Experts Worry About Chilling Effect of Federal Regulations on Treating Pain

Undertreated pain is a long-standing problem in health care. The American Cancer Society suggests that up to 50% of seriously ill and dying cancer patients in the United States suffer from pain that could be adequately treated with available drugs. Myriad factors contribute to the problem; chief among them is that many doctors are not well trained in pain management, particularly with opiates such as methadone, morphine, and oxycodone.

But also part of the problem, says Russ Portenoy, M.D., chairman of the Department of Pain Medicine and Palliative Care at Beth Israel Hospital in New York, is that oncologists and physicians alike are increasingly reluctant to prescribe adequate pain relief to their patients because they fear subsequent investigations from law enforcement, particularly the U.S. Drug Enforcement Agency (DEA).

“The DEA had previously been viewed [by physicians] as relatively enlightened,” Portenoy said. “Sadly, events during the last 6 months suggest the agency has become confused about its mission and is now willing to pursue policies that worsen undertreatment [of pain] in an effort to reduce prescription drug abuse.”

Fear of Investigation

According to Judith Paice, Ph.D., research professor of medicine at Northwestern University Feinberg School of Medicine in Chicago, the roots of the tension between physicians and the DEA dates back to the emergence of OxyContin (oxycodone hydrochloride) abuse, which became widespread during the late 1990s. In 2001, Glen A. Fine, the inspector general of the Department of Justice, accused the DEA of not doing enough to combat illegal prescription drug use, which he claimed was even more prevalent than the abuse of cocaine. In response to these charges, the DEA in that same year released a four-part action plan to stem the flow of OxyContin into illegal markets. As part of this plan, DEA officials increasingly targeted physicians and pharmacists.

But even before the DEA’s action plan, physicians were becoming hesitant to prescribe opioid painkillers. Several high-profile indictments heightened their fears. Among them was the case of Frank Fisher, M.D., a Harvard-trained pain specialist, who in 1999 was charged in California with drug distribution, fraud, and 15 counts of murder, all related to high-dose prescriptions of opioid painkillers. Fisher was exonerated on all of the counts, but it took 5 years for the charges to be dropped, thrown out, or dismissed, and the process cost Fisher hundreds of thousands of dollars in legal fees.

Ronald Libby, Ph.D., a professor of political science at the University of North Florida, estimates that the number of physicians now being investigated for prescription drug diversion could number as high as 1,500 per year. “The DEA needs to demonstrate to Congress that they’re making progress in the war on drugs,” Libby said. “And targeting physicians is an easy way to come up with the numbers. Now, most doctors are terrified to write these prescriptions.”

A Reversal at the DEA

Aware of physicians’ growing unease, DEA officials in 2000 met with David Joranson, director of the Pain and Policy Studies Group at the University of Wisconsin’s Comprehensive Cancer Center, and other experts to collaborate on a policy to balance medical use of painkillers with efforts to stem their illegal diversion. Their efforts resulted in a document called “Prescription Pain Medications: Frequently Asked Questions for Health Care Professionals and Law Enforcement Personnel.” Routinely called the FAQ, the document was published in hardcover form and on the DEA’s Web site in August 2004.

“We thought this was a watershed event,” recalled Portenoy, who spent 2 years working on the project. “It was the first time the DEA had reached out to the medical community to express support for the view that treatment of chronic pain is of paramount importance.”

But then, without warning, the DEA pulled the FAQ off its Web site in October. The DEA’s solc comment was that the FAQ was withdrawn because it contained “misstatements.” However, it has been widely speculated that the DEA pulled the FAQ after it was cited by defense attorneys representing William E. Hurwitz, M.D., a controversial pain specialist who in December was convicted on 50 counts that included drug trafficking resulting in death and serious injury.

The current substitute for the FAQ is an interim statement—titled “Dispensing of Controlled Substances for the Treatment of Pain”—that describes how “DEA plans to address in a future Federal Register document the issue of dispensing controlled substances for the treatment of pain.” The interim policy statement was published in the Federal Register on Nov. 16. Comments from the public are now being received by the agency, which plans to issue a complete statement at some point in the future. The DEA declined to answer questions regarding its views on the subject for this article.

The interim statement reverses the FAQ on several points. For instance, the FAQ affirmed that neither the number of patients who receive opioids, nor the number of tablets prescribed to each patient, nor the duration of therapy, should constitute the sole basis for a DEA investigation. The interim statement, on the other hand, lists all these factors as potential indicators of diversion that could trigger an investigation. Another key change involves opioid refills. The FAQ sanctioned the practice of writing multiple prescriptions on the same day for future refills on different days. However, the interim statement identifies this as a recurring
tactic among physicians who divert prescription drugs into illegal markets. Paice says physicians often write multiple prescriptions at once for frail and elderly patients to minimize their travel. “But the [interim statement] claims you can’t do that,” she said. “That means the patient has to drive to the hospital to get that prescription.”

Libby suggests that the DEA’s focus on practitioners is misplaced. In his view, the real sources of diversion are wholesalers, drug store robberies, and online pharmacies that operate on the fringes of the law, often outside the United States. But “in some cases,” he conceded, “pain patients will scam their own doctors … . That’s a major source of diversion: These patients will get their drugs, take some of them, and sell the rest. And that’s how the DEA will build a case—they go from the patient to the doctor.”

In light of this view, Philip Cifarelli, M.D., J.D., a physician who practices law in Santa Ana, Calif., argues that physicians can protect themselves by carefully documenting opioid prescriptions on a patient’s medical record. “When the chart is well documented, it’s a non-issue with the DEA,” he said. “Problems happen when there’s no rationale as to why these medications were prescribed.”

### Lawsuits and Pain Management

If there’s a view that the DEA and physicians both share, it’s that terminally ill patients nearing the end of life should not be denied adequate pain treatment. Lester Tomlinson was an 85-year-old man with mesothelioma whose requests for painkillers went unheeded during the last weeks of his life at a nursing home in Northern California. Tomlinson died in agony on Feb. 12, 2001. Soon after, Kathryn Tucker, J.D., director of legal affairs with Compassion and Choices, an end-of-life advocacy group based in Seattle, sued Tomlinson’s doctors for inadequate pain management and won—only the second time such a case had been successfully tried. (The first, also involving an 85-year-old lung cancer patient named William Bergman, was also tried by Tucker.)

California now mandates that physicians undergo 12-hour continuing medical education for pain management every year. Michigan and West Virginia had adopted similar policies in a trend that Tucker hopes will continue to grow. “Inadequate education surrounding pain is a huge and pervasive problem,” she said. “I’ll tell you anecdotally, when you sit across the table from a defendant during a deposition and ask about his training in pain management, and he answers, ‘an oncology course in medicine 30 years ago and a brown-bag lunch,’ you practically fall off your chair,” she said.

Tucker’s approach is to use the tort system to advocate for improved pain management. Portenoy, who emphasizes that physicians in general do not like tort as a tool for health care reform, concedes that findings against egregious offenders in pain care are a wakeup call for the entire community. “No one wants a flurry of lawsuits,” he said. “But among the group I hang out with, the reality of having these cases go forward successfully was met with some sense of satisfaction.”

Moving forward, issues concerning pain management will likely gain in profile. According to Portenoy, medical schools and residency programs now view education about pain and its treatment as a critical and unmet need. “What we [also need] is a rekindling of the events in the early 2000s,” he added.

“That’s when the DEA was reaching out to the medical community in a search for balance regarding ways to both treat patients and minimize the risk of diversion. We need to get the DEA and the state medical boards and law enforcement together to support an initiative that will remove barriers to more effective care.”

—Charles Schmidt