



Association of American Physicians & Surgeons
1601 N. Tucson Blvd. Suite 9 Tucson AZ 85716
800.635.1196
www.AAPSONline.org

The Politics of Pain & Painkillers: Drug Policy & Patient Access to Effective Pain Treatments

**Friday, Sept 17, 2004 121 Cannon HOB
11 am – 12:30 pm**

NO SAFE HARBORS FOR DOCTORS: Response to DEA Pamphlet on Prescription Pain Medications

The prospect of being criminally prosecuted as drug dealers and of spending the rest of one's life in jail has, unsurprisingly, had a chilling effect on the willingness of doctors to treat pain. In an effort to provide reassurance to doctors and consistent standards to law enforcement and regulatory agencies, on August 11, 2004, the DEA issued *PRESCRIPTION PAIN MEDICATIONS: Frequently Asked Questions and Answers for Health Care Professionals, and Law Enforcement Personnel*.¹

This document is intended to provide content to the policy of balance, a policy hoping to promote pain relief while preventing abuse of pain medications. However, the recent and continuing prosecution of a number of doctors sends a contrary message. There is no safe harbor for the treatment of chronic pain as long as doctors are subject to criminal prosecution and the draconian penalties reserved for drug dealers, when the case hinges on a disagreement between practitioners as to what is proper treatment for a patient.

Criminal law requires bright line rules so that both perpetrators and enforcers will know when a crime has occurred. Yet this document underscores the complexity of pain management, particularly in patients who might be addicts or engaged in criminal activities. In addressing the professional disagreements and confusion regarding pain treatment in this population, it illustrates the diversity of professional opinion, the evolution of practice standards, and the scope of professional discretion applicable in the treatment of chronic pain. For example, experts disagree on such issues as the propriety of opioid treatment in addicts, the interpretation and management of a patient's deviation from medical instructions, and the proper physician response to suspected criminality. The fact that this document has just been issued underscores that practice standards are evolving. This contradictory and confusing professional context is simply not susceptible to the bright-line rules that criminal law properly requires.

The regulation of medical practice through criminal law enforcement is misguided and counterproductive. It undercuts the legitimacy of law itself when criminal sanctions are applied where clear norms are difficult to define, and it deprives the medical profession of the experience of the most compassionate, courageous, and innovative physicians, while intimidating the rest into an ineffectual cautious conventionalism in their approach to patients with chronic pain.

In what purports to be reassurance to physicians, the authors assert, "Although physicians have expressed concern about criminal prosecution when treating such patients (those with severe pain who develop patterns of abuse or addiction, or engage in criminal activity), the

arrest and indictment of a physician cannot occur unless he or she can be shown to have knowingly and intentionally distributed or prescribed controlled substances to a person outside the scope of legitimate practice.” While the plain meaning of this language imparts that criminal intent should properly be ascribed to those who are selling prescriptions or medications without any medical pretense or in a sham medical encounter, prosecutors have successfully asserted that “the scope of legitimate practice” is limited to whatever the government expert defines as “appropriate” care. This application of the civil malpractice standard in a criminal case, which effectively substitutes negligence for criminal intent, vitiates the safe harbor.

The document proposes what might appear to be reasonable rules, but which in application are fraught with ambiguity and inconsistency. For example, physicians who encounter patients who exhibit *problematic drug-related behaviors* (those indicative of possible addiction or diversion) “must control the behaviors, diagnose the comorbidities, and react in a way that is both medically appropriate and consistent with the laws and regulations that apply to the medical use of controlled drugs.” But the document advises that “[t]hese behaviors should not be taken to mean that a patient does not have pain, or that opioid therapy is contraindicated. Rather, they indicate the need for assessment, informed diagnosis and appropriate management. Management may or may not include continuation of therapy, depending on the circumstances. If the decision is made to terminate the physician-patient relationship, there must always be a good faith effort to avoid patient abandonment by providing referrals.”

Question 21 asks, “*If a patient receiving opioid therapy engages in an episode of drug abuse, is the physician required by law to discontinue therapy or to report the patient to law enforcement authorities?*” The document replies, “Federal drug laws do not require physicians to report to law enforcement authorities patients who have engaged in drug abuse. The controlling federal legal standard is that the physician must issue prescriptions for controlled substances only for legitimate medical purposes and in the usual course of professional practice. . . . In states with no specific legal requirements on this subject, if continued opioid therapy makes medical sense, then the therapy may be continued, even if drug abuse has occurred. Additional monitoring and oversight of patients who have experienced such an episode is recommended. . . . Incontrovertible evidence of criminal activity, such as diversion, is grounds for termination of the doctor-patient relationship.”

