FDA Revisits Hydrocodone Reclassification

February 06, 2013
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Is hydrocodone less likely to cause addiction than morphine or hydromorphone? The US DEA wants the FDA to reclassify the Schedule 3 opioid to Schedule II.

The FDA's Drug Safety and Risk Management Advisory Committee during a meeting January 24-25 voted 19 to 10 in favor of reclassifying hydrocodone-containing compounds (eg, Vicodin, Lortab, Norco) from Schedule III drugs under the Controlled Substances Act to Schedule II.

The FDA is likely to accept the panel’s decision, changing the rules for some 47 million patients who receive prescriptions for hydrocodone-containing products annually. It would also be a change in the agency’s historical position that says stricter controls on hydrocodone could limit patients’ access to pain medicine.

The debate is not new—Vicodin, in particular, snares the spotlight as the drug of choice among high-profile abusers (sports figures, movie stars) in a fairly evergreen cycle of 5 to 7 years. It was displaced early in the new millennium by the overpowering media attention focused on the presumably more “potent” single-agent oxycodone product OxyContin. The undiluted controlled-release oxycodone, nicknamed “hillbilly heroin” for the power of its effect when crushed and snorted or prepared for IV injection, has long been assumed to produce greater euphoric effects, and so carry greater potential for addiction, than its combination hydrocodone-acetaminophen cousins. Currently there is no single-agent hydrocodone product available in the United States.

In a letter to the FDA prior to the hearing, Robert DuPont, MD, a former director at the National Institute on Drug Abuse and now president of the Institute for Behavior and Health, a nonprofit group working to reduce illegal drug use, noted that a lot more is known now about the potency and abuse potential of hydrocodone than when it first was classified as a schedule III controlled substance 40 years ago.

But Wilson Compton, MD, division director at the National Institute on Drug Abuse, points out that good data are lacking to show that hydrocodone products are less addictive than oxycodone products. In fact, research on active drug users has found relatively little difference in the quality of the feelings produced when the abusers are given hydrocodone, oxycodone, and hydromorphone. In a 2008 paper published in the journal Drug and Alcohol Dependence, University of Kentucky researchers stated that “The data suggest that the relative potency of these 3 commonly abused opioids do not differ greatly from one another ....”

Winners and losers
The DEA’s renewed effort to press the FDA to revise the scheduling of hydrocodone has vocal detractors and supporters, divided along now-familiar lines: The attempt to curb addiction and overdose by staunching the flow hydrocodone, say those opposed, will create barriers to treatment for many who suffer from chronic pain and extreme hardship for those who rely on the less burdensome regulations to obtain the medication. Currently prescriptions for hydrocodone combination agents can be written for 6 months of refills without a doctor’s visit and refills can be phoned or faxed to the pharmacy. If the drug is reclassified, a 30-day prescriptoin will only be renewed at an office visit. Vulnerable groups include those unable to travel, nursing home and other confined residents, and those living in remote locales, among others. In some states, NPs and PAs, would no longer be able to prescribe the drugs.

Those lobbying for the change cite sobering statistics: Prescriptoin analgesics are now responsible for more deaths than cocaine and heroin combined and since 2008, drug-induced deaths have surpassed those from traffic accidents. Three-quarters of all drug overdose deaths in the US are related to prescription drugs and there has been a four-fold increase since 1999 in the number of
deaths from opioids. In 2009, Americans consumed 99% of the 39 tons of hydrocodone used in the world as well as 81% of the 77 tons of oxycodone. Vicodin specifically is favored by US teens. Annual surveys taken over the last decade show that between 8% and 11% of high school seniors have used Vicodin illicitly, compared with about 5% for OxyContin.

**Trajectory**
If the FDA accepts the panel’s recommendation, it will be sent to officials at the Department of Health and Human Services, who will make the final determination. The FDA denied a similar request by the DEA in 2008, but the law enforcement agency requested that the FDA reconsider its position in light of new research and data.

Last year, the Senate unanimously passed a measure offered by Sen. Joe Manchin, D-W.Va., to elevate the hydrocodone combinations to Schedule II as an amendment to the FDA’s Safety and Innovation Act, but the House did not include the measure in its bill.

The DEA's administrator could issue an emergency order that would reschedule the drugs for 2 years, as it did when drugs such as K2 and Spice, synthetic forms of marijuana, emerged as a problem. The DEA has declined comment.

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