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## New DEA Statement Has Pain Doctors More Fearful

Agency Reneges on Guidelines Worked Out for Narcotics

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An extensive effort to ease tensions between physicians who specialize in treating pain and the Drug Enforcement Administration over the use of morphine-based painkillers has backfired -- leaving many pain doctors and patients more fearful than before that they could be arrested for practicing what they consider good medicine.

The DEA triggered the new impasse this month when it published a statement clarifying its position on a number of issues central to pain medicine. The document discusses when a doctor is at risk of being investigated for alleged prescription drug diversion, whether patients with known drug problems can ever be prescribed narcotic painkillers and whether doctors can give patients prescriptions to be filled on a future date.

On all these issues, the new DEA position is at odds with a set of guidelines negotiated over several years by DEA officials and a group of leading pain-management experts. Those guidelines were posted on the agency's Web site in August as part of an effort to reassure doctors who properly prescribe narcotics, but several weeks later the document was abruptly removed and described by the agency as inaccurate and unofficial.

Pain-management experts have responded to the new notice with dismay, saying its provisions may well result in the denial of pain relief to millions of sufferers.

Howard A. Heit, a pain and addiction doctor in Fairfax County, said yesterday that "over 90 percent" of patients and doctors could face investigation under the new guidelines.

"This approach is chilling to me, and I work with the DEA all the time," Heit said in an interview. "General practitioners will see this and say, 'Why should I prescribe opioids and risk getting into trouble?'"

In a letter to the DEA last week, David E. Joranson, a University of Wisconsin pain expert who led the negotiations with the agency, accused it of unilaterally changing important and long-standing practices. Some of the changes, the letter said, leave doctors confused about how they should prescribe painkillers and "are likely to interfere in medical practice and pain management."

In explaining why it took down the guidelines in early October, the DEA said the document contained misinformation that would soon be corrected. The reworked version published Nov. 16 in the Federal Register toughened the agency's position on some of the most sensitive issues.

The new DEA statement said, for instance, that the earlier guidelines were incorrect in saying that the number of patients in a doctor's practice receiving prescription narcotics, the number of tablets they receive, and how long their therapy lasts "do not, by themselves, indicate a problem."

In its November statement, the DEA said all three of those factors "may indeed be indicative of diversion." In addition, the statement said, "it is a longstanding legal principle that the Government 'can investigate merely on suspicion that the law is being violated, or even just because it wants assurances that it is not.'"

The August guidelines also said it was legitimate for doctors to give patients a number of prescriptions for an opioid painkiller with instructions that they be filled on future dates. Because some controlled drugs can legally be dispensed only in small quantities, this practice allows patients to avoid returning weekly or biweekly for another prescription. It is frequently done by pain-management physicians, and Russell Portenoy, a top pain specialist at Beth Israel Medical Center in New York, said it has been discussed and recommended in medical journals and doctor training sessions.

But in the Federal Register, the DEA said that practice is clearly illegal.

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"We're seeing more of an emphasis on law enforcement and less on the legitimate use of prescription narcotics," said Portenoy, who also took part in negotiations with the DEA. He said the agency has changed the "tone of the dialogue in a way that is very worrisome."

The issue of prescription narcotic use -- and abuse -- has become a thorny one as illegal diversion has increased at the same time that the usefulness of prescription narcotics in pain treatment has become better understood.

The DEA has arrested hundreds of doctors and pharmacists in recent years on painkiller-related drug charges, including prominent McLean pain doctor William E. Hurwitz, who is now on trial in Alexandria. Many members of Congress have been demanding action to stop the illegal use of powerful prescription opioids such as OxyContin and Dilaudid, which have been implicated in the deaths of many illicit users.

Sen. Jeff Sessions (R-Ala.) captured the mood when he introduced a bill this month to help states prevent prescription drug abuse. "Over the past 10 years," he said, "the abuse and diversion of prescription drugs has grown from a regional crisis to a national epidemic." Sen. Richard J. Durbin (D-Ill.) co-sponsored the legislation.

Many in the pain-management field, however, say narcotic painkillers are often the best -- or only -- way to relieve chronic pain. But fear of a DEA investigation, pain specialists say, is keeping some worried physicians from writing medically appropriate prescriptions, and patients are suffering needlessly as a result.

Working with the DEA since 2000, the Pain & Policy Studies Group at the University of Wisconsin at Madison Medical School and several other organizations focused on end-of-life issues sought to create a generally accepted and "balanced" approach to prescription narcotic use and control. It was these groups, working with representatives of the DEA, that hammered out the guidelines, presented in a frequently-asked-questions (FAQ) format, that were posted on the DEA Web site this summer.

The DEA declined to comment on the letter from the Pain & Policy group or the criticism of its new notice in the Federal Register. Regarding the original FAQ document, spokesman Ed Childress said "it was meant to be a general guideline, not an official statement of the agency."

In the Federal Register statement, the DEA did acknowledge that chronic pain is a serious problem for many Americans and said most doctors prescribe controlled painkillers legitimately. The agency said it would address that aspect in more detail in the future.

"The document will be aimed at providing guidance and reassurance to physicians who engage in legitimate pain treatment while deterring the unlawful conduct of a small number of physicians and other DEA registrants who exploit the term 'pain treatment' as a pretext to engage in prescription drug trafficking," the statement said.

What concerns experts such as Joranson and Portenoy is that they thought the collaborative process leading up to the issuing of the FAQ guidelines had done precisely that.

Advocates for aggressive pain management said the DEA's abrupt turnaround appeared to have been triggered when defense lawyers tried to introduce the earlier pain guidelines in the trial of Hurwitz, the McLean doctor, in late September.

The DEA took the document off its Web site soon after. About two weeks later, U.S. Attorney Paul J. McNulty, who is prosecuting Hurwitz, filed a motion asking that the guidelines be excluded as evidence, saying that they do "not have the force and effect of law." U.S. District Judge Leonard D. Wexler ruled in favor of the government.

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