

Federal Agencies Monitor Physician Prescribing for Pain

Physicians need to perform their due diligence and practice caution when prescribing addictive pain medications to relieve their patients' chronic pain due to increased federal monitoring of pain prescriptions.

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Dr. Elisa Clark is a neurologist who specializes in pain management. This is a difficult specialty area for many reasons. It is not always easy to pinpoint the cause of pain and, when you manage to do so, the treatment problems begin. Individual patients react to pain relievers differently. Finding the proper pain relief and the correct dosage for a given patient can be tricky. The only true measure of pain severity is the patient's reported experience. This should be sufficient, as Dr. Clark sees it. After all, it's the patient's painful experience that is the target for the treatment. Moreover the experience of pain has deleterious side effects that deprive patients of the adequate rest, nourishment, and activity they need in order to recover. But relief for neurologic pain comes chiefly from natural and synthetic opiates, which are controlled substances because they are addictive. So advances in pain management that encourage aggressive pain relief have been met by reservations about abuse, addiction, or sale of narcotics by patients. Hence, insurance companies and regulatory and legal agencies have begun to scrutinize prescriptions for controlled substances and the physicians who write them in the interest of safeguarding patients and society from addiction and the antisocial behaviors it can engender.

These pain treatment challenges engage Dr. Clark. She is a founding partner in a pain management clinic, maintains her own neurology practice, and conducts clinical research into chronic pain management. She is concerned that regulatory attention to pain prescriptions will undo more than a decade's work in educating physicians that patients do not have to suffer from pain. She has taken a strong pro treatment position on the issue and advocates for appropriate pain management through her clinical work and research publications.

Patrick Moran is a private patient of Dr. Clark's. He came to her office several weeks after an auto accident. He had been the front seat passenger in a car that did not have inflatable air bags. It appears, on x-ray, that one of Patrick's lumbar vertebrae twisted slightly when Patrick's right knee hit the dashboard on impact. He has been in severe, debilitating pain since a day after the accident and has remained as immobile as possible. Dr. Clark prescribed oxycodone and asked Patrick to return in 3 days so she could start him on some exercises as soon as the pain was under control. When he returned, Patrick Moran said he was still in severe pain and could hardly walk.

Dr. Clark knows that muscle inactivity at this point will only slow Patrick's recovery and could add to associated pain. She wants to increase his oxycodone to free him of pain and get him moving again. Her research has shown that some patients improve only with much higher dosages of pain reliever than others. Dr. Clark suspects, however, that her prescribing patterns are being monitored by both insurance companies and pharmacies. Her opiate prescriptions have attracted suspicion and attention. Regulatory agencies worry that, because there is no way to prove someone is in pain, physicians may prescribe opiates to "patients" who are not really in pain but who are either addicted to the drugs or wish to sell them. Dr. Clark does not intend to withhold what she thinks Patrick Moran needs to progress in his program of pain relief and returned function. To do so for her own protection would be unprofessional and unethical.

On the other hand, if federal DEA officials show up in her office and threaten her license to prescribe controlled substances or her freedom, all of her patients will suffer.

Legal Analysis

Dr. Clark's concerns are not unfounded. Federal officials have burst into pain clinics and arrested the physicians there in the past [1], charging them with anything from drug trafficking to manslaughter. The Drug Enforcement Agency (DEA) points to cases like that of Dr. Graves to justify their actions. In *Florida v Graves*, a Florida physician was found guilty of 4 counts of manslaughter, as well as racketeering and drug charges, and sentenced to nearly 63 years in prison [2]. Investigations of Dr. Graves began when several pharmacists became suspicious of his prescribing patterns—some because the combination of medications seemed unusual to their past experience, some because the dosages seemed high, and some because of the frequency of the prescriptions. When Dr. Graves became aware of the pharmacists' concerns, he contacted Florida's State Attorney's office, asking for help and admitting his suspicion that some of his patients might be abusing their medications or diverting the drugs to others. The State Attorney did not inform Dr. Graves of their pending investigation but instead sent an agent posing as a patient to Dr. Graves and enlisted a few of his patients to wear wire taps during their appointments with him. Once the State Attorney's office had concluded their investigation, Dr. Graves was indicted for the overdose deaths of 4 of his patients, racketeering, and delivery of a controlled substance.

The manslaughter charges against Dr. Graves alleged that he was responsible for the overdose deaths of his patients due to his "culpable negligence" [3]. Dr. Graves was accused of illegally prescribing medications "not in good faith or in the course of his professional practice as a physician which caused the deaths of four patients" [4]. Dr. Graves argued, first, that he was not negligent in prescribing the medications and, second, even if he had been negligent in prescribing, his prescriptions had not *caused* the deaths of the patients—the patients' abusive usages of the drugs caused their deaths. Dr. Graves maintained that his patients lied to him to obtain prescriptions, did not take medications according to his instructions, and, in some cases, abused alcohol while taking medications. Pain specialists testified for Dr. Graves that patients develop high tolerances for certain medications, such as Oxycontin (a brand of oxycodone) and Xanax, which in turn necessitated high dosages and more frequent prescriptions. The prosecution argued that Dr. Graves was selling prescriptions for cash "without any real examination, diagnostic testing, or follow-up" [5]. The jury sided with the prosecution, sentencing Dr. Graves to 62.9 years in prison.

Dr. Graves was the first physician to be found guilty of manslaughter for the overdose deaths of patients. Legal liability and criminal guilt require plaintiffs and prosecutors to prove an element of causation in every case. Prior attempts to prosecute physicians had failed because physicians argued successfully that a patient's choice to abuse medications was an intervening cause that eliminated the physician's responsibility for an overdose death of a patient. Many physicians are now wary to prescribe pain medications regularly and some patients have been left to shop for physicians willing to risk government investigations in the interest of sparing their patients from chronic pain. An estimated 50 million people suffer from undertreated pain, and many physicians and patients still maintain that oxycodone is the best treatment for chronic pain. Despite repeated studies concluding that pain is consistently undertreated and a 2002 National Institute of Health report that people with cancer suffer needlessly from pain, physician apprehension of prescribing pain medications continue because of government investigations and DEA warnings [6].

The Federation of State Medical Boards published minimal standards for prescribing pain medications; physicians who prescribe pain medications in states that have adopted these standards will be free from prosecution if they "take a complete patient history, conduct a physical exam, develop a treatment plan, obtain informed consent, periodically review the care plan, consult a specialist when necessary, maintain complete and accurate medical records, and comply with controlled substances laws" [7]. These standards, however, are minimal and lack specific guidance for physicians willing to prescribe medications that are effective and safe when used for pain relief but are dangerously addictive if crushed into powder and used as a street drug. Many other states have begun investigations and prosecutions of pain specialists for the oxycodone-related deaths of their patients. Since the Dr. Graves conviction, pain specialists have become more concerned about what constitutes due diligence on their part if they suspect a patient is lying to them about their pain or their drug usage.

Questions for Discussion

1. When prescribing highly addictive medications like oxycodone, what measures can physicians take to protect their patients from adverse outcomes and themselves from liability?
 2. How can physicians advocate for appropriate pain management for their patients?
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