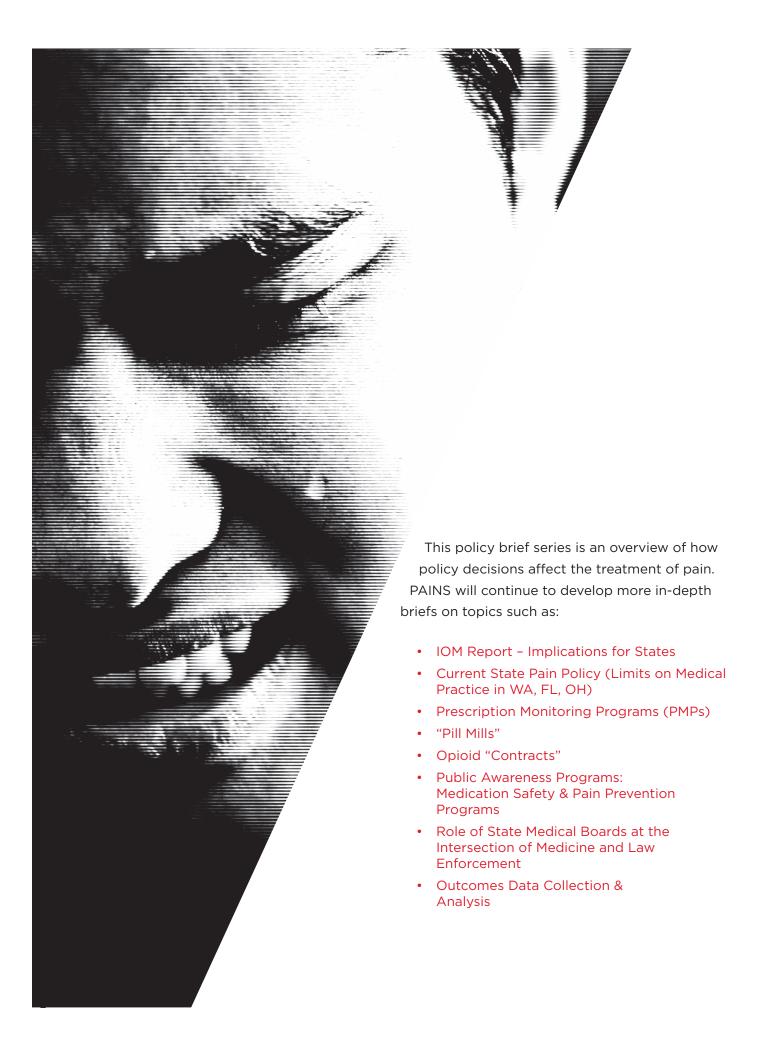


POLICY BRIEF #1: OVERVIEW



"Addressing the enormous burden of pain will require a cultural transformation...Effective pain management is a moral imperative, a professional responsibility, and the duty of people in the healing professions."

Institute of Medicine, Relieving Pain in America, 2011



INTRODUCTION

Pain is one of the most devastating public health problems affecting Americans today. In 2011, the Institute of Medicine (IOM) published *Relieving Pain in America: a Blueprint for Transforming Prevention, Care, Education and Research*, articulating the magnitude of this issue. Not including children, veterans and those who are institutionalized, the IOM reported that at least 100 million adults are affected by pain at a cost of \$560-635 billion dollars annually, including medical expenses and lost wages. Pain affects employers, who bear the burden of lost productivity due to "presenteeism," i.e., workers who show up for income and health insurance benefits, but are distracted by so much pain that they are unable to fulfill their duties. Pain affects all of us: children who miss school, parents who cannot participate in their children's lives; employees who cannot fully contribute and employers who count on them. And, pain affects communities, siphoning away its citizens to a world of isolation.

Pain is not sensational, front-page news. However, pain will affect us all at one time or another during our life's journey. For some, it will be a mild and brief encounter; for others, it will be years of agony. Those living with chronic pain don't march on Washington or their state capitol. Their energy and efforts are focused on activities of daily living that many of us take for granted. Some, who have found effective ways to manage their pain, however, have taken up the mantle of advocacy. But, for many, pain remains a silent and isolating epidemic. State legislators and regulators play an important role in promoting appropriate care for those who struggle to live with unrelenting pain.

