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November 5, 2013

The Honorable Kathleen Sebelius
U.S. Department of Health and Human Services
200 Independence Avenue, S.W.
Washington, D.C. 20201

Re: Support for Rescheduling Hydrocodone Combination Products

Dear Secretary Sebelius:

On behalf of the American Society of Health-System Pharmacists (ASHP), I am writing to commend the Food and Drug Administration (FDA) for their October 24, 2013 decision to recommend the rescheduling of hydrocodone-containing combination products to Schedule II drugs under the Controlled Substances Act.[1] ASHP is the national professional organization whose 40,000 members include pharmacists, pharmacy technicians, and pharmacy students who provide patient care services in acute and ambulatory care settings, including hospitals, health systems, and clinics. For 70 years, the Society has been on the forefront of efforts to improve medication use and enhance patient safety.

Rescheduling of hydrocodone-containing combination products would be consistent with the recommendation of the FDA's Drug Safety and Risk Management Advisory Committee (the Committee), which voted 19 to 10 in favor of rescheduling this therapy in January, 2013.

Further, ASHP Policy states[2]:

> To advocate that the Drug Enforcement Administration (DEA) reschedule hydrocodone-containing products to Schedule II based on their potential for abuse and patient harm and to achieve consistency with scheduling of other drugs with similar abuse potential.

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1 Statement on Proposed Hydrocodone Reclassification from Janet Woodcock, M.D., Director, Center for Drug Evaluation and Research (http://www.fda.gov/drugs/drugsafety/ucm372089.htm)

2 ASHP Policy 1314, DEA Scheduling of Hydrocodone Combination Products (http://www.ashp.org/DocLibrary/BestPractices/policypositionsandrationales2013.aspx)

This policy was developed through ASHP's Council on Therapeutics, its Board of Directors, and House of Delegates after carefully weighing the potential public health benefit of rescheduling these therapies against concerns about restricting patients' access to treatment and increasing administrative and other burdens on pharmacists, physicians, and other clinicians.

As defined by the DEA, Schedule II controlled substances are those that "have a high potential for abuse which may lead to severe psychological or physical dependence." Hydrocodone as a single-ingredient product is included in Schedule II. However, at lower dosages and with the addition of acetaminophen, these combination products have been assigned to Schedule III. In contrast, oxycodone is designated as Schedule II regardless of dosage or whether the drug is provided as single ingredient or as a combination product with acetaminophen. Schedule III controlled substances are those that "have a potential for abuse less than substances in Schedules I or II and abuse may lead to moderate or low physical dependence or high psychological dependence." ASHP has found no evidence that the lower dose of hydrocodone contained in these combination products, or the addition of acetaminophen, lowered the abuse potential of hydrocodone. Recent data from the CDC show that every year since 2003 more deaths have occurred from overdoses of opioid pain relievers, including hydrocodone combination products, than from overdoses of cocaine and heroin combined.

Based on an assessment using the criteria the DEA considers when determining whether to control or reschedule a drug, ASHP believes that hydrocodone combination products are similar to other controlled substances found in Schedule II and should therefore be assigned to Schedule II.

The proposed change to a more restrictive schedule will require heightened recordkeeping and security processes, which could in turn make providers reluctant to prescribe these therapies for patients who need pain management. The Society also notes that the DEA criteria mentioned in the preceding paragraph were never intended to take into account potential administrative and other burdens on pharmacists and other clinicians (e.g., stricter recordkeeping and security processes).

We believe that these are valid concerns. However, in balancing these concerns, we concluded that increased control of drugs with high abuse potential is in the best interests of patients and public health. In addition, the Society does not believe that the inability to prescribe refills (which would be a primary impact of rescheduling) would have as broad an impact on patient access as initially feared. Data from the FDA materials provided to the Advisory Committee prior to its vote demonstrates that a majority of prescriptions for these products were issued for treatment of acute pain with an average duration of therapy of 14 days.[3] This information

[3] Briefing Information for the January 24-25, 2013 Meeting of the Drug Safety and Risk Management Advisory Committee (http://www.fda.gov/AdvisoryCommittees/CommitteesMeetingMaterials/Drugs/DrugSafetyandRiskManagementAdvisoryCommittee/ucm334275.htm)

indicates that the burden on patients and providers should be less than feared because by their very nature prescriptions for acute pain treatment would have limited or no refills.

ASHP believes that this schedule change is necessary to address the public health crisis associated with abuse of hydrocodone combination therapies. However, the Society acknowledges that the full impact of this change on patients, physicians, pharmacists, and other health care providers, is difficult to predict. Therefore, we recommend that the FDA, DEA, and other stakeholders monitor the effect of rescheduling hydrocodone-containing products and other abuse-prevention efforts (e.g., prescription drug monitoring programs) to assess the impact of these actions on patient access to hydrocodone-containing medications and on the practice burden of health care providers. The Society and its members are available to assist these agencies in these efforts.

In closing, the Society strongly supports the FDA's decision to recommend rescheduling of hydrocodone-containing combination products in the interest of protecting public health. If you have any questions or wish to discuss our comments further, please contact Chris Topoleski, Director Federal Regulatory Affairs at 301-664-8806 or by email at ctopoleski@ashp.org.

Sincerely,

Kasey K. Thompson, Pharm.D., M.S.
Vice President
Policy, Planning and Communications

cc: Margaret Hamburg, M.D., Commissioner, U.S. Food and Drug Administration
Janet Woodcock, M.D., Director, Center for Drug Evaluation and Research (CDER), Food and Drug Administration