

An advisory panel set up by the Food and Drug Administration (FDA) voted on Friday, January 25, 2013 for tighter restrictions to be placed on Vicodin and other hydrocodone products. Vicodin/ hydrocodone products are currently classified by the U.S. Department of Justice Drug Enforcement Agency (DEA) as Schedule III Controlled Substances, a category of drugs considered to have a lesser potential for abuse than those in Schedule I and II. Physicians can prescribe medications from the Schedule III category using one of several acceptable methods: written, oral (by phone), or by fax and this medication can be refilled 5 times within a 6 month period. In contrast, prescriptions for Schedule II medications must be written out, one for each month, and with no refills. Physicians must follow additional rules, limits and reporting regulations as well as the pharmacies that dispense controlled drugs (in how these drugs are stored, record keeping, and notification protocols).

The DEA claims Vicodin/hydrocodone products are now the most frequently abused painkillers in the U.S., caused by fairly lax prescribing practices of Schedule III drugs. This agency asked the FDA to convene a panel to review and make recommendations about the reclassification of these specific pain medications. The majority of the panel viewed Vicodin/hydrocodone as being pharmacologically comparable to opioids and having similar potential for abuse, therefore, they recommended reclassification of these pain medications as Schedule II controlled substances (along with opioids).

Conflict of opinion surrounds this recommendation for tighter prescribing restrictions. Some members of the medical community, pain medicine societies, and advocates believe this change will cause undue hardship for patients. Addiction specialists feel the extensive use and accessibility of these particular painkillers increases the risk of overdose, addiction and/or abuse, including by people who use them for non-medical reasons and who may steal them or obtain them illegally from drug dealers. While the FDA has not yet made a decision as to whether it will adopt these recommendations, it is important to realize this is not a new development.

The debate and push (by way of public petitions) to have hydrocodone /hydrocodone-combination products be placed under the more restrictive category of Schedule II substances has been going on since 1999. A few months earlier, a leading national newspaper ran a story about tactics used by the DEA to crack down on the growing problem of painkiller use/abuse such as arresting doctors who were overprescribing these drugs and closing down pharmacies that dispensed too many painkillers or were charged with other violations. Wholesalers have also been targeted (i.e., referred to as the “middlemen” between pharmaceutical companies and pharmacies) for sending large shipments of controlled substances to certain pharmacies or locations or being charged with failure to report suspicious shipments to the DEA — some distributors have lost their licenses as a result and others have restricted or terminated shipments to pharmacies that could pose a threat to them. This problem appears to be worse in some states (like Florida, known for its “pill mills”) forcing patients to travel extensively in search of a pharmacy that would fill their prescription. While prescription drug abuse has increased substantially over the past 10 to 15 years, access to pain medication/ pain management needs to be protected for people who legitimately suffer from chronic pain.

The White House, Office of the National Drug Control Policy issued a Press Release on October 1, 2012 which describes a new program they will offer, White House Drug Policy Office and National Institute on Drug Abuse Unveil New Training Materials to Combat National Prescription Drug Abuse Epidemic. This program is created for physicians, medical interns and residents so they can learn how to properly prescribe pain medications and address prescription drug abuse. This initiative is sponsored by the National Institute on Drug Abuse (NIDA) which also allows participating healthcare professionals to earn continuing medical education (CME) credits.

### For more information

“FDA Panel Votes for Tighter Controls on Vicodin” by Kristina Fiore (MedPage Today) published on January 25, 2013, available at:  
<http://www.medpagetoday.com/PublicHealthPolicy/HealthPolicy/37024>

“F.D.A. Panel Votes to Restrict Drugs Like Vicodin” by Sabrina Tavernise (New York Times) published on January 25, 2013, available at:  
<http://www.nytimes.com/2013/01/26/health/fda-vote-on-restricting-hydrocodone-products-vicodin.html>

“A New Painkiller Crackdown Targets Drug Distributors,” by Barry Meier (New York Times ) published on October 17, 2012 available at:  
<http://www.nytimes.com/2012/10/18/business/to-fight-prescription-painkiller-abuse-dea-targets-distributors.html>

“White House Drug Policy Office and National Institute on Drug Abuse Unveil New Training Materials to Combat National Prescription Drug Abuse Epidemic,”— Press Release issued on October 1, 2012, that can be viewed at:  
<http://www.whitehouse.gov/ondcp/news-releases-remarks/ondcp-nida-announce-new-elearning-tools-combat-rx-drug-abuse>