Chronic pain often causes suffering and misery that diminishes the quality of one's life, the will to live, and even life itself. To address the challenge of this public health issue, an alliance has formed to advance the IOM report recommendations that will truly transform pain care in America. The Pain Action Alliance to Implement a National Strategy (PAINS) is a national alliance of professional societies, consumer advocacy organizations, and others who believe there is a moral imperative to improve the treatment of pain.

Members of PAINS believe that policymakers and others formally tasked with the responsibility to make public policy decisions need current information about the management of pain and the effect that their decisions can have on people who live with pain and the providers who care for them.

PAINS will support policy makers by publishing a series of policy briefs and hosting a peer-reviewed website to provide policy makers and others with well researched, objective information and access to expert views on complex matters.

Charles, 64, is a Medicaid patient from Washington State. He lives with terminal liver disease and serious pain. His community health clinic refused to refill his existing, low-dose opioid therapy, which was prescribed by a pain care specialist. Other pain medications were potentially fatal to Charles because of risk factors that would further damage his liver. With his pain medication, Charles was able to function and participate in his life, but without it he became debilitated by pain and his family went into a serious crisis.

Keenly aware that her husband could not go on living in agony, Charles' wife Jennifer called 62 providers given to them by the state. Not a single provider would see Charles. Jennifer met with legislators and was eventually able to find a provider, a process that took months while Charles endured senseless suffering.

Unfortunately, Charles' story is not unique in Washington, a result of state rules governing the prescribing of prescription pain medication. Those rules, which impose restrictions upon doctors once certain dosage levels are reached, have driven many healthcare providers from their moral imperative to help relieve suffering.





INTEGRATED PAIN MANAGEMENT

Recognizing that chronic pain is complex—far more than a physical sensation—the IOM report recommends a "bio-psychosocial" approach to pain management—one that takes into consideration the whole person: mind, body, and spirit. PAINS supports this recommendation and takes it a step further by embracing an "integrated" (as it is referred to in the IOM report) model of pain management. Comprehensive pain programs that utilize this model have been shown to be safe, effective in treating pain, and cost-effective¹. This common sense approach is also good medicine.

Today, most pain policies focus on single modality treatments, particularly on issues related to opioid analgesics and the prevention of their diversion, misuse and abuse. PAINS recommends that, as pain policies are developed at the state and federal level, it is imperative that an integrated approach, such as described by the IOM report, be considered and supported. In May 2010, the Pain Management Task Force of the Office of the Army Surgeon General issued a report called, *Providing a Standardized DoD and VHA Vision and Approach to Pain Management to Optimize Care for Warriors and their Families*, which mandated integrated pain management.

The report called for a comprehensive pain management strategy that is "holistic, multidisciplinary, and multimodal in its approach, utilizes state of the art/science modalities and technologies, and provides optimal quality of life for soldiers and other patients with acute and chronic pain." All people in the United States are deserving of this model of care.

Integrated Pain Management (IPM):

- · Is informed by evidence
- Is patient-centered and reaffirms the importance of a healing, covenantal partnership between practitioner and patient
- Focuses on the whole person—mind, body, spirit, in the context of the individual's community/ environment
- Brings together all appropriate therapeutic approaches and healthcare professionals to reduce pain, improve function, and achieve optimal health and healing
- Supports the individualization of care, recognizing that no single treatment or paradigm may be perfectly suited for every patient, especially those in chronic pain

MORE ABOUT THE PAIN ACTION ALLIANCE TO IMPLEMENT A NATIONAL STRATEGY (PAINS)

The vision members of PAINS share is that "all Americans who struggle to live with pain, especially those with chronic pain, will have access to integrated pain care consistent with their goals and values." Its mission is "to advocate for and act collectively to actualize recommendations set forth in the IOM report." Those recommendations provide a "blueprint" for transforming the way pain is prevented, assessed, treated, taught and researched.

Participants of the PAINS alliance support the sixteen recommendations made by the IOM committee (See box to the right).

The IOM committee has no implementation authority; however, it offers a unique window of opportunity for positive change. It is up to those agencies named in the report and others to act on the recommendations made. It provides a touchstone for legislators and regulators to develop policy that will improve the environment for treating pain and the lives of those who struggle to live with it.