These examples appear to leave substantial room for physician discretion in the management of patients with problematic behavior and reassert the primacy of the doctor’s ethical duty to the patient in the prohibition of patient abandonment. How does physician discretion in the management of these circumstances square with the assertion that the “legal system does not allow practitioners to consciously disregard indications that illegal drug-related activities might be occurring” offered in response to Question 27, which explains the circumstances in which DEA might investigate and prosecute a doctor. What is within the scope of professional discretion under the answer to Question 21 is rendered an actionable offense under Question 27.

The risk to doctors for failure to police their patients for possible illegal behavior amounts to an improper delegation of police responsibility that is incompatible with their duty to patients, as it undercuts the relationship of trust necessary to effective patient care.. Patients are subject to the anxieties of their doctors regarding their behavior and the risk that their treatment will be terminated against their will and without recourse. The whole legal edifice of due process is designed to avoid arbitrary punishment at the hands of the state. Yet this document gives official blessing to punishment by doctors of their patients through discontinuation of pain treatment, when their patients are suspected of deviation from social norms. What the police

authorities could not do on their own authority, they now expect doctors to do as an exercise of medical authority, at the risk of criminal prosecution if a prosecutor disapproves of a doctor's clinical decision..

The position the document takes regarding the management of problematic behavior exposes the inherent inconsistency of the current medical attitude toward addiction. On the one hand, it supports a patient's right to pain treatment. On the other hand, it asserts the propriety of medical paternalism. The decision to treat or terminate treatment is predicated not on a patient's free consent, but on the doctor's determination of what is appropriate--with *input* from the patient. This paternalism denigrates the patient's role in determining his medical care, while it enhances professional liability for a patient's drug abuse or criminal behavior. The patient's misbehavior is viewed as merely symptomatic of the disease of addiction, while the practitioner's failure to take what some expert deems as an appropriate response is viewed as tantamount to criminal intent under the Controlled Substances Act. It is an ironic paradox that the humane impulse that leads us to view addiction as a disease has the inhumane consequence of holding physicians responsible for the criminal or self destructive acts of the addicts they care for.

This document expresses the most enlightened contemporary attitudes regarding the use of opioids in the management of chronic pain. It asserts the propriety of treating chronic pain with opioid medications and emphasizes the dramatic social cost of undertreated pain. It recognizes both the public and professional prejudice against the use of opioids, the controversial nature of the treatment, and the differences of opinion among professionals. However, the attempt to bring medical sophistication to law enforcement agencies and police sophistication to doctors is misguided in its inception. The prevention of diversion and abuse cannot be the responsibility of doctors without imposing an insuperable conflict of interest between a doctor and his patients and without undercutting the professional commitment to the primacy of the patient .that the ethical practice of medicine requires.

This document is an attempt to reconcile the irreconcilable. Unfortunately, it devolves upon the backs of doctors and their patients a police function that the police have been unable or unwilling to perform. At its worst it is a hypocritical attempt to give lip service to concern for the problem of undertreated pain without any intent to stop the rain of terror that has been imposed upon compassionate physicians.

The promulgation of the guidelines implicit in this document has unwittingly played into the hands of the federal government that wants to take over the regulation of medicine. The idea that a law enforcement agency, the DEA, should be the ultimate arbiter of proper medical practice under the threat of criminal penalty is itself an absurdity. However enlightened the specific recommendation contained in this document, the regulation of medical practice belongs in a medically competent state agency that recognizes the evolving nature of medical practice and can distinguish the fallibility of physicians from criminal intent.

There is nothing more chilling to medicine than the application of criminal law designed to deal with drug traffickers to physicians in their offices in the management of complicated patients in an evolving medical environment. No guideline will fix the chilling effect. The DOJ should cease and desist in its current prosecutions and leave the regulation of medicine to competent state authorities.

¹ It is available on-line at http://www.deadiversion.usdoj.gov/faq/pain_meds_faqs.pdf..