

Pain Control in the Police State of Medicine (Part II)

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On August 31, 2002, I announced my decision to phase out my pain practice by the end of this year unless the persecution of physicians devoted to the treatment of chronic pain with opioid medications is brought under the control of competent medical authorities. I have made this decision in response to a prosecutorial approach that targets physicians based on the misbehavior of a small percentage of their patients who may be involved in illegal behavior.

When doctors are charged, their practices are closed summarily, without warning and without provision for cushioning the blow to innocent and suffering patients. The patients are subjected to the abrupt cutoff of medications and clinical support. The stigma that those people suffer, both as pain patients on opioid medications in general and as former patients of accused doctors in particular, tends to foreclose most opportunities for effective continuing care. I announced my decision four months in advance of my expected closing date to provide my patients an opportunity to make other arrangements for care and to prevent the disruptions that would follow closure of my practice without warning by the authorities. The full text of my announcement may be read at www.drhurwitz.com.

In this article, I want to elaborate on the context of my decision and on the kinds of policies that would allow the medical profession to be more responsive to the mostly hidden epidemic of untreated and inadequately treated pain.

The Evolving Context of Pain Practice

Over the last decade, the prevalence and severity of chronic pain in the U.S. has been increasingly appreciated.¹ According to a recent survey,² 9 percent of US adult population (25 million people) suffer from moderate to severe pain, two-thirds of whom (16 million) have had their pain for more than five years. The majority of those with the most severe pain do not have it under control and suffer substantially in their enjoyment of life, their social relations, and their economic productivity.

Beginning in the mid-1980s, there was a reconsideration of the previous rejection of opioid therapy for non-malignant pain.^{3,4} Encouraging clinical experience with chronic opioid administration to cancer patients and to methadone-maintained addicts dispelled fears of this therapeutic modality and led to refinements in terminology that distinguished physical dependence (provocation of an abstinence syndrome upon discontinuation) and tolerance (increased dose required to maintain physiological effects) from addiction (compulsive use for non-medical purpose despite harm). Early research indicated that patients without a prior history of addiction ran little risk of becoming addicted through pain treatment with opioids.⁵ A small pilot study in 1990 suggested that addicts with chronic pain could be safely treated and that treatment diminished illicit drug use and improved functional

status.⁶ In 1997, the American Society of Addiction Medicine affirmed that physicians are obligated to relieve pain and suffering in their patients, including those with concurrent addictive disorders.⁷ A study published in 1998 reviewing the relationship between the prescription of opioid analgesics and indicators of drug abuse from 1990 to 1996 concluded that while opioid prescription had increased substantially, opioid abuse represented a declining proportion of drug abuse during this period.⁸

The acceptance by professional bodies of opioid therapy for chronic, non-malignant pain continued throughout the 1990s, as indicated by the passage of Intractable Pain Acts in a number of states, the approval by the American Pain Society and the American Academy of Pain Medicine of *The Use of Opioids for the Treatment of Chronic Pain: A consensus statement from American Academy of Pain Medicine and American Pain Society* in 1996, and the adoption by the Federation of State Medical Boards of *Model Guidelines for Regulating the Use of Controlled Substances in the Treatment of Pain* in May, 1998.

In spite of the increasing expert support for opioid therapy, physicians have received mixed signals regarding the acceptability of this treatment. Over the last few years public attention has been focused on OxyContin® (sustained release oxycodone) with stories of overdose deaths, pharmacy robberies, and allegedly corrupt doctors. State medical boards have not uniformly accepted expert professional opinion.⁹ But a more ominous development is the increasing pace of state and federal criminal prosecution of physicians engaged in pain practice. Examples include Drs. Frank Fisher,¹⁰ James Graves,¹¹ Denis Deonaraine,¹² Randolph Lievertz,¹³ and Cecil Knox.¹⁴

This is apparently part of a federally coordinated strategy to stop the diversion of OxyContin and other prescription medications at the source—by targeting doctors whose practices focus on medical pain management.¹⁵ This strategy, however, appears to contradict the stated policy of the Drug Enforcement Administration (DEA) that preventing drug abuse “should not hinder patients' ability to receive the care they need and deserve.”¹⁶ In his talk before the American Pain Society on March 14, 2002, Asa Hutchinson, the Director of the DEA elaborated on this position as follows:

I'm here to tell you that we trust your judgment. You know your patients. The DEA does not intend to play the role of doctor. Only a physician has the information and knowledge necessary to decide what is appropriate for the management of pain in a particular situation. The DEA is not here to dictate that to you. We do not intend to restrict legitimate use of OxyContin or other similar drugs. We will not prevent practitioners acting in the usual course of their medical practice from prescribing OxyContin for patients with legitimate medical needs. We never want to deny deserving patients access to drugs that relieve suffering and improve the quality of life.

