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PAIN MANAGEMENT

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>
> Kathleen M. Foley, M.D.

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PATIENTS IN PAIN

Casualties of the war on drugs

BY KATHLEEN M. FOLEY, M.D.

Recently one of my patients, a woman in her early sixties who was suffering from severe chest pain following surgery for lung cancer, went to her local pharmacy to fill prescriptions for the pain medications that I had prescribed. The pharmacist warned her that the medications were very powerful and that she could become addicted to them. The patient responded by refusing to take the prescribed pain medications. When I discussed this with her two days later, after her husband called saying she was still in severe pain, she said, “I’d rather be in pain than have anyone think I’m an addict.” This clinical anecdote captures the reality of the undertreatment of pain, which is one of the serious, unintended consequences of the war on drugs.

Current media attention has focused on the abuse of the prescription opioid pain medication OxyContin. But by highlighting OxyContin’s illegal use by drug abusers, we are failing to educate the public about the essential role such analgesic drugs play in safely providing relief for millions of patients suffering from severe pain. These news stories help perpetuate long standing misconceptions about pain management. Public surveys have demonstrated that they have a negative impact on pain patients’ access to opioid treatments.

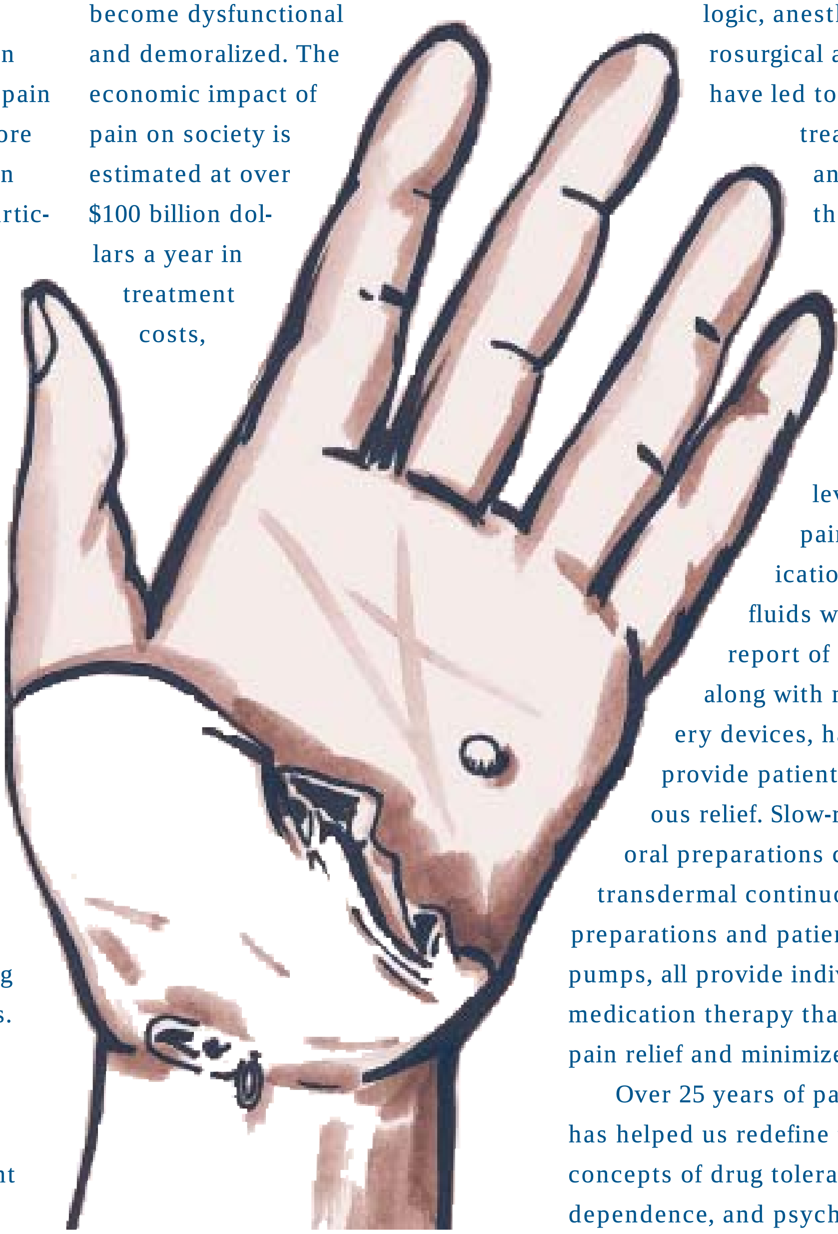
This sensationalizing of prescription opioid abuse adds to the impact of national anti-drug campaigns like “Just Say No to Drugs” that promote the idea that anyone can become an addict, viewing the risk of addiction as a problem of the drug and not the person. Indeed, the war on drugs must not become a war on patients. These misconceptions have influenced the attitudes and behaviors not only of patients and pharmacists, but also of healthcare professionals who report fear of addiction as a major barrier to treating acute and chronic pain patients with opioids. In fact, the likelihood of addiction as a result of medically prescribed pain medication is extremely low.

