
■ CHAPTER 12 ■

Policy Barriers to Pain Control

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State attorneys general (AGs) are not doctors; nor, for the most part, do they have a medical background. They do, however, represent consumers of medical care: They have responsibilities regarding abuse or neglect, and they ensure that consumers receive the “benefit of the bargain” and are not shortchanged when they purchase medical treatment.

In 2002 and 2003, the National Association of Attorneys General (NAAG) sponsored a series of listening conferences focusing on end-of-life care. State AGs were disturbed to learn that many of their constituents were suffering from pain that could be treated but was not. They were surprised to learn that over 40% of the residents of nursing homes in their states were in moderate to excruciating pain every day—and remained so 2 to 6 months after reporting it (Teno, Weitzen, Wetle, & Mor, 2001).

The listening conferences raised three consumer questions: (1) Will my wishes be known and honored? (2) Will my pain be managed? (3) Will I receive competent care? The answer to question number two was “probably not.” Many reasons were cited for this gap in patient care, including fear of patient addiction, particularly if opioids were prescribed; insufficient medical education about pain management, which affects what doctors and hospitals do in practice; and the effects of state and federal public policy toward drugs.

While state AGs can have some impact on professional education, it is in the arena of public policy that attorneys general can make the biggest difference. As the chief legal officers for their states, they provide advice and counsel to state agencies, including medical licensure boards and law enforcement bureaus. They issue official opinions that—in most, if not all, states—have the effect of law, unless they are overturned by a court of competent jurisdiction. They can facilitate discussion between law enforcement and the medical community about the balance between effective pain management and the battle against diversion of prescription drugs.

LAW ENFORCEMENT

The state and federal governments have joint jurisdiction over narcotics in general and prescription drugs in particular. The same agencies that combat street dealing of prescription drugs and try to track those drugs to their sources also enforce the laws against cocaine, heroin, methamphetamine, marijuana, hashish, and ecstasy, to name a few.

The same agencies, if not the same agents, that raid marijuana fields, bust methamphetamine labs, interdict the importation of heroin, and engage in armed battles with street dealers are checking records in the offices of doctors who are registered with the Drug Enforcement Administration (DEA) to administer scheduled drugs by prescription. A doctor usually dreads the appearance of a narcotics agent.

Diversion is real. Drugs are sold on the street that should be available only by prescription, because they are dangerous when misused. These drugs are being abused and are causing damage to our society. Some are stolen from patients, sometimes by family members. Some are stolen from doctors' offices, pharmacies, factories, distributors, or supply trucks. Some are smuggled in from other countries. Some, unfortunately, come from doctors—doctors who grossly overprescribe, who may not even have seen the patient, and who are essentially selling drugs rather than providing care.

Pain is real, too. It can be described as chronic, acute, debilitating, sharp, dull, throbbing, excruciating, moderate, severe, intense, or exquisite; whatever its description, it is real. In proper patient care, it can and should be relieved. Overaggressive enforcement in combating diversion, without

sensitivity to needs and perceptions within the medical community, hampers effective pain management by causing medical practitioners to alter treatment, which leads to inadequate pain management.

In October 2001, the DEA and 21 health organizations published a joint statement, “Promoting Pain Relief and Preventing Abuse of Pain Medications: A Critical Balancing Act” (DEA, 2001). The statement said, in part, “Preventing drug abuse is an important societal goal, but there is consensus, by law enforcement agencies, health care practitioners, and patient advocates alike, that it should not hinder patients’ ability to receive the care they need and deserve.” By participating in this statement, the DEA committed to an official policy of balance between combating diversion and appropriate pain management.

In March 2003, the NAAG followed suit. At its spring meeting in Washington, D.C., with only one dissent and one abstention, NAAG passed a resolution calling for a balanced approach to promoting pain relief and preventing abuse of pain medications (NAAG, 2003). The resolution stated, in part,

Now, therefore, be it resolved that the National Association of Attorneys General:

1. Endorses the joint statement from 21 health organizations and the Drug Enforcement Administration, “Promoting Pain Relief and Preventing Abuse of Pain Medications: A Critical Balancing Act.”
2. Encourages states to ensure that any such programs or strategies implemented to reduce abuse of prescription pain medications are designed with attention to their potential impact on the legitimate use of prescription drugs. (NAAG, 2003)

At this point, the major players were on the same page. The administrator of the DEA was in agreement with the state AGs, and the state AGs could carry that message of balance to their drug agencies and local prosecutors. Egregious cases could still be prosecuted, but the prosecution would be accompanied by a restatement of the commitment to balance and an enunciation of why that particular case was worthy of criminal action. Borderline cases would be the province of state licensure boards, and aggressive pain management would be encouraged.