Participants of PAINS are committed individually to advancing the ideas detailed in *Relieving Pain in America* and believe that, by working collaboratively to promote the IOM recommendations, members of the alliance can improve the management of pain and policies that guide healthcare. Initial strategies of PAINS include the following:

- Hold governmental agencies named in the IOM report responsible for acting on specific recommendations;
- Engage and educate the American public, especially people struggling to live with pain, about the value of an integrated, bio-psychosocial model of care; and,
- Promote more and better coordinated pain research across all biomedical and social sciences.

PAINS currently consists of individuals representing a diverse range of healthcare professionals and people with pain (see back page for steering committee).

RECOMMENDATIONS FROM RELIEVING PAIN IN AMERICA (IOM):

- Improve the collection and reporting of data on pain.
- Create a comprehensive population-level strategy for pain prevention, treatment, management, and research.
- Promote and enable self-management of pain.
- Develop strategies for reducing barriers to pain care.
- Provide educational opportunities in pain assessment and treatment in primary care.
- Support collaboration between pain specialists and primary care clinicians, including referral to pain centers when appropriate.
- Revise reimbursement policies to foster coordinated and evidence-based pain care.
- Provide consistent and complete pain assessments.
- Expand and redesign education programs to transform the understanding of pain.
- Improve curriculum and education for healthcare professionals.
- Increase the number of health professionals with advanced expertise in pain care.
- Designate a lead institute at the National Institutes of Health responsible for moving pain research forward, and increase the support for and scope of the Pain Consortium.
- Improve 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.

Institute of Medicine, *Relieving Pain in America*. A Blueprint for Transferring Prevention Care, Education, and Research, 2011.





State legislators, regulators and other makers of public policy are obligated to protect the rights of their citizens, to promote the common good and well-being of all and to develop fair and equitable policies. Establishing credibility and trust with all their constituents is essential to the work of policy makers.

One of the principles underlying the IOM report is that "effective pain management is a moral imperative, a professional responsibility, and the duty of people in the healing professions." The basic question that policy makers must answer is, "What kind of society do we want to be?" Do we want to be a society that turns its head away from pain and suffering, or one that promotes wellbeing and public health? As a society do we wish to address the undertreatment of pain so that all people have the opportunity to reach their capacity -- to grow up, to become educated, to engage in productive/meaningful work, to create families and meaningful relationships, and to enjoy individual freedom?

In the Declaration of Montreal, delegates to the International Pain Summit of the International Association for the Study of Pain stated "that all persons have intrinsic dignity and that withholding pain treatment is profoundly wrong, leads to unnecessary suffering"... and declared that:

- All people have a right to access pain management without discrimination
- People in pain have a right to acknowledgement of their pain and to be informed about how it can be assessed and managed
- People with pain have a right to access appropriate assessment and treatment of their pain by adequately trained healthcare professionals²

There is growing evidence, however, that many people in the U.S. who struggle to live with pain have great difficulty accessing healthcare professionals and services necessary to help them manage their pain and live their lives with the highest quality possible. Most healthcare plans have not evaluated the cost efficacy of an integrated approach to treating pain and therefore do not cover it. People with pain are limited to the treatments, typically biomedical, that are within formulary parameters. Problems associated with the under-treatment of pain are exacerbated by the increasing abuse of prescription pain medications.

One consequence of the tension between these two important public health issues is that healthcare professionals are increasingly concerned about exposure to personal risks that may be associated with treating chronic pain. Although one study published in 2008 indicated that "criminal or administrative charges and sanctions against physicians for prescribing opioid analgesics are rare, "it did not address the "chilling effect" of investigations by the DEA, state medical boards or local prosecutors on physicians treating chronic pain. Some healthcare professionals worry more about personal risks associated with oversight and investigation by their state medical board and/or law enforcement than about the well-being of their patients. This shift in the locus of concern from patients to healthcare professionals themselves is reminiscent of the challenges to professional ethics presented by HIV/AIDS in the mid-1980s.

The emerging discussion about addressing pain treatment equity as a public health ethics issue is promising and one that can be of help to policy makers as they grapple with competing policy concerns. It is time to take off the blinders and see that pain is all around us but that its ethical challenges are ones we can take on together⁴.



For nine years Sue was a nurse who worked with newborn babies in the intensive care unit. Twelve years ago, Sue was rear-ended on her way home from work by a distracted driver and has spent every day since with disabling back pain. She had to give up nursing because of the pain and she still struggles every day to get out of bed to work as a self-employed legal consultant.