Pain is a serious public health issue in the United States. More than 50 million people live with chronic pain associated with various diseases. Each year, 25 million people experience acute pain as a result of injury or surgery. Between 70 and 90 percent of cancer patients with advanced disease experience pain, despite the fact that 95 percent of cancer patients could obtain relief with proper treatment.

A major study of over 10,000 seriously ill, adult, hospitalized patients found that 50 percent of dying patients had significant pain in the last three days of their lives.

Studies have demonstrated that patients with cancer, AIDS, sickle cell disease, and arthritis have been needlessly undertreated for pain. The elderly in nursing homes, children, and women are the disproportionately undertreated groups. Over 35 percent of elderly cancer patients living in nursing homes have inadequate pain treatment for the level of their pain, based on international standards of the World Health Organization. Interviews with parents of children who died of cancer reported that pain was inadequately controlled in more than 37 percent of their children in the last days of life. Minorities, particularly African Americans and Hispanics, are also at substantial risk for undertreatment of pain.

Although differences in access to care and variation in quality of care play a role in this under treatment, it appears that access to pain medications is a major limiting factor. A recent study showed that African American and Hispanic patients with severe pain are less likely to obtain commonly prescribed pain medications because pharmacies in non-white communities do not adequately stock opioids; pharmacists cited concerns about illicit use of drugs and fear of theft as reasons for not stocking analgesic medications like opioids. This demonstrates how the widespread undertreatment of pain reflects strong societal attitudes toward both pain and its treatment with analgesic drugs.



The impact of untreated pain is significant. Unrelieved pain interferes with all aspects of life, diminishing activity, appetite, sleep, and social interactions. The psychological effects of pain can be devastating, causing feelings of anxiety, hopelessness, and depression. Chronic unrelieved pain often leads patients to consider or commit suicide. Families of people living with pain often become dysfunctional and demoralized. The economic impact of pain on society is estimated at over $100 billion dollars a year in treatment costs, workmens' compensation costs, lost wages, and lost days of work.

These economic and social costs of unrelieved pain are largely avoidable. Decades of research and clinical experience have led to both pharmacological and conceptual advances in pain treatment. Improved methods to measure patients' pain, coupled with increased knowledge of the numerous pain syndromes and the role of radiologic, anesthetic, and neurosurgical approaches, have led to improved treatment. Opioid analgesics remain the mainstay of the treatment for moderate to severe pain. Advances in our ability to correlate the levels of these pain killing medications in body fluids with patients' report of pain relief, along with new drug delivery devices, have helped to provide patients with continuous relief. Slow-release opioid oral preparations can, along with transdermal continuous-release preparations and patient-controlled pumps, all provide individualized medication therapy that maximizes pain relief and minimizes side effects.

Over 25 years of pain research has helped us redefine the important concepts of drug tolerance, physical dependence, and psychological dependence or addiction. We now have a better understanding both from our clinical experience in treating large numbers of cancer patients with chronic pain and from advances in basic science. This knowledge needs to be incorporated into the everyday practice of physicians to facilitate their ability to appropriately prescribe opioid drugs for patients.