That train of good intentions was derailed in the fall of 2004.

Following the issuance of the joint statement on pain policy, the DEA published on its Web site a series of frequently asked questions (FAQs), with answers that were consistent with the new policy. The FAQs appropriately assured the medical community that factors such as the number of pain patients, number of prescriptions written, and dosages prescribed would not, by themselves, trigger a DEA investigation.

In the fall of 2004, however, the DEA was involved in the prosecution of Dr. William Hurwitz. That prosecution stemmed from an Organized Crime and Drug Enforcement Task Force investigation in Virginia that included the DEA, the Federal Bureau of Investigation (FBI), the Bureau of Alcohol, Tobacco, and Firearms (ATF), the Internal Revenue Service (IRS), the U.S. Attorney, and local police departments. During the trial, the defense sought to introduce into evidence the FAQs from the DEA Web site. The DEA removed the FAQs from the Web site, announced that they were inaccurate and incorrect as a matter of law, and issued an interim policy statement emphasizing that it could initiate an investigation based on just about anything. The court denied the defense motion to introduce the FAQs.

Lawyers can debate whether the court would have allowed the FAQs into evidence or whether, if introduced, they would have had any impact on the Hurwitz jury, which convicted the doctor on 50 counts of drug trafficking. A nonbinding statement of what might or might not trigger an investigation will not negate overwhelming evidence of guilt and would be, in the words of Perry Mason, “irrelevant and immaterial.”

The withdrawal of the FAQs and the issuance of the interim policy statement, however, proved to be very relevant and very material to the delivery of health services. Members of the medical community perceived the move as a shift in DEA policy and believed that they could and would be investigated on the basis of the number of patients they treated for pain, the number of prescriptions they wrote for pain medication, and the dosages. Patient care was adversely affected.

On January 19, 2005, 30 state AGs and the attorneys general for the District of Columbia and Puerto Rico wrote a letter to DEA Administrator Karen P. Tandy (NAAG, 2005a). The letter referred to the 2001 joint

consensus statement and the 2003 NAAG resolution, and to the fact that “both these documents reflected a consensus among law enforcement agencies, health care practitioners, and patient advocates that the prevention of drug abuse is an important societal goal that can and should be pursued without hindering proper patient care.”

The letter continued,

The “Frequently Asked Questions and Answers for Health Care Professionals and Law Enforcement Personnel” issued in 2004 appeared to be consistent with these principles, so we were surprised when they were withdrawn. The Interim Policy Statement, “Dispensing of Controlled Substances for the Treatment of Pain,” which was published in the *Federal Register* on November 16, 2004, emphasizes enforcement and seems likely to have a chilling effect on physicians engaged in the legitimate practice of medicine. As attorneys general have worked to remove barriers to quality care for citizens of our states at the end of life, we have learned that adequate pain management is often difficult to obtain because many physicians fear investigations and enforcement actions if they prescribe adequate levels of opioids or have many patients with prescriptions for pain medications. We are working to address these concerns while ensuring that individuals who do divert or abuse drugs are prosecuted. There are many nuances of the interactions of medical practice, end-of-life concerns, definitions of abuse and addiction, and enforcement considerations that make balance difficult in practice. But we believe this balance is very important to our citizens, who deserve the best pain relief available to alleviate suffering, particularly at the end of life. (NAAG, 2005a, p. 2)

The attorneys general requested a meeting with Tandy during their spring meeting in March, or as soon thereafter as possible; the meeting took place in April. In the meantime, the attorneys general responded to the DEA’s request for comment in the *Federal Register*. Thirty-two AGs signed comments dated March 21, 2005, and made the following recommendations:

