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Medicolegal Sidebar

The Law and Social Values: Prescription Pain Killers

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Introduction

In civil and criminal cases, judges in the US legal system often are faced with conflicting societal norms that ultimately influence the outcome of a lawsuit, and set legal precedent. Of interest to medical professionals is the recent concern about the increasing use of opioid analgesics by patients. While it is recognized that opioid drugs have legitimate uses for some patients who suffer from pain, there is also a serious social concern about prescription drug-related addiction and deaths related to prescription-drug overdoses in the United States, and the problem may have reached epidemic proportions [10]. The problem may arise, at least in part, because of overprescription of opioids by US physicians [10]. According to the Centers for Disease Control and Prevention (CDC), opioids and heroin were implicated in 28,647 overdose deaths in 2014 [16]. In the preceding year (2013), the Drug Enforcement Agency (DEA) reported 46,471 deaths from drug overdoses in the United States; more than half of these resulted from prescription painkillers and heroin [9]. To place the figure in perspective, fewer people died from car crashes or from firearms in the United States during that year, according to the CDC [9].

The issue of how to balance the competing risks of treating pain (whether acute postsurgical pain or chronic pain from conditions like cancer) and causing addiction (particularly in otherwise healthy people) is a current and lively social debate [11, 17]. From a societal standpoint, the risk of creating addiction to powerful drugs in patients who do not really need such medications is a valid public health concern. On the other hand, as Daniel B. Carr MD, MA, Professor of Public Health and Community Medicine at Tufts School of Medicine, has remarked, CDC guidelines should not "inadvertently encourage undertreatment, marginalization, and stigmatization of the many patients with chronic pain that are using opioids appropriately" [5].

The Prescription Drug Era

In 1994, Purdue Pharma—a developer of prescription analgesic medications—

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introduced a website that targeted physicians and their patients who were experiencing pain [15]. The website informed patients with chronic or acute pain that they were being undermedicated because of a general reluctance on the part of physicians to prescribe narcotic pain relief medications. This reluctance, according to the website, was based on unfounded physician fears about creating dependence on prescription analgesics [15]. In the book, *Our Daily Meds* [14], author Melody Peterson suggested that pharmaceutical companies used marketing and promotional materials to suggest to patients that their suffering was needless, because doctors were too hesitant "to propose narcotics like OxyContin, which offered powerful relief" [14]. OxyContin is an extended-release form of the opioid oxycodone, and was introduced to the market by Purdue Pharma in 1996. The drug would prove to be a resounding commercial success, accounting for USD 1.6 billion in sales, or about 94%, of the company revenue in 2003.

In time, patient deaths from OxyContin use or abuse began to occur, and several states, such as Kentucky, filed lawsuits against Purdue Pharma for illegally promoting OxyContin and downplaying its addictive potential. Purdue Pharma marketed OxyContin on its ability to last 12 hours (versus their competitors pain meds, which only lasted 8 hours). In reality, OxyContin rarely, if ever, lasted 12 hours [17]. Physicians often increased the dosage of OxyContin or patients simply chose to self-medicate.

In 2007, in a consolidated federal legal action, Purdue Pharma agreed to pay more than USD 600 million in fines related to the improper branding and promotion of OxyContin. More recently, a Kentucky judge ordered Purdue Pharma to unseal secret documents related to the marketing of OxyContin [2]. Not surprisingly, the company has challenged the judicial order in an appeal filed with the Kentucky Appeals Court [3].

From this experience, and because of a general increase in the incidence of narcotic prescriptions at the time, the federal government expressed concern that patient access to several highly addictive pain killers may be too easy. The CDC modified its guidelines earlier this year to advise that physicians should adopt an even more conservative and cautious practice toward prescribing long-acting narcotic pain medications [6].

