February 1, 2013

Douglas C. Throckmorton, M.D.
Deputy Director for Regulatory Programs
Center for Drug Evaluation and Research
Food and Drug Administration
10903 New Hampshire Ave., Bldg. 31, rm. 2417
Silver Spring, MD 20993-0002

Re: FDA-2012-N-0548; Drug Safety and Risk Management Advisory Committee; Notice of Meeting; Community pharmacy perspective regarding the public health benefits and risks of drugs containing hydrocodone either combined with other analgesics or as an antitussive.

Dear Dr. Throckmorton:

The National Community Pharmacists Association (NCPA) would like to take this opportunity to express our concerns with the possible rescheduling of hydrocodone-containing products. NCPA represents the interests of America's community pharmacists, including the owners of more than 23,000 independent community pharmacies, pharmacy franchises, and chains. Together they have more than 315,000 employees including 62,400 pharmacists, and dispense over 41% of all retail prescriptions.

While pharmacists share concerns regarding the abuse, misuse and diversion of these prescription drugs, these concerns must be balanced with the impact on patients who legitimately need access to them. There are numerous hydrocodone-containing combination products that patients need to treat moderate to severe pain from various conditions. Rescheduling the products to Schedule II would create significant hardships for all – leading to delayed access for vulnerable patients with legitimate chronic pain, especially those in nursing home and long-term care settings.

NCPA would like to share the following viewpoints for your consideration:

- States Can Reschedule Controlled Substances: Under Federal law, states can act on their own to place tougher restrictions on the prescribing and dispensing of controlled substances. As a result, any state may classify these products as Schedule II without a change in Federal law, based upon the public health needs and experience of their citizens.

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- Products Will Be Harder to Obtain to Treat Pain: Hydrocodone in combination is one of the last non-Schedule II drugs available to treat moderate to severe pain. If these products are reclassified into Schedule II, prescribers will no longer be able to phone in prescriptions to pharmacies for their patients. Schedule II drugs can only be filled after a pharmacy receives a hard copy valid prescription signed by the prescriber– a physician cannot phone the pharmacy except in an emergency for a small supply with a follow up hard copy prescription to the pharmacy.

  At the public meeting held January 24-25, 2013, it was discouraging to hear several comments related to how easy the process was of calling in an emergency supply of a Schedule II medication. It is very important to note this is not an easy process nor does it allow for timely and continued access to needed medications. In most instances there is a significant lag time that will often pass before the physician can be reached to provide the required written order that must accompany an emergency fill. This means delays in properly caring for the patient's needs.

  In addition, products in Schedule II cannot be refilled. Pharmacy contact with the prescriber would increase from once every six months to monthly. Although NCPA is appreciative of DEA's rule to allow a prescriber to issue multiple Schedule II prescriptions at the same time, up to a 90 day supply, pharmacies rarely encounter prescriptions that have been written pursuant to this DEA rule. Prescribers and patients find the rule to be unworkable for most situations.

  Also, physician assistants and nurse practitioners may be prohibited from prescribing CIIs in many states, which may greater restrict access for patients with legitimate clinical needs and could harshly affect rural areas with already overbooked physicians. It is ironic that while the Department of Health and Human Services (HHS) is looking to these "physician extenders" to provide increased levels of care for an expanded population eligible for health care per the Affordable Care Act, these same prescribers could be completely shut out of providing care for patients with pain care needs.

  Finally, while electronic prescribing for controlled substances is authorized by DEA, implementation of the program is still in progress. Some states prohibit prescribers from electronically sending prescriptions for Schedule II products to pharmacies. Therefore, the inclusion of these products in Schedule II could result in additional barriers for patients in rural areas where the prescriber may be miles away.

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- Challenges to Pharmacies Will Increase: There are dozens of different dosage forms and strengths of these products stocked by pharmacies. If implemented, placing these products into Schedule II will result in significantly higher administrative overhead costs to comply with additional secure storage, recordkeeping, and inventory management requirements. For example, many pharmacies in the U.S. would likely be forced to purchase and install significantly larger safes. In addition, depending on state law, pharmacies would be required to maintain a perpetual inventory on these products, which would mean literally counting each Schedule II pill in storage on a regular basis.

- Rescheduling Would Likely Increase the Value of Illicit Hydrocodone Products and This May Lead to Increased Crimes in Pharmacies: As you are aware, the issue of pharmacy crime is very serious and unfortunately on the rise. NCPA has serious concerns that pharmacies may become even larger targets than they are today for criminals wanting to profit from an increased street value associated with these products. The safety of pharmacists and their patients should not be put at risk unnecessarily.