From our clinical experience of developing and implementing scientific guidelines for the use of opioids for cancer pain patients, we have demonstrated that tolerance is not a limiting factor in their use. Initially, it was believed that patients would become tolerant to opioids, reducing the medication's effectiveness to control pain; however, patients can take opioid drugs for months or even years and still obtain adequate relief. Patients taking opioids on a perpetual basis may become physically dependent; that is, if they stop taking the drug abruptly, they may show signs of withdrawal. Slowly tapering a patient off the drug, however, eliminates these withdrawal symptoms. Addiction, on the other hand, is the term used to characterize behaviors of compulsive drug use despite harm. When physicians and patients confuse tolerance and physical dependence with addiction, patients become stigmatized and pain therapy is threatened.

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Sometimes patients with pain develop behaviors that are misinterpreted as drug seeking behaviors; they request increased doses or take more medicine than prescribed. Studies of cancer patients have demonstrated that this phenomenon of pseudo addiction is seen in people who are inadequately treated for their pain. Once pain is managed, these behaviors stop. When patients are given pumps to self administer opioid medications, they consistently take only what is needed to maintain relief. Furthermore, experience has shown that known addicts can benefit from supervised use of opioids to treat pain due to cancer, surgery, or recurrent illnesses.

Advances in our understanding of the molecular biology of opiate receptors, neurotransmitters, and endogenous pain modulatory systems is now providing the scientific rationale for how we use opioid drugs, and how we develop new agents to block the development of tolerance and physical dependence.

Despite these well-studied medical and conceptual advances, pain remains poorly managed. What accounts for the astonishing gap between the degree of relief that is possible and the suffering that still persists? The efforts to improve pain treatment are complicated because the type of drugs that effectively treat pain are the same drugs that are commonly abused.

Concerns about opioid substance abuse and diversion dominate American opioid drug policy, shaping attitudes and behavior toward patients with pain whose complaints are interpreted as drug-seeking behavior rather than as legitimate requests for treatment. Fear of addiction and abuse has stigmatized these drugs, contributing both to clinician reluctance to prescribe them and patient concerns about use. Under the Harrison Act of 1918, opioid analgesics are legally defined as controlled substances to be regulated by international, national, and state laws. Pharmaceutical companies producing them, physicians prescribing them, and pharmacists dispensing them require special licenses and must follow strict regulations. The prescribing of opioid drugs, in contrast to other medications, is carefully regulated by the Drug Enforcement Agency (DEA) and various state agencies. Physicians must be licensed by state medical authorities and registered with the

DEA before prescribing controlled substances. In a survey of more than 1,300 licensed physicians in New York, more than 30 percent of respondents reported concern that the state's drug regulatory agency might scrutinize their prescription records. Some 30 percent admitted to prescribing fewer refills and less effective medications because of concerns about possible investigation.

Changing attitudes and behaviors towards pain and its management will require more than developing scientific guidelines and evidence-based approaches. It will require institutionalizing these new concepts and ideas in healthcare education, public education, and public policy. It will require the development of advocacy strategies that focus directly on well-identified barriers to quality care of patients with pain.

There are encouraging signs that pain management is finally starting to achieve the status it deserves in healthcare and public policy. Under new regulations of the Joint Committee on Accreditation of Health Care Organizations (JCAHCO), hospitals and healthcare facilities must regularly assess, monitor, and manage pain in all patients or risk losing their accreditation. Each healthcare facility must now document how they assess pain and develop programs to assure the competency of their healthcare professionals to manage pain. Pain has now been designated as a fifth vital sign to be recorded with blood pressure, pulse rate, respiratory rate, and temperature. In response to these new standards, hospitals and healthcare facilities are developing quality improvement programs to demonstrate their commitment to improving pain management.

In 2001 the DEA, along with 42 leading healthcare groups supporting pain management, released a landmark consensus statement calling for a balanced policy on prescription pain medications. The statement marks the first time the DEA has collaborated with such groups to support better pain management. Attention to these policy issues has been encouraged by the growth of various initiatives representing coalitions of healthcare professionals and patients. Now there are 46 state cancer pain initiatives, coordinated by the Alliance of Cancer Pain Initiatives, that advocate for quality pain care at a state level. By focusing their attention on reducing the regulatory and legislative barriers to quality pain care, these groups serve as excellent models for reform, supporting both professional and public education programs. To insure that the needs of pain patients are voiced, the American Pain Foundation supports grassroots efforts that heighten the awareness of chronic pain as a serious public health issue, which impacts the quality of life of more than 50 million Americans.