1. We urge DEA to clearly restate its commitment to the balance policy released in 2001 and commit to balance in all public communications. We also recommend that DEA consider appointing an Advisory Committee both to reassure all major groups (health care professionals, consumers, state and federal law enforcement officers) that are affected by DEA's actions and to assist DEA in translating balance policy into practice;
2. In commencing investigations, focus on factors that distinguish the criminal trafficking and diversion of pain medications from the legitimate and responsible practice of medicine and other health professions;
3. Develop a clear statement of policy that the preparation of multiple prescriptions on the same day with instructions to fill on different dates can be a legitimate practice;
4. Allow health care professionals to determine how to interpret communications by family members consistent with the requirements of their professions and licensing boards;
5. Develop an Advisory Committee or commission an Institute of Medicine study to consider in depth the medical, ethical, law enforcement, and policy issues involved in prescribing pain medications to former and current addicts for the treatment of pain and to report recommendations;
6. Consider the changing realities of health care and the patient population in the United States, in addition to changes in the nature of drug abuse, as policy regarding prescription pain medication is developed. (NAAG, 2005b, p. 2)

The comments of the attorneys general—as well as comments from the medical and law enforcement communities, consumers of health care, and others interested in this issue—are under consideration by the DEA in its effort to formulate a new policy statement. It is unknown at this writing whether the DEA will enlist the assistance of an advisory committee or work with the medical community in any other official manner.

On April 12, 2005, Tandy met with NAAG President Bill Sorrell and AGs Joe Curran of Maryland and Drew Edmondson of Oklahoma to discuss the states' concerns relative to the balance issue. On April 14, Hurwitz was sentenced, and Tandy took the opportunity to make the following comments at a press conference:

DEA's enforcement strategy against doctors like Hurwitz hasn't changed. We employ a balanced approach that recognizes both the unquestioned need for responsible pain medication and the possibility, which today's case graphically illustrates, of criminal drug trafficking.

To the million doctors who legitimately prescribe narcotics to relieve patients' pain and suffering, you have nothing to fear from Dr. Hurwitz's prosecution and no reason to refrain from providing your patients with pain medications when you deem it medically necessary. (Tandy, 2005a)

Tandy took the opportunity to reiterate that the DEA recognizes and appreciates the balance between the efforts against diversion and the promotion of effective pain management. She also assured doctors that the practices of Dr. Hurwitz were well out of the mainstream and that the appropriate treatment of patients' pain should not be affected.

On August 26, 2005, the DEA published in the Federal Register a clarification of its interim policy statement of January 18, 2005, pertaining to the writing of multiple, predated prescriptions ("Clarification of Existing Requirements," 2005). While still not green-lighting this practice (which many physicians use in the treatment of chronic pain), the clarification suggested ways that new prescriptions could be issued without forcing the patient to return to the doctor's office, a hardship for patients in rural areas and those with mobility limitations.

It remains to be seen whether the DEA's final policy statement will be dramatically different from its interim policy statement. The interim statement stressed what the agency could do as a matter of law: Under law, very little is required to initiate an investigation. If this fact is emphasized in the final statement, physicians will be "chilled" in their practice and patients will suffer.

Tandy could not meet with the AGs in March, because the dates of their meeting were the same as her presentation of budget materials to Congress. She made that presentation on March 16, 2005, and listed the agency's "remarkable achievements" over the past year as follows:

- collapsing Caribbean transit organizations that were moving at least 10 to 12 percent of the U.S. cocaine supply;
 - maintaining dramatic reduction in the availability of LSD in this country through aggressive law enforcement;
 - indicting 34 of the 42 current Consolidated Priority Organization Targets (CPOTs), the leaders of the most wanted international drug supply organizations;
 - indicting nine and arresting four of Columbia's North Valley Cartel leadership who have been responsible for a third to a half of the cocaine brought into this country—two of the four individuals arrested are CPOTs;
 - dramatically reducing the number of methamphetamine 'super labs' in America, forcing large-scale producers to retreat into Mexico;
 - dismantling a Canadian-U.S. trafficking organization responsible for 15 percent of the U.S. ecstasy supply was a major contributing factor to a 10 percent decrease in the purity of MDMA pills (the lowest annual purity since 1996) and a corresponding 13 percent increase in price; and
 - initiating more than 144 investigations involving the online sale of controlled substances without a prescription.
- (Tandy, 2005b, pp. 2-3)

These are admirable accomplishments and precisely what the DEA should be doing—things that state and local law enforcement do not have the resources or jurisdiction to do. But perhaps the DEA should defer to state and local law enforcement the regulation of their physicians. And, for the most part, state and local law enforcement should defer to medical licensure boards judgments regarding appropriate or inappropriate pain management.

MEDICAL LICENSURE BOARDS

Most doctors know that the odds are slim that they will become the subject of a DEA investigation, particularly an investigation that results in prosecution. Unless they are prescribing for pay without attention to a patient's overall medical condition and management or dealing drugs for profit, physicians would have far more concern that aggressive pain management, particularly involving the use of opioids, would come to the attention of the licensure board rather than of the DEA.

