DEA Retraction of Pain FAQ Angers, Scares Doctors and Patients

In August, after a long collaborative process with leading academic pain management specialists, the Drug Enforcement Administration (DEA) posted a document designed to provide guidelines for physicians involved in opioid pain management therapy. The document, "PRESCRIPTION PAIN MEDICATIONS: Frequently Asked Questions for Health Care Professionals and Law Enforcement Personnel," sought to balance the imperatives of drug law enforcement and those of medicine and, at least according to the pain professionals involved in the process, marked a fairly enlightened approach to navigating the turbulent intersection of law and medicine.

But in early October, the DEA pain FAQ mysteriously disappeared without warning to any of the pain professionals involved in creating it. The pain FAQ contained "misstatements" and was not an official document, the agency tersely explained. On November 16, the DEA posted an "interim policy statement" on the Federal Register, detailing its objections to the earlier collaborative FAQ and hewing to a much harder line on the diversion of prescription medicines.

The move comes as one prominent pain physician, Northern Virginia's Dr. William Hurwitz, is on trial for alleged drug diversion. Hundreds of other physicians have been arrested or disciplined in recent years on similar charges. Combined with the federal government's recently announced campaign against prescription drug diversion, the new DEA statement is bound to have a chilling effect on the willingness of doctors to prescribe adequately for the estimated 50 million Americans suffering from chronic pain.

Where the pain FAQ said that the number of patients or the number of pills prescribed "should not be used as the sole basis for an investigation," the new statement said a high number of pain patients or a large quantity of prescribed pills "may indeed be indicative of diversion." As if that weren't enough, the agency asserted for good measure that the government "can investigate merely on suspicion that the law is being violated, or even just because it wants assurances it is not." In other words, the DEA can investigate a pain doctor whenever it feels like it.

While the pain FAQ said that physicians could write multiple prescriptions for a pain patient on a given day, the new statement expressly said they could not and qualified such behavior as indicative of possible diversion. And while the pain FAQ said that prescribing opioid pain medications to people with histories of drug abuse could be done if precautions were taken, the new statement said the FAQ "understated the degree of caution that a physician must exercise to minimize the risk of diversion when dispensing controlled substances to known or suspected addicts." In other words, if you have any history of substance use, count on having a very difficult time getting any doctor to subscribe pain medications for you.

The new DEA statement has been greeted with anger and dismay in the pain management community. In a November 24 letter to the DEA's Office of Diversion Control, Dr. David Joranson, director of the University of Wisconsin's Pain Policy Studies Group, who had worked closely with the DEA in crafting the original pain FAQ, complained that "DEA's abrupt withdrawal of support for the FAQ, without any consultation with coauthors about its concerns, raises questions about
what communication the pain management community can expect to have with DEA." The DEA's changes, Joranson added, "are likely to interfere in medical practice and pain management."

Joranson also accused the DEA of failing to recognize "the well-established principle in federal law that enforcement of the Controlled Substances Act is not intended to interfere with ethical medical practice and patient care," a principle, he pointed out, the DEA has endorsed in the past. And he had particulars.

Regarding the new statement's criticism of the pain FAQ on whether a high number of pills prescribed in itself indicates a problem, Joranson pointed out that the FAQ was in line with Model Guidelines published by the Federation of State Medical Boards of the US, and that the DEA had earlier submitted written testimony supporting the federation guidelines.

As for the DEA's assertion of its ability to investigate any pain doctor for the merest suspicion of wrongdoing, Joranson warned that it is "this attitude that will exacerbate practitioner fears of investigation, even thought they could ultimately show, after a costly and demoralizing process, that the prescribing was medically appropriate."

Joranson also took issue with the DEA's stance on prescribing to people with histories of drug abuse. "The interim policy statement does not recognize that it is within the scope of federal law to prescribe opioids for the purpose of treating pain in patients with an addictive disease or a history of substance abuse, as did the FAQ." Even people who have substance abuse problems sometimes suffer severe pain from cancer or other diseases, Joranson noted. "Is DEA suggesting that it objects to the use of opioids in the treatment of pain in this population of medical patients?" he pointedly asked.

Further comments by Joranson in the letter (linked to below) challenge both the relevance and factuality of arguments presented by the DEA in its new statement.

Another academic pain specialist who had worked closely with the DEA on the pain FAQ, Dr. Russell Portenoy of Beth Israel Medical Center in New York City, told the Washington Post this week that the DEA has changed "the tone of the dialogue in a way that is very worrisome. We're seeing more of an emphasis on law enforcement and less on the legitimate use of prescription narcotics," he added.

Physicians, scholars, and pain advocates not involved in the collaborative process with DEA were less restrained in their reactions. "It's pretty obvious to me what they're up to," said University of North Florida Professor Ronald Libby, who is writing a book on the tangled intersection of law and medicine in pain management. "They basically don't want to be held to any standard for practicing pain medicine," he told DRCNet. "In the pain FAQ, the DEA basically said that there had to be criminal intent on the part of the doctor for it to bring charges, but they don't want to hold to that because then most of these cases they've been bringing against doctors will just collapse. What they are doing now is putting doctors on trial for the behavior of their patients."

"This is the sort of deceptive obfuscation we've come to expect from the DEA," said Siohban Reynolds, executive director of the patient advocacy group the Pain Relief Network (http://www.painreliefnetwork.org). "And it's replete with threats not only against doctors but against the very integrity of medicine. The DEA has been completely dishonest," she added. "I am very dismayed."

Although academic pain specialists like Dr. Portenoy and the University of Wisconsin pain group had spoken with DRCNet in the past, they did not respond to interview requests this time around. Reynolds thinks she knows why. "The academic pain specialists have had all their effort and good will trampled on," she said. "I feel very sad for them. On the other hand, the good news is
that the pain management world will be extremely hard-pressed to continue to act as if the DEA and the Department of Justice are acting in good faith. We are watching a witch hunt going on and even these guys are beginning to understand that."

California physician Frank Fisher, himself a victim of overzealous prosecutors in a notorious Northern California case in which he was exonerated, isn't so sure. "The fact that law enforcement regulates medicine at all is a fundamental problem," he told DRCNet. "Doctors have been trying to work with the DEA on this for the past 15 years, but nothing gets better. Still, as a practical matter, most of the doctors are saying let's try again."

"What pain specialist with any responsibility is going to waste his time with this again?" disagreed Libby. "They are busy, busy people, and they were clearly used by the DEA. They put their time, energy, and professional reputations on the line, and the DEA burned them. How can anyone take the DEA at its word again?"

If the DEA's maneuvers around the pain FAQ and the new statement represent a retrenchment and a harder line toward pain doctors, the timing of the move also strongly suggests that the DEA had more sinister and nefarious reasons. Attorneys for Dr. Hurwitz had moved in late September to introduce the pain FAQ in his trial. The pain FAQ vanished from the DEA web site a few days later. Two weeks after that, US Attorney Paul McNulty, who is prosecuting Hurwitz, filed a motion seeking to have the pain FAQ excluded because it "did not have the force and effect of law." Presiding US District Court Judge Leonard Wexler ruled in favor of the government.

"This is all about winning," said Libby. "I'm sure these guys believe in what they're doing, but they have to justify their jobs and shut these 'drug dealer' doctors down. Now that prescription drugs are as much a part of the drug war as Schedule I substances, the doctors are legal game."

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