Federal Prosecution

As part of its effort to control narcotic use, the Department of Justice prosecutes prescribing physicians when it determines that opioid use is inappropriate. We believe that this stance may have a chilling effect on those clinicians who adhere to ethical and appropriate standards of prescribing opioids.

Unlike a medical malpractice case, which is a civil lawsuit with damages usually limited to monetary remedies, criminal liability arising from opioid prescriptions can result in lengthy periods of incarceration for physicians who are convicted—up to life imprisonment [7].

Physicians and surgeons need to also understand that criminal indictment for the alleged overprescribing of opioids is not in the same category of prosecution as healthcare fraud cases. Rather, opioid overuse cases are governed by a subset of federal laws that address the illegal distribution of drugs under the Controlled Substances Act (CSA), 21 U.S.C. §841 [1]. That particular federal statute makes it illegal to knowingly or intentionally distribute or dispense a controlled substance [1]. In these cases, therefore, the government essentially accuses the physician or surgeon of being a drug dealer.

Case Law

In 1971, the Nixon administration created the federal DEA, which became the leading administrative body for enforcing the CSA.

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In *United States v Moore* (1975), the US Supreme Court addressed the prosecution of physicians under the CSA, 21 U.S.C. §841 [19]. In a lower-court ruling, Dr. Thomas W. Moore had been convicted for prescribing large amounts of methadone to patients without the proper physical examinations or specific instructions for the use of methadone. Furthermore, Dr. Moore had charged fees according to the amount of methadone prescribed, instead of billing for the medical services provided.

The *Moore* conviction was reversed by the US Court of Appeals on technical grounds, and the US Supreme Court admitted it for further review [19]. The Supreme Court held that registered physicians could still be prosecuted under §841 when their activities fell outside the usual course of professional practice. In its ruling, the Supreme Court in *Moore* made two points. First, the Court clarified that doctors were not exempt from liability under the CSA by virtue of being authorized and registered to prescribe such substances. Second, the Court held that doctors can be prosecuted under §841 "when their activities fall outside the usual course of professional practice" [19]. The Court also set forth an objective good-faith standard to determine the culpability of a doctor who may have acted in good faith (ie, generally accepted standard of medical practice).

Since this 1975 ruling, other legal cases have reflected societal tensions concerning public policy and judicial enforcement of controlled substance laws against physicians and surgeons. A somewhat more lenient view than that reflected in the *Moore* decision was taken in the 4th Circuit ruling in *United States v Hurwitz* [18]. In this case, the question was whether a doctor violated §841 by acting "without a legitimate purpose or beyond the bounds of accepted medical practice." Dr. William E. Hurwitz ran a pain-management clinic in Virginia to treat patients with chronic pain. Some of his patients had developed a preexisting addiction to opioids and were illegally selling prescription drugs, although later Dr. Hurwitz would profess ignorance of this.

Dr. Hurwitz was convicted in 2004, on several counts of distributing narcotics. A lengthy prison term was ordered, with a USD 2 million fine and seizure of his property. This ruling was then overturned on appeal by the US Appellate Court on grounds that the trial judge had erred in not letting jurors consider Hurwitz's defense (that the doctor had prescribed the medications in good faith, and as part of his regular practice of medicine). The Court ruled that "some latitude must be given to doctors trying to determine the current boundaries of acceptable medical practice" and that a doctor "should not be held criminally liable if the doctor acted in good faith when treating his patients." The case went on to a second trial in 2007, in which Dr. Hurwitz was convicted, and ended up serving approximately 4 years in prison.

Legal Notice

One possible alternative to the aggressive prosecution and conviction of physicians for illegal narcotic prescriptions is to create a safe-harbor provision based on notice. Under this model, no criminal prosecution would occur unless notice of unusual prescribing patterns or misuse of narcotics by patients was first served upon the physician. After such notice, the physician should be given the opportunity to remediate existing practice patterns, or provide evidence to prove to the US Department of Justice that the nature of one's practice (such as particularly sick patients with severe pain, or a high volume of chronic pain patients) justifies aggressive prescription of controlled substances. As it stands today, no such model exists to protect physicians who might be legitimately prescribing more opioid pain medications than their peers.