She's also the victim of so-called "pill mills," but not in the way you'd think. Sue, who lives in Florida, is a victim because of Florida's effort to close pill mills by passing new laws resulted in legitimate pain clinics being closed. She now has to drive two and a half hours to find a doctor to treat her pain. She constantly worries that her doctor may stop seeing people with pain, making it even harder for her to find the treatment she needs to function. Why? Because Florida chose to fight the pill mills by making legitimate pain management clinics adhere to 95 pages of onerous new rules, something other types of clinics don't have to do. That scares doctors, and as a result, many in Florida have stopped treating pain.

WHY THE TREATMENT OF PAIN AND PAIN POLICY IS CONTROVERSIAL

There are many reasons that the treatment of pain has become controversial and challenges the ethics of both policy makers and healthcare providers, including:

- · Abuse of prescription pain medications
- · Inappropriate reimbursement
- Unreasonable/misguided patient expectations
- Direct to consumer marketing of prescription drugs
- · Fragmentation of healthcare delivery
- · Unintended consequences of public policies
- · Lack of data

There is no question that competing public health concerns, i.e., the under-treatment of pain and the abuse of prescription drugs, present a major policy dilemma in the United States. The question that must be addressed is how to curtail the abuse of prescription pain medications and not make it more difficult for people struggling with chronic pain to receive the medications they need⁵.

However, there are also a number of other factors that add to the controversy surrounding pain treatment and the travesty of *improper* treatment, including those listed above.



States and localities across the nation are creating their own programs to stop harm from nonmedical and medical use of opioids without blocking access for patients in pain. In Utah, a collaborative effort combined physician and patient education with a media campaign to

raise awareness. Subsequently, the state saw a 28% reduction in opioid-related overdose deaths from 2007-2010. No mandatory prescribing limits or other restrictive policies were necessary to achieve this success.

Lynn Webster, MD

Medical Director CRILifetree
President Elect
American Academy of Pain Medicine



A major challenge to people living with pain is that pain management is not a unified field, and care is often not coordinated. There are various types of providers who treat pain, from primary care, to interventionalists, to psychiatrists, to chiropractors, and others. Each professional track requires different training, different areas of focus, and different approaches to treating pain. For example, a primary care physician may rely on prescription medication as a first-line therapy in addressing pain, but may or may not be familiar with the intricacies of dosing, or have experience in the management of chronic pain. Interventionalists may rely on giving regular injections, which may also provide temporary relief, but may not address the underlying cause of the pain. A psychiatrist may offer an anti-depressant combined with therapy. Chiropractors may utilize spinal adjustments that enable relief for a short period of time, but do not take into consideration other contributing factors. These are all different approaches that a patient may experience and possibly benefit from. Typically care that a patient receives is based on a random selection process of providers who are covered by their insurance plan.

Dollar-driven decision-making has led to inappropriate pain treatment, such as unnecessary surgeries, routine injections of questionable benefit, and over-reliance on prescription pain medications. It has also denied access to services such as physical therapy, diet and nutrition counseling, chiropractic care, psychological counseling and other approaches which may provide significant benefit. Often the primary, even singular, treatment available is what the person's insurance covers as opposed to integrated pain management that often results in the best outcomes.

Controlled substances and medical and pharmacy practice policies enacted to govern opioid medications and prevent abuse and diversion come into play when healthcare practitioners prescribe, dispense, or administer opioids to relieve pain. These policies should represent a government's dual obligation not only to establish a system of drug controls to prevent abuse and diversion, but also to ensure the adequate medical availability of needed medications. This is referred to as the Central Principle of Balance...

People experiencing pain unquestionably also play a role in the success or failure of a treatment program. As a society, we have come to expect "quick fix" solutions even for complex problems. Healthcare consumers are clearly influenced by direct to consumer drug marketing. People living with pain are no different. This marketing approach fuels the belief that there is a pill that will fix everything. It is, without question, far easier to take a pill or get an injection than it is to do the hard work sometimes required to achieve wellness. This, of course, is also true for clinicians. It's much easier to write a prescription or to give a shot than it is to engage in the work/process required in a bio-psychosocial or integrated approach to pain management.