Mr. Hutchinson's words, however, have provided scant assurance to the many physicians who shun patients for fear that prescribing opioids will bring unwelcome police attention, nor have his words had much impact on the behavior of his agents, who continue to conduct a reign of intimidation. The DEA and its state counterpart agents are embarked on a program of harassment of pain patients through repeated investigations, seizures, and arrests without charges or followed by dropping unsubstantiated charges. Similarly, they pay intimidating "visits" to pharmacists and physicians to "advise" them on how to practice their professions. This type of law enforcement by intimidation has not been seen in the Western world since before the Second World War, and, so far as I am aware, has never been seen in the United States of America. So, we already are perilously close to a situation in which the police agencies simply will not allow medicine to be practiced in conformity with honest and ethical standards.

The fact that this approach so far has only targeted practitioners of pain medicine should be no source of comfort to physicians in other fields. If police disruption is permitted to displace medical judgment in this field, then it can do the same elsewhere. "Divide and conquer" is the oldest strategy of tyranny.

Principles of Pain Management

Pain specialists broadly agree on the following general principles of opioid use in pain management.

1. Treatment is to be individualized according to patient response, with upward titration of dose until adequate relief is provided or intolerable side effects develop. This principle is referred to as "titration to effect." Individuals vary in their response to different medications, both with respect to the efficacy of analgesia and with respect to the pattern of side effects. A corollary to this principle is that doctors must rely upon their patients' reports of pain, relief, and side effects, to provide effective treatment. Although pain in many clinical circumstances correlates with visible pathology, for many patients it does not.

2. Opioid medications are not all equivalent. They vary in their analgesic efficacy, their pharmacokinetic characteristics, and in their side-effect profiles. In my clinical experience, oxycodone, for example, tends to be less sedating than morphine or methadone.

3. There is no ceiling to opioid analgesic effect. Doses may range from less than 100 mg per day of morphine or its analgesic equivalent to more than 10,000 mg per day.¹⁷ Given the small size of many opioid formulations, patients on high doses may require hundreds of tablets daily.

4. The discontinuation of opioid therapy is clinically problematic. Although there are medications to mitigate acute withdrawal symptoms, even gradual dose reduction entails increased pain, which may persist for weeks or months. Rapid reduction from high doses may provoke severe, possibly life-threatening withdrawal symptoms in medically unstable patients. Physicians must take these consequences of withdrawal into consideration with their patients when deciding whether and how to terminate a patient's opioid treatment.

Policy Considerations

The current scientific understanding of pain, addiction, and opioid pharmacology is in tension with the laws, legal doctrines, and attitudes that evolved in response to the earlier (and persistent) conception that equates physical dependence and opioid tolerance with addiction. To implement the DEA's avowed intention to arrive at a balanced policy, it should avail itself of specialized experts in

pain medicine, addiction, and epidemiology. The issues raised in the attempt to achieve an optimal balance that maximizes access to effective pain control with a minimum of diversion and abuse are complex. There is little data to guide policy development. Current technologies for evaluating pain, monitoring treatment, and tracking diversion are crude. There is great variation in the level of expertise in pain management among physicians and also a severe shortage of clinicians skilled and experienced in the use of opioids. The uncertainties, ambiguities, and conflicts that abound in the world of pain, addiction, and drug control cannot be papered over with a consensus statement. There is much work to be done to lay the groundwork for a balanced drug policy.

The enforcement policy that has emerged is anything but balanced. The use of criminal prosecution as a primary means of enforcement eventually will eliminate most honest and competent physicians from chronic pain practice, thus deepening the national health care crisis of under-treated pain. Given the enormous criminal penalties imposed for controlled substance offenses, even the smallest risk of erroneous conviction drives most physicians out of pain practice. Those few remaining come under ever-increasing pressure, both from patient demand and enforcement scrutiny, and they have fewer colleagues to come to their defense.

The policy of targeting physicians based on patient misbehavior establishes a standard of perfection in selecting patients that no doctor could meet. It forces doctors who try to treat pain to act like police, reinforcing a perverse medical paternalism that subverts the ethical imperatives designed to protect patient autonomy and dignity. This distortion of the patient-physician relationship stigmatizes patients and erodes their trust. At the same time, it assigns doctors a function that they are ill-qualified to perform.

