

Evaluating the Risks of Unwarranted Prosecution

Part 1: The Criminalization of Pain Management

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ABSTRACT

Despite reassurances to the contrary from regulatory officials, many physicians are concerned that prescribing opioid analgesics in chronic pain treatment is accompanied by an unacceptable risk of unwarranted prosecution. The validity of this fear is evaluated by examining the standards through which physicians are targeted and prosecuted. Prohibition law is identified as an error in social policy that distorts the standards employed in the regulation of medical practice.

Introduction

Undertreatment of chronic pain is a continuing public health disaster.^{1,2} It has resisted repeated attempts at resolution, including enactment of laws regarding intractable pain, patients' bills of rights, and promulgation of medical board guidelines. These attempts have failed, at least in part because of a perception, common among physicians, that unacceptable risks of unwarranted prosecution accompany the prescription of opioid analgesics when these substances are employed in treatment of chronic pain.³ A debate rages over the accuracy of physicians' perceptions of risk. Law enforcement officials claim that criminal prosecutions weed out only the occasional "bad apples," those found in every profession.⁴ These officials assert that lack of education in pain management is the primary factor accounting for the epidemic of undertreated chronic pain.⁵ Voices within both organized and academic medicine reject this perspective. They attribute the pain crisis instead to misplaced regulatory zeal.⁶ The Association of American Physicians and Surgeons goes so far as to characterize the regulatory environment surrounding chronic pain treatment as a witch-hunt. This organization consequently advises physicians to refrain from prescribing opioids to treat chronic pain.⁷

As long as a perception of unacceptable risk persists, valid or not, undertreatment of chronic pain will continue unabated. Therefore it is essential to determine whether or not there is any basis in reality for physicians' reluctance to prescribe opioid analgesics for chronic pain.

Red Flags

Law enforcement targets physicians for prosecution as drug dealers under standards called "red flags." These standards are unrelated to the evidence-based standard of care. The significance of evaluating the legality of medical practice using *non-medical standards* cannot be overstated. It is key to understanding, and ultimately to correcting, errors in social policy that lie at the root of the pain management crisis.

Phases of Investigation

Investigation of a physician suspected of criminal prescribing proceeds through phases resembling those in the investigation of any suspected drug trafficker. These include a targeting phase, a surveillance phase, and a sting operation. After a sting operation fails, as it often does, an investigation may be transformed into a *records case*.

The Targeting Phase

The prescription of what appears to law enforcement officials to be *a large quantity of opioids* is a red flag. For example, a prosecutor said, in his opening statement: "The drugs were prescribed in such outrageous volumes, truly staggering quantities of very pernicious opiates."⁸ When the accused physician's medical records were analyzed, the "staggering quantities" he had prescribed turned out to be an amount of OxyContin sufficient to treat only 46 severely afflicted pain sufferers.

The Surveillance Phase

Police, lurking in the parking lot of the targeted physician's clinic, observe a larger number of patients coming and going than they imagine the doctor should be seeing. In this manner, they identify a *high volume practice*. This is red flag. License plates on the cars in which patients arrive are traced, in order to find where the drivers live. This reveals that some patients have *traveled to see the physician*. This is another red flag.

The Myth of Available Treatment

The two preceding red flags are an expression of the myth of available treatment. This myth persists in denial of the facts that (1) practices where chronic pain is effectively treated are rare, and (2) as a result they are busy. The myth enjoys plausibility because almost everyone has experienced an episode of acute pain, and has received effective treatment for it. People naturally assume that the same high quality of care will be available if they ever develop chronic pain. The unfortunate reality is that nothing could be further from the truth. The myth of available treatment was debunked in a recent survey commissioned by the American Pain Society.¹ This survey found that: (1) Many chronic pain victims fail to obtain acceptable pain control, in spite of repeated attempts to find it, through visits to numerous physicians. (2) One third of chronic pain sufferers report that their pain is out of control. (3) The more severe the pain, the worse the odds that a sufferer will receive satisfactory treatment.

Further Surveillance

Continuing surveillance reveals patients whose appearance arouses investigators' suspicions. These people may simply be poor, and may be visiting the targeted physician to obtain treatment for any number of medical conditions other than chronic pain. Because of their appearance, however, they are assumed to be drug addicts in search of a fix. *Shabby appearance* is a red flag.

The physician under surveillance is observed to spend only five to 10 minutes with each patient. Common sense dictates that a drug-dealing doctor could easily find out and write a prescription for what people want within a time frame of one to two minutes. What law enforcement is in fact observing are patient visits that, when judged by accepted industry standards, last a typical length of time. In the context of a drug trafficking investigation, this mundane observation takes on sinister implications. It becomes a red flag.