There are several examples of unintended consequences of one-sided policy developed with presumably good intentions. In an effort to address prescription drug abuse, people with pain are facing increasing challenges to accessing pain care, greater stigmatization among health care providers who refuse to treat them, and more pharmacies refusing to fill prescriptions for certain pain medications or from certain providers.

Well-intended attempts at "balanced" policy have not always resulted in fair and equitable treatment for people with pain. Fair and ethical policy must also be based on facts, and sometimes the facts are missing or confusing.

What are the Facts?

Chronic pain is an enormous problem. It is expensive to individuals and society, and healthcare professionals have not been adequately trained to manage persistent pain. The IOM report, *Relieving Pain in America*, made a significant contribution towards addressing the under-treatment of pain. For the first time, there is a clear picture of the scope of chronic pain – one of the major public health issues in the U.S., that affects more people than those with cancer, diabetes and heart disease combined.

Pain is expensive: The cost of pain in humanistic terms (e.g., the loss of jobs, relationships, concepts of self and even life itself) is incalculable. In economic terms, the cost to our

Scope of the problem as summarized by the IOM: Acute and chronic pain affects large numbers of Americans, with at least 100 million U.S. adults burdened by chronic pain alone. The annual national economic cost associated with chronic pain is estimated to be \$560-635 billion. Pain is a uniquely individual and subjective experience that depends on a variety of biological, psychological, and social factors, and different population groups experience pain differentially. For many patients, treatment of pain is inadequate not just because of uncertain diagnoses and societal stigma, but also because of shortcomings in the availability of effective treatments and inadequate patient and clinician knowledge about the best ways to manage pain. Some answers will come from exciting new research opportunities, but changes in the care system also will be needed in order for patients' pain journeys to be shorter and more successful. In the committee's view, addressing the nation's enormous burden of pain will require a cultural transformation in the way pain is understood, assessed, and treated. IOM, Relieving Pain in America, 2011

society is between \$560-635 billion, annually. Treatment, often requiring a personalized and comprehensive approach, does not fit neatly into a singular reimbursement code.

As discussed earlier in this brief, reimbursement issues contribute enormously to how pain treatment is approached. Comprehensive Pain Programs (CPP) that provide integrated pain management have been shown to be effective in managing pain and helping people regain function. However, "a major obstacle to effective CPPs is the lack of understanding of third-party payers who refuse to cover such programs, even though CPPs are known to be beneficial in significantly reducing pain and disability. Efforts of third-party payers to contain costs have paradoxically steered patients away from treatments

that demonstrably reduce healthcare utilization and toward more expensive therapies with poorer outcomes...." Simply put, there is little financial incentive for healthcare providers to take on complex and challenging patients with pain when they will not be reimbursed for their services.

Healthcare professionals have not been appropriately trained to treat chronic pain. Financial concerns about reimbursement for care is compounded by a lack of basic medical, nursing, pharmacy and dental school training about pain management. While pain is a leading reason that people seek medical attention, there are only an estimated 3,488 physicians who have received advanced training or specialty in treating pain in the past decade – an enormous disparity considering the scope of the problem⁷.

Medical schools' inadequate attention to comprehensive pain education has been quantified. A recent study of 117 U.S. and Canadian medical schools found that only four U.S. schools offer an elective course on pain⁸. Most schools incorporate pain into another required course. The study also found that over the four-year course of U.S. medical school education:

- the total number of pain sessions taught ranged from 1 to 28 (mean of 9, median of 7); and
- the total number of pain teaching hours ranged from 1 to 31 (mean of 11, median of 9)⁸.

The gap between knowledge and need is enormous. At best, this lack of basic education contributes to wavering confidence and uncertainty about available, safe and effective treatment options. Combined with cultural biases and attitudes toward people with pain and confusing and unclear policy that attempts to regulate pain care options, it creates an environment ripe for pain patient abandonment. While increased and improved health care provider education is necessary, it is not sufficient to transform pain care.

In response to this problem, the National Institutes of Health Pain Consortium has selected 11 health professional schools as designated Centers of Excellence in Pain Education (CoEPEs). The CoEPEs will act as hubs for the development, evaluation, and distribution of pain management curriculum resources for medical, dental, nursing and pharmacy schools to enhance and improve how healthcare professionals are taught about pain and its treatment. Twenty institutes, centers and offices at NIH are involved in the consortium.