Diversion of lawful prescription drugs by patients should be approached as the law-enforcement problem that it is. It is misbehavior of a type that physicians alone cannot detect or deter effectively. Physicians usually can screen out the wholly fraudulent patient without a pain syndrome at all, but current medical technology includes neither a pain "meter" nor other objective test to ensure against other forms of deception or medication misuse by patients. Therefore, law enforcement agencies must take the primary role in enforcement, as they have the tools and the training to do so effectively. Pain physicians should be viewed primarily as the ally of criminal law enforcement and not its targets. Pain physicians can assist law enforcement by providing information on patients and medications, and cooperation in law enforcement investigations.

I am not suggesting that the confidentiality of the patient-physician relationship should be casually sacrificed to the public interest in preventing the diversion of controlled substances. Whether, to what extent, and with what safeguards for patient privacy such a policy should be undertaken must be determined after a careful analysis of the competing social utilities. Current law affords almost no protection to patient privacy, as prescriptions for Schedule II controlled substances are subject to inspection by authorities, and prosecutors appear to have no difficulty in obtaining warrants to seize the medical records of targeted doctors.

Conclusions

While difficult, the problems of diversion and abuse are not insoluble, given good will and cooperation among physicians, professional regulators, and criminal law enforcers. The main impediment to progress at the moment appears to be the attitudes of

criminal law enforcement agents and prosecutors, who insist upon treating the “upstream” segments of lawful drug distribution as “suspects” rather than the victims of patient dishonesty and the potential allies of law enforcement. The pattern of investigation and prosecution proceeds with no apparent reference to the professional regulatory guidelines that have been developed in recent years. Police should do the policing, doctors should do the doctoring, and professional regulators should develop and review professional standards, while each should cooperate with the others.

Physicians, under the supervision of professional regulatory agencies such as medical boards, should be permitted to exercise medical judgment without fear of criminal prosecution. Federal and state controlled substance prohibitions should be amended to clarify the intent of current law that there be a safe harbor protecting honest medical judgment from criminal charges. This step is necessary to restore the traditional balance in drug enforcement policy, and to protect the relative competencies of federal versus state authorities and professional regulators versus police personnel.

The oppression and intimidation of doctors by the DEA and state boards of medicine has a long history. The fears provoked by this history will not quickly fade. Furthermore, there is at least some indication that our current state of relative ignorance concerning the drug diversion problem has been perpetuated by the police agencies themselves. Bringing out the truth of this situation will help the honest and dedicated medical professionals who are trying to reduce the toll of human suffering, and it will only hurt those public officials who truly do wish to create a police state of medicine. For the moment, let us take the DEA's leader at his word. But his word must be implemented by decisive and comprehensive action. Dramatic action is needed now if doctors are to feel free to treat their patients' pain. I suggest the following:

1. Re-affirm and implement the principles that were articulated in the consensus document of October 2001, and in the speech by Asa Hutchinson, Director of the DEA, before the American Pain Society in March of 2002 with visible changes in training, procedure, and administration that make all official participants in the process—from Mr. Hutchinson, to local U.S. Attorneys and their assistants, to field agents—fully and publicly accountable for the government's adherence to its declared policy. As the regulated physicians and pharmacists are working in the open, then so also should all government agencies and their employees. Without transparency, there will never be accountability by public servants.

2. Suspend current prosecutions against physicians who treat pain unless and until a review by a panel of nationally recognized experts in medical pain management has found that there is an absence of good faith by the physician. If only the physician's adherence to standards of care can be questioned, then the case is not an appropriate one for the criminal process, and should be referred to the professional regulatory authorities.

3. Design a mechanism to ensure that physicians who treat pain in good faith will have safe harbor protection from criminal prosecution, and a mechanism to improve the skills, techniques, and performance of those whose good-faith performance is found wanting in professional sophistication. Forbid the DEA and other police agencies from paying visits to physicians and pharmacists to provide “advice” on how to practice medicine or pharmacy.

4. Work with the acknowledged professional experts to develop and refine effective mechanisms to deter or apprehend those who would divert prescribed medications without substantial adverse effect on legitimate pain patients.

5. Fund new research in several critical areas: (a) new medical treatments that hold out the potential for responsibly reducing opioid dosages, such as the co-administration of opioid antagonists; (b) new medical technologies that hold out the potential for more objective assessment of patient symptoms; and (c) epidemiological research to determine more precisely the incidence and causes of controlled substance diversion from medical practices as opposed to other sources, such as pharmaceutical thefts or embezzlements, or international smuggling.

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