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April 23, 2014

Michele M. Leonhart, Administrator
US Drug Enforcement Agency
8701 Morrissette Drive
Springfield, Virginia 22152

Re: AANS/CNS Statement on Hydrocodone Prescribing Policy: Docket No. DEA-389

Dear Ms. Leonhart:

On behalf of the American Association of Neurological Surgeons (AANS), the Congress of Neurological Surgeons (CNS), and the AANS/CNS Section on Pain, we appreciate the opportunity to provide our concerns regarding the Drug Enforcement Agency's (DEA) effort to reclassify hydrocodone combination products from Class III designation to Class II. Although we share the agency's concern and awareness of the serious problem of prescription drug abuse, we disagree that reclassifying hydrocodone products is the appropriate solution. As such, AANS and CNS have taken the following position on the issue.

AANS/CNS Position Statement

Neurosurgeons believe that patient safety considerations should 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 would move hydrocodone combination drugs 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.

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

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become strained as the ability of nurse practitioners and physician assistants to prescribe Schedule II drugs varies state by state.

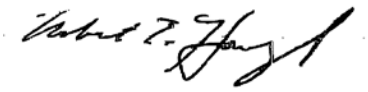
While many groups, such the American Society of Addiction Medicine, Physicians for Responsible Opioid Prescribing, and Public Citizen's Health Research Group have hailed the vote as a major move to prevent hydrocodone abuse, others point to the increased burden that will be faced by patients who suffer 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.

Conclusion

Thank you for your time and attention. We feel the suffering inflicted on patients in pain would outweigh the benefits of reclassifying hydrocodone. We do not support the decision to reclassify.

Sincerely,



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