

FDA panel votes for tougher curbs on vicodin, other painkillers

January 26 2013, by Amanda Gardner, Healthday Reporter



Debate over the move has pitted patients in chronic pain against those fighting drug abuse.

(HealthDay)—A U.S. Food and Drug Administration advisory panel voted Friday to place tougher restrictions on prescription painkillers containing hydrocodone, potentially moving medications such as Vicodin into the same class as narcotics such as Oxycontin and Percocet.

Vicodin (hydrocodone plus [acetaminophen](#)) and other hydrocodone-containing drugs remain widespread targets for abuse, and the U.S. [Drug Enforcement Administration](#) has long requested that the FDA [advisory panel](#) undertake the review. The panel spent two days discussing the issue before voting on Friday afternoon, the *Associated Press* reported.

Currently, the medications are classified as Schedule III drugs but the DEA wants them placed within the more tightly controlled Schedule II designation, alongside painkillers such as [Oxycontin](#) and Percocet.

The FDA is not required to follow the recommendations of its advisory panels, but it typically does.

The issue has become a contentious one.

Supporters of a move to Schedule II status point to tragic deaths and suicides that have been the result of misuse of these [prescription drugs](#).

But, opponents of that tougher classification fear that tightening access to the drugs would mean that people who really need them to ease pain will not be able to get them.

"This is really a decision of access versus diversion [for non-medical use]," explained Dr. Lynn Webster, president-elect of the American Academy of Pain Medicine, who said his organization was not necessarily in favor of or opposed to reclassification.

However, "it will have an impact on a lot of patients who have been receiving them for some time for legitimate purposes" if these drugs are reclassified, Webster added.

Dr. Andrew Kolodny, president of Physicians for Responsible [Opioid Prescribing](#), called such concerns "completely bogus."

"Even if we change hydrocodone-containing products from Schedule III to Schedule II, it in no way jeopardizes access," he believes. "What this means is that patients who might be able to go to their doctor every six months would now have to see their doctor every three months [to get a prescription]."

Kolodny also contends that "people who are on long-term opioids are more likely to be harmed by that treatment than helped. There is very little difference between a heroin molecule and a hydrocodone

molecule."

Few people seem to dispute the fact that too many of these opioid drugs are too widely available, even though the pharmaceutical industry has recently developed "abuse-resistant" formulations to help fight misuse.

Overall, some 22 million Americans have misused prescription painkillers of one kind or another since 2002, according to a report released earlier this month by the U.S. Substance Abuse and Mental Health Services Administration. The agency noted that [prescription painkillers](#) now rank only behind marijuana as a [drug](#) of abuse in the United States.

According to Webster, patients typically do not use two-thirds of the hydrocodone-containing medications they've been prescribed, meaning those leftover pills might become available for misuse.

"That suggests that there are way more drugs being prescribed than is necessary," Webster said. "And we know that basically 80 percent of all drugs used for non-medical purposes come from the medicine cabinet at home."

Added Kolodny, who is also chair of psychiatry at Maimonides Medical Center in New York City: "We have an epidemic of people with opioid addiction. That's what's really causing overdose deaths."

According to Kolodny, "changing hydrocodone-combination products from Schedule III to Schedule II may be the single most important federal intervention that could be taken to bring this epidemic under control."

Webster said he remained "seriously concerned about both of these issues [access and diversion]," but also felt that there were alternatives to

reclassifying.

"We need more education about how to safely prescribe these drugs and identify people who are safe candidates and prescribe less," he said. "At the same time, we need a national campaign that informs the public and people who are receiving the medications that it's dangerous to have leftover medications and that they need to find ways to dispose of their medications or not accept a prescription."

More information: Visit the [U.S. National Library of Medicine](#) for more on prescription drug abuse.

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