

## **FDA Recommends New Restrictions on Prescription Painkillers Containing Hydrocodone**

Three television networks, major newspapers, wire sources and consumer medical journals reported that the Food and Drug Administration recommended [tighter controls](#) on prescription painkillers containing hydrocodone in an effort to stem the tide of medication abuse. Reaction to the recommendation is not all positive. While legislators in states dealing with high rates of prescription painkiller hail the move, pharmacy organizations and physicians' groups have expressed reservations about it.

The [CBS Evening News](#) reported that the Food and Drug Administration "recommended tighter controls on some of the most commonly prescribed painkillers," medicines containing hydrocodone.

[ABC World News](#) reported that the agency's "plan would allow fewer refills. After three months, patients would be forced to go back to their doctor before getting more medicine." In addition, patients would have to take prescriptions to a pharmacy, and physicians would not be allowed to phone them in.

The [CBS Evening News](#) reported that under tightened controls, medications such as Vicodin (hydrocodone with acetaminophen) would be placed "in the same category as OxyContin [oxycodone]." CBS News medical correspondent Jon Lapook, MD, explained that it will become much harder for patients to get the prescriptions, and it will cause more trouble for physicians who prescribe them. The potential trade-off to greater patient and physician inconvenience will be better oversight of the medications the patient is taking and for how long.

On the [NBC Nightly News](#), NBC News chief medical editor Nancy Snyderman, MD, explained that the FDA's move "follows a debate pitting patients who need narcotics for pain control against otherwise healthy people who access the medications and abuse them." Snyderman pointed out that the move is controversial within the medical community. "The American Medical Association and pharmacy organizations are worried this will be a burden to patients who are already suffering." Brian Bruel, MD, of the MD Anderson Cancer Center, was shown saying, "By making hydrocodone more regulated and harder to prescribe and dispense, our patients are probably going to have a difficult time getting good control of their pain."

The [Wall Street Journal](#) (10/25, Burton, Martin, Subscription Publication, 5.91M) reports that the American Cancer Society, as well as some pain medicine groups, echo Dr. Bruel's concern. Yesterday, the National Community Pharmacists Association said that the agency's decision will, in all likelihood, "pose significant hardships for many patients and delay relief for vulnerable patients with legitimate chronic pain."

On its front page, the [New York Times](#) (10/25, A1, Meier, Subscription Publication, 9.61M) reports, "Dr. Janet Woodcock, director of the agency's Center for Drug Evaluation and Research, said she expected the new regulations to go into effect" sometime in 2014. The FDA's recommendation now "requires the approval of the Department of Health and Human Services and adoption by the Drug Enforcement Administration." According to Federal data, prescription medications are involved in about 75 percent of US overdose deaths. Medicines containing hydrocodone make up approximately 70 percent of all opioid prescriptions.

The [Los Angeles Times](#) (10/24, Healy, 3.07M) reports that the National Institute on Drug Abuse is anticipated to favor the proposal under which "products containing the opioid painkiller hydrocodone, including combination analgesics...will be classified by the Drug Enforcement Agency as Schedule II substances, with added restrictions in who may prescribe them and how they may be dispensed by pharmacies." Currently, hydrocodone products are Schedule III substances, medicines "considered to have 'moderate to low potential for physical and psychological dependence.'"

According to the [AP](#) (10/25, Perrone), "ease of access" to hydrocodone and hydrocodone combination medicines has made them "many health care professionals' top choice for treating chronic pain, everything from back pain to arthritis to toothaches." Unfortunately, according to the DEA, hydrocodone "consistently ranks as the first or second most-abused medicine in the US each year," along with oxycodone. In a statement made yesterday, Dr. Woodcock said, "The FDA has become increasingly concerned about the abuse and misuse of opioid products, which have sadly reached epidemic proportions in certain parts of the United States."

[Bloomberg News](#) (10/24, Edney, Lopatto, 1.91M) reports that Sen. Chuck Schumer (D-NY) hailed the FDA's move. In a statement, the senator said, "I'm very pleased that the FDA has heeded my call and will tighten up control of one of the most highly prescribed – and abused – drugs on the market." Back in January, Sen. Schumer called upon the agency "to tighten controls on the drugs to 'combat an unprecedented spike in prescription drug abuse in New York state and the' US."