"Doctors, who don't lack for compassion or medical skills, often offer only limited treatments to patients disabled by chronic pain," said Lonnie Zeltzer, M.D., cochair of Mayday Fund Special Committee on Pain and the Practice of Medicine, and the director of the Pediatric Pain

Program at the University of California, Los Angeles. "With little or no specific training in pain management, and working in systems that make it much easier to treat common conditions like high blood pressure than a complex problem like pain, doctors may intend to help but leave most patients under-assessed and under-treated. Minorities, children and women often faced the highest risk of under-treatment." 6

FUTURE ISSUE OF PAINS FOR STATE POLICY MAKERS

It is important to act on what we know. However, there is much more information needed by policy makers. Questions that need to be answered in order to establish fair and equitable policy that impacts the care of those living with chronic pain include:

- What are the real reasons physicians are concerned about treating chronic pain?
- What is the impact of long-term opioid use for chronic pain?
- What is the real data about abuse and addiction of prescription pain medications?
- · What is the impact of pain contracts?
- What are cost and productivity/disability outcomes considerations for workplace injuries and workers compensation?
- What is the role of state departments of health/ epidemiology?

Future issues of the PAINS policy brief series will address these questions and present examples of public policies that make a positive contribution and policies that have been proven not to work or to be of questionable benefit. Some of the policy issues that will be addressed include:

- Pill Mills
- Prescription Monitoring Programs (PMPs)
- Fail First or "Step Therapy"
- Therapeutic Switching
- · Restrictions on Prescribing and Mandatory Referrals
- Mandatory Health Care Provider Pain Education
- Pain Contracts and Pain Registries
- · Data Collection, Research and Evaluation of Policies

Examples of innovative or proven policy regarding the treatment of pain will also be presented.



PAINS seeks to be the driving force behind implementation of recommendations made in the IOM report, *Relieving Pain in America*. Members of the PAINS alliance will work collaboratively to change attitudes about those living with pain and improve outcomes of care and to promote innovative and promising practices and public policy to truly transform the way that pain is approached in America. Some of those which will be highlighted include:

PAINS wants to assist policy makers responsible for making fair and equitable policies that protect the rights of their citizens, prevent harm and promote the common good and well-being of all those they serve. Participants are confident that objective well-researched information and access to opinions of leading national experts will lead to such policies which will, in turn, contribute to better care for the millions of Americans struggling day-after-day to live with chronic pain.

- Successful public education campaigns targeted at preventing chronic pain and the misuse of prescription pain medications
- Healthcare professional education to promote integrated pain management
- Progressive state board policies that protect and preserve provider/patient relationships and protect the public
- Dialogue between medical specialists and law enforcement to build understanding and trust
- Effective Prescription Monitoring Programs (PMPs) that provide prescribing healthcare professionals with "real time access" and improve patient care



GLOSSARY OF TERMS

Acute pain: Pain that comes on quickly, can be severe, but lasts a relatively short time.

Addiction: A primary, chronic, neurobiologic disease whose development and manifestations are influenced by genetic, psychosocial, and environmental factors. It is characterized by behavior that includes one or more of the following: impaired control over drug use, compulsive use, continued use despite harm, and craving.

Biomedical model: This is the dominant, modern way that health care professionals diagnose and treat a condition in most Western countries. According to this model, good health is the freedom from pain, disease, or defect. It focuses on physical processes that affect health, such as the biochemistry, physiology, and pathology of a condition. It does not account for social or psychological factors that could have a role in the illness. The focus is on objective laboratory tests rather than

the subjective feelings or history of the patient. "Traditional biomedical models purport that pain, like other biologically mediated phenomena, is directly related to the biology of the organism. In the case of pain, the medical model would predict that the greater the injury or nociceptive input, the greater the pain intensity experienced by the organism. Although this assumption is intuitively valid and anecdotally supported, empirical support is often limited. Knowledge of the extent or degree of sustained injury or physiologic insult remains a poor predictor of reported chronic pain."

Biopsychosocial model:

A framework that accounts for the biological, psychological, and social dimensions of illness and disease. The biopsychosocial model provides a basis for the understanding and treatment of disease, taking into account the patient, his/her social context, and the impact of illness on that individual from a societal perspective. The model

states that ill health and disease are the result of interaction among biological, psychological, and social factors.