In 2003, the DEA prosecuted 50 doctors; in 2004, 42. However, approximately 350 disciplinary actions are taken against doctors by state licensure boards each year. For this and other reasons, doctors tend to practice conservatively, which can result in the undertreatment of pain. Two surveys that demonstrated this fact:

A 1990 survey of oncologists studied the reasons for inadequate cancer pain management and found that 18% rated excessive regulation of analgesics as one of the top four barriers (Von Roenn, et al., 1993); a 1991 survey of Wisconsin physicians found that more than half would at least occasionally reduce dosage, quantity, or refills, or prescribe a drug in a lower schedule due to fear of regulatory scrutiny. (Weissman, Joranson, & Hopwood, 1991)

These surveys tell us what we intuitively know: If a doctor has two options and one is more likely to attract regulatory scrutiny, he or she will lean toward the safer option. That would be appropriate if the two options were equally efficacious and of equal benefit to the patient. But if the doctor's medical judgment says one thing and his or her sense of caution says another, then the patient will suffer needlessly.

In May 1998, the Federation of State Medical Boards of the United States (FSMB) adopted Model Guidelines for the Use of Controlled Substances for the Treatment of Pain (FSMB, 1998). This effort, supported in part by a Robert Wood Johnson grant, considered in a nationally organized manner the issue of effective pain management as it relates to standards of practice for medical professionals. The guidelines were submitted to state licensure boards for adoption in their regulation of professional conduct. The preamble to the suggested guidelines states:

The Board encourages physicians to view effective pain management as a part of quality medical practice for all patients with pain, acute or chronic, and it is especially important for patients who experience pain as a result of terminal illness. All physicians should become knowledgeable about effective methods of pain treatment as well as statutory requirements for prescribing controlled substances.

Inadequate pain control may result from physicians' lack of knowledge about pain management or an inadequate understanding of addiction. Fears of investigation or sanction by federal, state, and local regulatory agencies may also result in inappropriate or inadequate treatment of chronic pain patients. Accordingly, these guidelines have been developed to clarify the Board's position on pain control, specifically as related to the use of controlled substances, to alleviate physician uncertainty, and to encourage better pain management.

Physicians should not fear disciplinary action from the Board or other state regulatory or enforcement agencies for prescribing, dispensing, or administering controlled substances, including opioid analgesics, for a legitimate medical purpose and in the usual course of professional practice. (FSMB, 1998)

In light of the surveys described by Joranson and others, these statements, to be embodied in the codes of state licensure boards, were welcome words of assurance. Effective pain management was an appropriate part of medical practice, even if it involved opioid analgesics, and doctors should not fear regulatory action when engaging in such appropriate practice.

There was, however, a gap in the guidelines. Doctors could be sanctioned, even prosecuted, for inappropriate overtreatment of pain, but no similar opprobrium existed for the undertreatment of pain.

The FSMB went back to work and, in May 2004, adopted a new Model Policy for the Use of Controlled Substances for the Treatment of Pain, which was submitted to state boards (FSMB, 2004). Significantly, the preamble of the new model policy contained the following language:

For the purposes of this policy, the inappropriate treatment of pain includes nontreatment, undertreatment, overtreatment, and the continued use of ineffective treatments.

[T]he Board will consider the inappropriate treatment of pain to be a departure from standards of practice and will investigate such allegations, recognizing that some types of pain cannot be completely relieved and taking into account whether the treatment is appropriate for the diagnosis. (FSMB, 2004)

As of this writing, nine states have adopted the new model policy and other states have it under review. If the optimal result is the appropriate, effective treatment of pain, equal emphasis must be placed on overtreatment and undertreatment. Patients and their family members and advocates must insist that pain be treated aggressively and licensure boards must be made aware of instances where that does not happen.

