

**Position Statement  
on  
HYDROCODONE PRESCRIBING POLICY**

**Background**

The FDA's Drug Safety and Risk Management Advisory Committee has been evaluating the status of hydrocodone combination drugs, such as Vicodin®, Lortab®, Norco®, and Vicoprofen®. In January 2013, this committee voted 19 to 10 in favor of reclassifying combination medications containing hydrocodone from Schedule III drugs under the Controlled Substances Act to Schedule II. This would impose significantly stricter prescribing rules on drugs containing hydrocodone. This change would also affect anti-tussive medications containing hydrocodone. Understandably, this action was prompted by the increasing implication of hydrocodone in deaths related to narcotic overdoses. The death rate from hydrocodone combination drug overdoses has tripled in the last 20 years. Over 130 million prescriptions for hydrocodone were written in the United States in 2011, making it the most prescribed narcotic analgesic. The United States is responsible for 99 percent of the world's use of hydrocodone, per the International Narcotics Control Board. Additionally, the change is being driven not only by the increase in hydrocodone-related mortality, but also by the increasing number of DEA interventions due to skyrocketing narcotic distribution by select retail pharmacies.

**AANS/CNS Position Statement**

Neurosurgeons believe that patient safety considerations need to be balanced with the need for patients to have appropriate and ready access to pain relief medications. Reclassifying hydrocodone combination drugs would create an unreasonable burden on providers and patient care. It would require more frequent office and emergency room visits, unnecessarily increasing the time and resources allocated to refilling these medication prescriptions, which are often used in modest amounts for peri-operative pain management. A change from Schedule III where they now reside, to Schedule II would also eliminate the ability of providers to prescribe up to 5 refills on a single prescription. Classifying hydrocodone combination drugs is a further burdensome and insufficient solution.

**Rationale**

As noted, reclassifying hydrocodone combination drugs would move hydrocodone combinations from Schedule III, which contains medications such as Tylenol® with codeine and buprenorphine, to Schedule II where it would be placed in the same class as hydromorphone, methadone, morphine, oxycodone, fentanyl, methylphenidate, and barbiturates. Schedule II drugs are described as having a high potential for abuse which may lead to severe psychological or physical dependence. It should be appreciated as well that plain hydrocodone is already classified in Schedule II. This change would move combination drugs into that category as well.

In practice this change would have significant implications with regard to hydrocodone combination drug prescribing practices. Schedule III drugs are eligible for up to 5 refills on a single prescription, while Schedule II drugs cannot be refilled without a new prescription. At most a single 90-day supply could be prescribed at once. Moreover, the direct involvement of mid-level practitioners, relied on more frequently than ever to assist with the significant burdens of everyday medical practice, would become strained as the ability of nurse practitioners and physician assistants to prescribe Schedule II

drugs varies state by state. The rules for each state may be found at:  
[http://www.deadiversion.usdoj.gov/drugreg/practioners/mlp\\_by\\_state.pdf](http://www.deadiversion.usdoj.gov/drugreg/practioners/mlp_by_state.pdf).

While many groups, such as the American Society of Addiction Medicine, Physicians for Responsible Opioid Prescribing, and Public Citizen's Health Research Group have hailed the vote as a major move to prevent hydrocodone abuse, others point to the increased burden that will be faced by patients who suffer from chronic pain. It is a foregone conclusion, as some have pointed out, that the increased burden will cause some patients to obtain hydrocodone products illegally rather than going through legitimate channels.

As practitioners in a surgical subspecialty who also interact with a significant number of patients in chronic pain as well as peri-operative pain, we strongly believe that this schedule change will result in reduced quality of care and likely increased illicit narcotic abuse, some of the very goals the FDA seeks to avoid. Pain management, in general, is an extremely important and under-addressed aspect of healthcare worldwide, and narcotic use, in particular, is an important complex problem within pain management that needs careful consideration.