During the surveillance phase, investigators conduct interviews with informants who claim to have duped the targeted physician into prescribing controlled substances. These criminals are ideally suited to confirm the suspicions of law enforcement because both groups are predisposed to think in terms of acquiring drugs to support a habit. Following the physician's arrest, informants are reported to have made the following sorts of accusations:

"The doctor got me addicted."

"He ruined my life."

"The doctor didn't spend any time with me."

"The doctor never examined me."

"The doctor would write prescriptions for anything I wanted. I wanted OxyContin. That's an evil drug, man."

Statements such as these appear in the news media and are later offered in the courtroom as evidence of guilt.

After work, the physician is followed home. On the morning of his upcoming arrest, the door to his house will be kicked down. His home will be searched for drugs and money, and for evidence that he is a flight risk, so that he may be denied reasonable bail.

At the end of the surveillance phase, accumulated evidence consists of rumors, red flags, and uncorroborated accusations made by informants who are often motivated by the promise of a reduced prison sentence for whatever crime they were most recently caught committing. Conspicuously absent from the investigation at this point is any review of the targeted physician's practice based on medical standards.

The Sting Operation

As the investigation continues, undercover agents are wired and sent into the suspect's clinic, posing as patients. During their visits, they attempt to entrap the physician into issuing illegal prescriptions. Police parked in a van outside the clinic record the radio transmissions of these encounters so that they may later be used in the courtroom as evidence.

Reason suggests that the outcome of a sting operation should make or break an investigation. Reason, however, does not necessarily prevail. In the testimony below, an investigator discloses that a series of stings, attempted by a parade of undercover drug agents, failed to result in issuance of a single prescription for a controlled substance.

Q: Mr. Hallinan: Yeah, and on the briefings you got ... you were ... told that numerous agents were sent into Dr. Fisher's office to try to con him into giving them narcotics without any medical reason, right?

A: Agent Weatherford: I believe that's the reason.

Q: And none of them got them, did they?

A: I don't believe so.⁸

Rather than abandoning their case, prosecutors instead charged the physician with murder. The exculpatory evidence revealed in the above testimony was withheld from the physician's defense team until his lawyer elicited it on cross-examination.

The Records Case

After a sting operation fails, there remains an option through which a zealous prosecutor may still pursue a conviction. In the context of pain management, drugs and money inevitably change hands. As a result, when a physician is accused of drug dealing, the physical elements of the crime are already a given. At the outset, the prosecutor is three-quarters of the way to a conviction. All that remains is to prove that the physician *intended* to deal drugs, rather than to practice medicine.

A SWAT team raid is launched against the targeted physician's clinic. The physician is arrested, patient files are seized, and a medical expert is hired to analyze them. A records case is constructed, based on expert testimony alleging departures from the standard of care for pain management.

The appellate court reversal of a records case conviction against Dr. Lloyd Stanley Naramore illuminates conflicts that arise when evidence in the form of expert testimony, concerning the medical standard of care, is employed in criminal court:

When the issue is whether there is reasonable doubt, a jury is not free to disbelieve undisputed facts. What occurred here is generally known. The jury was not free to disbelieve that there was substantial competent medical opinion in support of the proposition that Dr. Naramore's actions were not only not criminal, but were medically appropriate.

When there is such strong evidence supporting a reasonable, noncriminal explanation for the doctor's actions, it cannot be said that there is no reasonable doubt of criminal guilt. This is particularly true in a situation as we are faced with here, where the only way the defendant's actions may be found to be criminal is through expert testimony, and that testimony is strongly controverted in every detail.

...[I]f criminal responsibility can be assessed solely on the opinions of a portion of the medical community which are strongly challenged by an opposing and authoritative medical consensus, we have criminalized malpractice, and even the possibility of malpractice.⁹

The transcript quoted below illustrates an *irrelevance* objection concerning the use of expert testimony about the standard of care in a records case.

Mr. Stotter: Well, the objection would be relevance. This isn't a civil negligence action, your Honor. What is the deviation ... alleged deviation from the ...

The Court: Goes to malice, Mr. Stotter. It goes to an understanding of the hazardous nature of the analysis ... I mean I don't know how much weight it has, but it certainly does, at least, play some part of the analysis, if there's a generally accepted standard in the industry that dictates a certain practice. And if the evidence suggests that Mr. Miller wasn't adhering to that, that may say something about malice.

Mr. Stotter: I don't think it's any more relevant than ... the failure to place the little "do-not-operate-motor-vehicle"[labels] on the jars. It may be an indication of a deviation or a standard of practice, but it's not evidence of malice.

Mr. Hallinan: I join in that motion. I mean this is not ... I've had medical board hearings before and this sounds exactly like the kind of proceedings before a medical board to find out if people are practicing medicine or are practicing pharmacy up to the standard of the community. And I ... I do not see that it has any relevance at all. That any of this testimony has any relevance to the charges of MediCal fraud, prescribing to addicts and murder.⁸

The preceding objection turned out to be an exercise in futility. It was overruled.