Oklahoma adopted the 1998 guidelines and currently has the 2004 model policy under review. Additionally, in 1998, the Oklahoma legislature addressed the issue of pain management as part of its code on controlled and dangerous substances. (63 O.S. 2001, sec. 2-551(B)) The amendments stated, in part:

The State of Oklahoma encourages physicians to view effective pain management as a part of quality medical practice for all patients with pain, acute or chronic. It is especially important for patients who experience pain as a result of terminal illness. (63 O.S. 2001, sec. 2-551(B))

If, in the judgment of the medical doctor or the doctor of osteopathic medicine, appropriate pain management warrants a high dosage of controlled dangerous drugs and the benefit of the relief expected outweighs the risk of the high dosage, the medical doctor or doctor of osteopathic medicine may administer such a dosage, even if its use may increase the risk of death, so long as it is not also furnished for the purpose of causing, or the purpose of assisting in causing, death for any reason and so long as it falls within policies, guidelines and rules of the Oklahoma State Board of Medical Licensure and Supervision or the Oklahoma State Board of Osteopathic Examiners. (63 O.S. 2001, sec. 2-551(C))

And, most significantly:

The Oklahoma State Board of Medical Licensure and Supervision and the Oklahoma State Board of Osteopathic Examiners shall issue policies, guidelines or rules that ensure that physicians who are engaged in the appropriate treatment of pain are not subject to disciplinary action, and the Boards shall consider policies and guidelines developed by national organizations with expertise in pain medicine or in a medical discipline for this purpose. (63 O.S. 2001, sec. 2-551(D))

In 1999, the Oklahoma State Board of Medical Licensure and Supervision (OSBMLS) adopted rules pertaining to intractable pain, perhaps in response to the 1998 legislative mandate (OSBMLS, 1999). Those rules provide, in part:

To treat a patient's intractable pain, as long as the benefit of the expected relief outweighs the risk, the physician may prescribe or administer Schedule II, III, IV or V controlled dangerous substances or other pain-relieving drugs in higher than FDA recommended dosages when, in that physician's judgment, the higher dosages are necessary to produce the desired therapeutic effect.

Nothing in this section shall limit a physician's authority to prescribe or administer prescription drug products beyond the customary indications as noted in the manufacturer's package insert for use in treating intractable pain, provided the drug is recognized for treatment of intractable pain in standard reference compendia or medical literature. (OSBMLS, 1999)

Policy barriers to effective pain management exist at every level, from the DEA to state licensure boards to local law enforcement. But with the impetus of ever-improving medical knowledge and research, and the force of public opinion, progress is being made, although sometimes with a temporary step backwards.

CONCLUSION

At the conclusion of the NAAG project on end-of-life care, a report was published titled “Improving End-of-Life Care: The Role of Attorneys General” (NAAG, 2003). The section dealing with pain management was co-written by David Joranson and Richard Payne. Joranson, as noted above, is director of the Pain and Policy Studies Group, University of Wisconsin Comprehensive Cancer Center; Payne is chief of the Pain and Palliative Care Service, Memorial Sloan-Kettering Cancer Center in New York.

Their conclusion shall be mine:

“While affecting the life quality of millions of Americans, pain management is an issue that, until recently, has existed with little public notice or concern. Attorneys general are in a strategic position to ensure that residents of their state receive medical care that offers effective pain relief. The tools are now available. Health care providers need to learn them and feel safe in prescribing the dosage of narcotics necessary to relieve patients’ pain. As states’ chief legal officers who advise governors, legislatures, and executive agencies, Attorneys General can improve state policies, physician practices, and public knowledge regarding effective pain relief. As one state assistant attorney general described his motivation to pursue this goal, “When you ask yourself, What have I accomplished in my term? You can say, I helped reduce the amount of human suffering in my state.” (NAAG, 2003) ■

W. A. Drew Edmondson is serving his third term as Attorney General for the State of Oklahoma. Before his election as Attorney General, Edmondson served three terms as Muskogee County District Attorney and one term in the Oklahoma Legislature. Edmondson is a Navy veteran with a tour of duty in Vietnam. Edmondson served as the 2002-2003 President of the National Association of Attorneys General (NAAG). Edmondson's presidential initiative during his NAAG term of office focused on examining the role of Attorneys General in improvement of care near the end of life. The selection of his presidential initiative was influenced by his wife, Linda, who worked as a hospital social worker for many years and served as director of the Oklahoma Association for Health Care Ethics and administrator of the Robert Wood Johnson grant to the Oklahoma Alliance for Better Care of the Dying. The cornerstone of Edmondson's initiative centered on three regional listening conferences which provided an opportunity for more than 50 attendees from Attorney General offices across the country to listen and learn about the barriers that prevent families from fulfilling the wishes of loved ones near the end of life. In 2004, Edmondson received the Dr. Nathan Davis Award from the American Medical Association, awarded annually to a statewide elected official for outstanding contributions in promoting the art and science of medicine and the betterment of the public health.

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