Despite this increasing attention to pain patients, there still exists a profound need for ongoing research and education, so that members of the healthcare community, the regulatory community, and the general public are well informed about the appropriate uses of opioid medications. Opioids are critical medicines for pain relief. Access to these drugs for legitimate medical uses is essential; regulation and enforcement of laws stemming from diversion and abuse are unavoidable. Doctors, patients, and the public at large must understand the true risks and benefits; the regulatory community must address abuse without inciting undertreatment; and the public must be informed with balanced, accurate information.

Kathleen M. Foley, M.D. is the director of the Project on Death in America at the Open Society Institute. She is an attending neurologist in the Pain and Palliative Care Service at Memorial Sloan-Kettering Cancer Center in New York City. She is also a professor of Neurology, Neuroscience, and Clinical Pharmacology at Cornell University Medical College.

The Pain and Policy Studies Group

Protecting patients from the war on drugs

"Pain prevented me from working the way I wanted to, from participating in my social life the way I wanted to, from being the kind of person that I was prior to my car accident. I began taking an opioid pain medication almost a year after the accident. I was a reluctant patient. I was fearful that those medications would impact my ability to think as a professional, that they would change my personality. Terrific doctors educated me on the realities of using pain medications, and it was profoundly positive in my life."

–**Mary Vargas**, 28, attorney

BY LORI McGLINCHEY

Most people assume that when a doctor decides to treat a patient's pain based on the best practice of medicine, she can write a prescription for the most effective medication and the patient can simply fill it at a pharmacy. It is not so simple. Pain management is complicated by a tangle of federal and state policies. Highly regulated prescription and practice policies impact physicians' prescription practices and may prevent patients from getting the medications they need to alleviate acute and chronic pain.

David Joranson, director of the Pain and Policy Studies Group (PPSG), a program of the University of Wisconsin Medical School, has spent the last 20 years untangling these drug policies and regulations. The PPSG has undertaken the only systematic analysis of the international, national, and state regulations that impact pain management with analgesic drugs. Joranson's work bridges the gap between regulators who work to prevent the illegal diversion of prescription medications and clinicians who treat pain patients. Joranson believes that balance must exist between effective pain management and laws designed to prevent abuse.

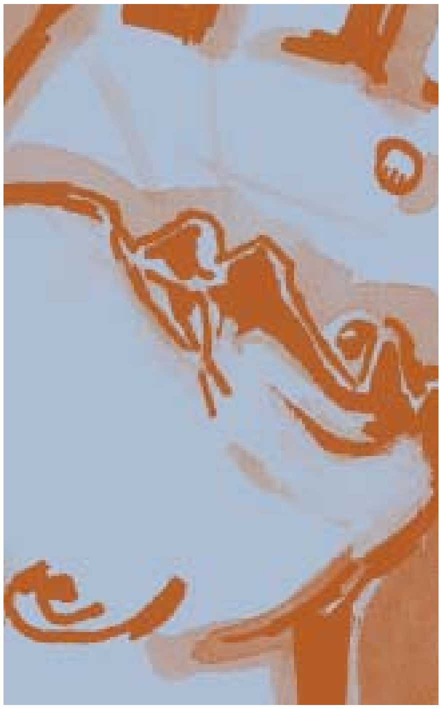
Opioids are the mainstay of pharmacological pain management. They are also controlled substances with addictive properties. Fear of abuse has stigmatized these drugs, contributing to both clinician reluctance to prescribe them and patient reluctance to take them. This fear, combined with well-publicized cases of physicians disciplined or prosecuted for allegedly over-prescribing these medications, has led to increasing distrust between the medical community and those in drug regulation and law enforcement. Strong evidence indicates that many physicians don't know the laws governing opioid pain medications. Few regulators know much about current methods of pain management.

In the fall of 2001, Joranson was instrumental in bringing the Drug Enforcement Administration (DEA), which monitors and regulates the use of opioid prescription drugs, together with a coalition of healthcare and pain prevention organizations. This unprecedented coalition issued a joint statement calling for balanced opioid pain medication policy.

