appear before you today and look forward to responding to any questions you may have.