Chronic pain: Ongoing or recurrent pain lasting beyond the usual course of acute illness or injury or, generally, more than 3 to 6 months and adversely affecting the individual's well-being. A simpler definition for chronic or persistent pain is pain that continues when it should not.

Cognitive-behavioral

therapy: An empirically supported treatment focusing on patterns of thinking that are maladaptive and the beliefs that underlie such thinking. Cognitive-behavioral therapy is based on the idea that our thoughts, not external factors, such as people, situations, and events, cause our feelings and behavior. As a result, we can change the way we think to improve the way we feel, even if the situation does not change.

Interdisciplinary:

Refers to efforts in which professionals from several disciplines combine their professional expertise and understanding to solve a problem.

Integrative Pain

Management: Integrated medicine is the practice of medicine that is informed by evidence, is patient-centered and reaffirms the importance of a healing, covenantal partnership between practitioner and patient, focuses on the whole person-mind, body, spirit, in the context of the individual's community/environment, brings together all appropriate therapeutic approaches (allopathic, osteopathic, and complementary) and healthcare professionals to reduce pain and achieve optimal health and healing, and supports the individualization of care. Integrated Pain Management (IPM) applies this approach to the treatment of pain.

Multidisciplinary: Often used interchangeably with "interdisciplinary," multidisciplinary care employs several types of clinicians in the treatment of a patient, but they may not be working together to decide on a treatment plan. The interdisciplinary approach calls for communication and coordination among the various clinicians.

Opioid: Any compound that binds to an opioid receptor. Includes the opioid drugs (agonistanalgesics and antagonists) and the endogenous opioid peptides.

Pain: An unpleasant sensory and emotional experience associated with actual or potential tissue damage, or described in terms of such damage.

Physical Dependence:

Physical dependence is a state of adaptation that is manifested by drug class specific signs and symptoms that can be produced by abrupt cessation, rapid dose reduction,

decreasing blood level of the drug, and/or administration of an antagonist. Physical dependence, by itself, does not equate with addiction.

Referred pain: Pain subjectively localized in one region although due to irritation in another.

Tolerance: Tolerance is a physiologic state resulting from regular use of a drug in which an increased dosage is needed to produce a specific effect, or a reduced effect is observed with a constant dose over time. Tolerance may or may not be evident during opioid treatment and does not equate with addiction.

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STEERING COMMITTEE MEMBERS

Myra Christopher

Steering Committee Chair Kathleen M. Foley Chair in Pain and Palliative Care at the Center for Practical Bioethics (Member of the IOM Pain Committee)

Daniel B. Carr, MD, FABPM, FFPMANZCA (Hon.)

Director, Program in Pain Research Education and Policy Tufts University

Janice Chambers

Founder and President National Fibromyalgia and Chronic Pain Association

James Cleary, MD, FAChPM

Associate Professor of Medicine, University of Wisconsin Director, Pain and Policy Studies Group

Lenore Duensing

Executive Director

American Academy of Pain Management

Katherine Galluzzi, DO

Professor and Chair of the Department of Geriatrics Philadelphia College of Osteopathic Medicine American Osteopathic Association

Jim G. Lemons, Ed.D.

Founder and Director The Lemons Center for Behavioral Pain Management

Martha Menard, PhD

Academic Consortium for Complementary and Alternative Healthcare

Chris Pasero, MS, RN-BC, FAAN

Pain Management Educator and Clinical Consultant American Association of Critical-Care Nurses American Society of Pain Management Nursing

Richard Payne, MD

Esther Colliflower Professor of Medicine and Divinity Duke University (Member of the IOM Pain Committee)

Joe Pierle

Executive Director
Missouri Primary Care Association

Orvalene Prewitt

Patient Representative Program Coordinator, Missouri Regional Arthritis Centers - KC RAC

William F. Rosenberg, MD

Founder Pain Relief Center Research Medical Center

Jason Schwalb, MD

Joint Pain Section
American Academy of Neurological Surgeons
and College of Neurological Surgeons
Department of Neurosurgery - Henry Ford
Medical Group

Jennifer Wagner

Executive Director
Western Pain Society

Lynn Webster, MD

Medical Director and Founder Lifetree Clinical Research & Pain Clinic

Lonnie Zeltzer, MD

University of California at Los Angeles (Member of the IOM Pain Committee)

For further information call 800 344-3829 or email mchristopher@practicalbioethics.org