David Joranson is uniquely positioned to create these kinds of coalitions. Before he worked to protect pain patients from restrictive regulations, he was himself a regulator—an administrator of the Wisconsin Controlled Substances Board. "In the mid-1980s a bill was proposed in Congress to make heroin available for treating pain in cancer patients. We looked at the proposal carefully, but could not see how physicians—who were already afraid to prescribe morphine—would suddenly embrace heroin," Joranson says. "Still, we could not just oppose the bill without taking some steps to address cancer pain, so we started the Wisconsin Cancer Pain Initiative. As the initiative concept took root in other states, restrictive state laws and regulatory barriers became more apparent, and I decided to start a policy studies program within the pain field."

Joranson stresses that making changes to a policy may not, by itself, result in appreciable changes in how practitioners, patients, or the public perceive state policy. Policy change must be accompanied by communication among healthcare professionals, policy makers, and the public. A state's policy should not only be balanced; it must be understood as balanced. The PPSG supports an aggressive communications program to improve access to information about pain relief and policy.

Although federal policy — which regulates controlled substances — recognizes the medical value of opioids for pain relief, many state policies do not. In 1998 the PPSG helped the Federation of State Medical Boards to develop model guidelines for the use of controlled substances in the treatment of pain. (State boards license physicians and govern medical practice.) Joranson helped bring state regulators together with physicians knowledgeable about effective pain management. They were able to reach an understanding about how public policy should be sufficiently flexible to allow good pain management in the states. These guidelines have been adopted in whole or in part by 18 states, providing a set of parameters within which physicians can practice adequate pain management without fear of investigation.



The Pain and Policy Studies Group does not limit its policy work to the United States. As a member of the World Health Organization Collaborating Center for Policy and Communications in Cancer Care, the PPSG supports a program of international policy studies to identify and address barriers to opioid availability in national policy and healthcare systems. PPSG sponsored a demonstration project in India that has shown it is possible to increase the use of opioid analgesics in treating pain without an increase in abuse and diversion. These results were published in the medical journal *The Lancet* (v. 358, July 2001).

One of the PPSG's major accomplishments was the preparation of guidelines for governments and health professionals to evaluate the national opioids control policies of any country in the world to determine if they provide for pain relief. *Achieving Balance in National Opioids Control Policy: Guidelines for Assessment* was published in 2000 by the World Health Organization.

Joranson believes that the increased media coverage of the abuse of pain medications makes the PPSG's work even more relevant as doctors and law enforcement professionals search for balanced ways of responding to diversion without interfering with patient care. "We have a lot of work ahead of us," says Joranson. "The vision of the program is that people who suffer from cancer, AIDS, surgery, accidents, and chronic conditions will have relief from their pain and a better quality of life, and that caregivers will know when and how to use opioid analgesics without fear of regulatory agencies."

Lori McGlinchey is a program officer for the Project on Death in America at the Open Society Institute.

400 West 59th Street
New York, NY 10019
Phone: (212) 548-0600
Fax: (212) 548-4622
www.soros.org

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OSI and a balanced pain policy

The experience of dying has changed over the past several decades, with many more people enduring prolonged deaths as a consequence of chronic, progressive disease. Needless suffering — physical, emotional, existential, and spiritual — too often accompanies these deaths, for both dying persons and survivors.

The mission of the Project on Death in America is to understand and transform the culture and experience of dying and bereavement through initiatives in research, scholarship, humanities, and the arts; and to foster innovations in the provision of care, public education, professional education, and public policy.

Mission Statement

The Open Society Institute is a private operating and grantmaking foundation that promotes the development of open society around the world. OSI's U.S. Programs seek to strengthen democracy in the United States by addressing barriers to opportunity and justice, broadening public discussion about such barriers, and assisting marginalized groups to participate equally in civil society and to make their voices heard. U.S. Programs challenge over-reliance on the market by advocating appropriate government responsibility for human needs and promoting public interest and service values in law, medicine, and the media. OSI's U.S. Programs support initiatives in a range of areas, including access to justice for low and moderate income people; independence of the judiciary; ending the death penalty; reducing gun violence and over-reliance on incarceration; drug policy reform; inner-city education and youth programs; fair treatment of immigrants; reproductive health and choice; campaign finance reform; and improved care of the dying. OSI is part of the network of foundations, created and funded by George Soros, active in more than 50 countries around the world.

For an ELECTRONIC VERSION EMAIL:
infoUSprograms@sorosny.org
or VISIT: www.soros.org

Open Society Institute
400 West 59th Street
New York, NY 10019