A judge in yet another case recognized the same relevance issue. He voiced concerns about it at trial, but allowed the evidence anyway. Later, the judge attempted to correct this through the following jury instruction:

These defendants are charged with illegally dealing drugs in an improper fashion. That's one thing. Their oaths as doctors, their requirements as doctors, is another, and it may be different. So whether what they did was legitimate medically, or illegitimate medically, is not an issue in this case. We are not the governing board of doctors. We're here to determine whether or not these defendants violated federal law in the handling of these drugs.¹⁰

The jury convicted anyway, and the accused physicians were all sentenced to long terms in federal prison.

Records cases are exceedingly dangerous to physicians because of the way expert testimony about the standard of care is used against them in criminal court. In a malpractice case, the plaintiff is required to prove that the accused physician was negligent or incompetent. On the other hand, during a records case, it is not necessary for the government to prove that accused physician was either. For the purposes of convincing a jury that a physician harbored criminal intent, *allegations* of substandard care are usually sufficient.

Prosecution in the Media

Before a physician is prosecuted in court, he is first persecuted by the news media. The following sorts of remarks are what the public will hear about him:

"We are shutting down suppliers of a highly addictive drug that has been improperly allowed to saturate the community."¹¹

"I think he'll turn out just like Kevorkian. These are highly toxic drugs. We're not even allowed to flush them down the toilet, for fear we'll contaminate the drinking water."¹²

The accused physician's office is described as having a "swinging door."

The scene outside his clinic is characterized as having a "tailgate party atmosphere." Alternatively, it may be described as resembling the line forming in front of a crack house.

The physician is accused of having passed out prescriptions for controlled substances as if they were candy.

Thousands of new drug addicts are said to have been created.

Opioid Prohibition, Safe-Harbor Provisions, and the Law of Unintended Consequences

The Harrison Act of 1914, as well as the more recent Controlled Substances Act of 1970, banned the possession and sale of opioids. When these prohibition laws were enacted, legislators assumed they could preserve a safe harbor for medical prescribing. Ironically, the very existence of such a safe harbor *compels* law enforcement to regulate the practice of medicine.

This consequence of prohibition law is inevitable because, in order to determine whether a doctor is a drug dealer, law enforcement must distinguish between what is medical practice and what isn't. Accomplishing this requires the application of standards, and as such is a regulatory function.

Law enforcement responded to this regulatory challenge in the only way it could. It developed standards for evaluating the legality of medical practice. These are the red flags discussed earlier. Backed as they are by the threat of criminal prosecution, red flags have usurped the role of the evidence-based standard of care in the management of chronic pain. The fact that red flags are the practice standards to which physicians must now adhere is confirmed by numerous federal appeals court decisions upholding the convictions of drug-dealing doctors.¹³

The Risks of Undertreating Pain

Yet another peril menaces physicians who manage chronic pain with opioid analgesics: the prospect that if they undertreat the disease, their conduct will result in malpractice lawsuits and administrative sanctions.

While it is generally recognized that nearly all pain can be satisfactorily controlled, survey results such as referred to above establish that all too frequently this doesn't occur. The frequency of unsatisfactory treatment outcomes is a reflection of widespread failure by physicians to employ the central practice element within the standard of care: titration to therapeutic effect. Many physicians attempt to rationalize their failure to effectively employ the practice of titration by invoking concerns about the risk of creating addiction. This is unacceptable because there are no studies indicating that the creation of addiction among pain victims treated with opioids is a significant clinical concern. Other physicians offer the excuse that using titration to therapeutic effect might expose them to adverse regulatory consequences. This is highly unethical. The resulting undertreatment of pain, while possibly conforming to community standards, may be characterized as reckless negligence.

Summary

- Opioid prohibition is a social experiment, accompanied by the unintended but apparently inevitable consequence of transferring responsibility for the regulation of pain management from the medical profession to law enforcement.
- Physicians are mistakenly targeted for criminal prosecution through use of red flags, which are non-medical standards developed by law enforcement for the purpose of determining the legality of medical practice.
- Risks of unwarranted prosecution are made greater by routine courtroom use of unproven allegations of substandard care as circumstantial evidence of criminal intent.
- The widespread practice of undertreating chronic pain increasingly puts physicians at risk for adverse civil and administrative consequences.

Conclusion

When law enforcement is assigned to regulate medically useful substances, threat of criminal prosecution is part of the package. This results in a regulatory environment in which the well-intentioned conduct of conscientious physicians may later be second-guessed by law enforcement as criminal. Safe-harbor provisions don't remove this threat; instead they offer physicians a promise of safety that hasn't been delivered and that, history suggests, probably never will be. Consequently, physicians remain well advised to refrain from prescribing opioid analgesics in the treatment of chronic pain, until such a time as unacceptable risks are eliminated.

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