NCPA would like to offer the following recommendations in lieu of rescheduling:

- Education for Prescribers: Mandatory prescriber education surrounding the use of these products is a key element to curb inappropriate prescribing and use. NCPA also supports efforts to verify that appropriate prescriber education has occurred via linking such education to the prescriber's DEA registration.

- Prescription Drug Monitoring Programs: NCPA also supports controlled substance prescription monitoring programs. There are ongoing efforts to link information between state databases as well as efforts to require prescribers to consult the database before prescribing. NCPA supports these efforts and believe they can go a long way in curbing inappropriate prescribing and use of hydrocodone-containing products.

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- Safe Drug Disposal: Since surveys show that over 70% of people abusing or misusing prescription medications obtained them from friends or family[1], it is vital that patients have the means to return unwanted prescription drugs for disposal. Current DEA rules prohibit pharmacies from taking back controlled substances. Although NCPA appreciates the DEA finally releasing a proposed rule to allow consumers to dispose of unwanted controlled substances, there are many potential roadblocks in the proposal that will need to be addressed. It is also frustrating that it took the DEA so long to release these rules, when Federal legislation authorizing the take back of controlled substances passed in 2010.

- Increased Uptake of Electronic Prescribing for Controlled Substances (EPCS): Even though the DEA now allows for EPCS, the uptake in the industry has been slow due to a variety of reasons. As practitioners and systems adjust, we will begin to see the benefits of EPCS, such as streamlined workflows for prescribers and pharmacies and improvements in the safety and efficiency of controlled substance prescribing.

- Expansion of FDA's Existing and Ongoing Efforts: The central component of FDA's new REMS for Extended Release and Long Acting Opioids is an education program for prescribers so that certain opioid drugs can be prescribed and used safely. Prescriber education regarding the risks and benefits of opioid drugs is critical. In addition, the REMS for transmucosal immediate-release fentanyl (TIRF) products could serve as a model for future REMS. FDA has worked very hard to strike the appropriate balance with these REMS and can use these programs to mitigate risks associated with use of hydrocodone combination products, rather than rescheduling the entire class.

- Target Illegitimate Internet Drug Sellers: NCPA supports FDA's recent initiative, the "BeSafeRx" campaign, to educate consumers about the dangers of illegal Internet drug vendors. These illegitimate sellers operate outside any legitimate prescriber-patient relationship and only serve to increase the amount of drugs illegally on the market for purposes of abuse and diversion.

- Limit the Quantities of Controlled Substances Dispensed via the Mail: Pharmacy Benefit Managers (PBMs) should be held accountable for the fact that they dispense large quantities of controlled substances through the mail. Oftentimes, certain medications that are prescribed will not work for a patient, a patient only needs a few doses or the patient expires, which can mean these large quantities can go to waste, or be stolen from a patient's mail box. Having these large quantities of controlled substances sitting around patients' homes does not serve the public interest.

[1] Substance Abuse and Mental Health Services Administration. *Results from the 2010 National Survey on Drug Use and Health: Summary of National Findings.* U.S. Department of Health and Human Services. [September 2011]. Available: http://oas.samhsa.gov/NSDUH/2k10NSDUH/2k10Results.htm

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- Shutting Down Rogue Pain Clinics: According to DEA, the practitioners in these clinics are responsible for the dispensing of millions of dosage units of oxycodone. NCPA supports efforts to shut down these rogue clinics, such as restricting a physician's ability to dispense prescriptions from a pain clinic.

It is important to note that many of these recommendations, namely prescriber education, prescription monitoring programs, disposal, and shutting down pill mills, are supported by the White House Office of National Drug Control Policy (ONDCP) to address diversion and abuse while ensuring legitimate patient access to medications. In addition, there is no mention of rescheduling in any of the ONDCP recommendations.

Conclusion

In conclusion, NCPA understands the concerns about diversion and abuse of these products and shares these concerns. Nevertheless, moving all of these hydrocodone products to Schedule II will result in significant barriers for patients who have a legitimate need for these products and it will result in adding to the nation's health care costs with no assurance of a reduction in diversion and abuse.

No evidence currently exists to show that reclassifying hydrocodone will curb misuse and abuse of pain medications. Oxycodone is already a Schedule II medication, and it is one of the most heavily abused medications. It is difficult to believe that moving combination hydrocodone products into the same Federal Schedule as oxycodone would have a measurable favorable impact.

There are better strategies to address this issue including electronic prescription drug monitoring programs and tracking systems, and we pledge to work with you and other policy makers to develop these viable alternative proposals. Thank you for considering our views.

Sincerely,

Ronna B. Hauser, PharmD
VP Policy and Regulatory Affairs
National Community Pharmacists Association (NCPA)

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