FDA panel weighs tougher restrictions on some prescription painkillers

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Drugs containing hydrocodone, which include Vicodin, would be affected.

(HealthDay)—A U.S. Food and Drug Administration advisory panel will meet Thursday and Friday to discuss the fate of certain painkillers that contain an opioid known as hydrocodone.

At issue is whether to reclassify some of these drugs—which include the commonly prescribed Vicodin (hydrocodone plus acetaminophen)—into a higher category of danger for misuse or abuse. Other opioid painkillers , such as Oxycontin and Percocet, are already classified in that higher category.

The U.S. Drug Enforcement Administration requested that an FDA advisory panel undertake the review; currently the drugs are classified as Schedule III drugs but the agency wants them placed within the more tightly controlled Schedule II designation. The FDA is not required to follow the recommendations of its advisory panels, but it typically does.

The painkiller 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 says his organization is 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.

But 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 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 explained. "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 remains "seriously concerned about both of these issues [access and diversion]," but also feels that there are alternatives to reclassifying.

"Regardless of what happens, 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."

An FDA spokesman said the advisory panel would most likely vote on the issue Friday afternoon.

More information: Visit the U.S. National Library of Medicine for more on prescription drug abuse.