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The proposed safe harbor would offer a level of comfort to those physicians whose good-faith objective is to help patients through the proper use of opioids without having to worry about criminal charges. Errant physicians who deliberately overprescribe narcotic medications for reasons unrelated to patient welfare could still be investigated and prosecuted, after being put on notice that their prescription practices were outside normal patterns. Thus, legislative tools such as safe harbors created by requiring notice before prosecution can facilitate a balance between the competing societal interests of allowing doctors to serve their patients' legitimate pain control needs, while focusing prosecutorial resources on those select individuals who cross the line in willfully and recklessly overprescribing controlled substances.

Physician Guidelines

Both the *Moore* and *Hurwitz* rulings suggest that physician caution is in order when it comes to prescribing narcotics to patients. The conflicting views of the courts means that there is an ostensible lack of a clear, definitive guiding principle for physicians who want to treat legitimate pain, whether chronic or severe, without fear of inciting criminal liability. The risk of ambiguity in prescription guidelines is that most reasonable physicians will probably err on the side of caution and prescribe opioids reluctantly, even if their sound clinical judgement dictates otherwise. Pain is highly subjective, and its experience varies from patient to patient, often influenced by complex cultural and social factors, in addition to individual patient variables and circumstances. The fear of potential exposure to federal criminal liability creates the risk that physicians will make clinical decisions tainted by the fear of criminal prosecution, ultimately compromising the quality of patient care provided.

One assurance for physicians is that the risk of legal sanctions related to prescribing narcotic pain medications is miniscule. This subject was investigated by Goldenbaum and colleagues [8], who identified cases where medical boards criminally prosecuted physicians for offenses related to inappropriate prescribing of opioid analgesics. The study found that only 725 doctors (or approximately 0.1% of practicing patient-care physicians) were charged with criminal and/or administrative offenses related to prescribing pain killers from 1998–2006. Of those charged, a majority (39%) were general practice/family medicine physicians. Only 3.5% were self-identified or board-certified pain specialists, the study found. Physicians charged with opioid prescription misconduct were statistically more likely to be older, male, and not board-certified. According to the study, there were an average of 658 DEA criminal and complaint investigations per year from 2003–2006 [8]. Goldenbaum and colleagues concluded that criminal or administrative charges for pain killer prescriptions are rare. Of note, these data are at least 10-years-old, and whether the risk of physician prosecution for prescribing narcotic drugs has increased in the meantime remains unknown.

For orthopaedic practices, narcotic prescriptions are necessary to treat the severe pain that follows musculoskeletal trauma and surgery. Many orthopaedic operations are being performed on an outpatient basis, using less invasive surgical methods. There is an emphasis in the profession on the preemptive use of painkillers and regional nerve blocks, and surgeons are generally alert to narcotic prescriptions. In multimodal analgesia approaches to elective outpatient surgery, orthopaedic surgeons should be alert to FDA recommendations that warn against using long-acting narcotics, particularly in patients who do not ordinarily use such drugs [4, 12, 13]. Outpatient surgery is particularly risky in that there may be a temptation to use long-acting narcotics that will continue to exert physiologic effects,

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such as respiratory depression, long after the patient has been discharged to the unmonitored, home environment. For most orthopaedic patients, a short course of narcotic pain medications during the acute recovery from surgery should suffice. The risk of patient addiction to a prescription drug in an orthopaedic practice certainly exists, but it is manageable. Patient education, use of modern pain relief measures, judicious use of narcotic pain medications, proper documentation, physician knowledge of the current recommendations and warnings relevant to narcotic medications, and timely referral of patients showing dependence on pain killers to another specialist are practical steps that can avoid the legal risk related to prescribing narcotic pain killers.

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