[Submitted via First-Class Mail and electronically to Kathleen.Sebelius@hhs.gov]

November 11, 2013

Secretary Kathleen Sebelius
U.S. Department of Health & Human Services
200 Independence Avenue, S.W.
Washington, D.C. 20201

RE: Opposition to Rescheduling Hydrocodone Combination Products

Dear Madame Secretary:

The pharmacy groups listed below have serious concerns about the Food and Drug Administration's (FDA's) October 24, 2013 announcement to recommend the rescheduling of hydrocodone-containing combination products as Schedule II drugs. Our organizations are committed to addressing abuse and diversion of these prescription drugs. While we appreciate the efforts of the FDA to address the serious issue of prescription drug abuse, we believe rescheduling hydrocodone is not the solution. Rescheduling will have a profoundly negative impact on patients who legitimately need these medications and a negligible impact on drug abuse.

Rescheduling hydrocodone products will create serious access barriers for patients who legitimately use these medications and could result in significant delays for patients trying to fill legitimate prescriptions for hydrocodone products. If these products are reclassified into Schedule II, prescribers will no longer be able to phone in prescriptions to pharmacies for their patients. Further, products in Schedule II cannot be refilled. As a result, patients who may have mobility limitations or chronic pain could now be required to travel long distances and suffer significant discomfort to see their physician for refills and to have their prescriptions filled. Similarly, rescheduling will present serious problems for patients who are confined to a nursing home or assisted living site, and for professionals working to make sure that such patients receive care and pain management in a timely and appropriate fashion. This requirement may

not only delay patient access to medications, but may also create significant expense[1], which may force some to unnecessarily endure chronic pain. While the Drug Enforcement Administration (DEA) has authorized electronic prescribing for controlled substances (ECPS), implementation of the program is still in progress. Even with implementation of ECPS, some state laws would still prohibit prescribers from electronically sending prescriptions for Schedule II products to pharmacies. In considering the burden on patients, it is important to remember that the vast majority of patients who use hydrocodone do so legitimately and these medications are as essential to their health as any other medication. Access barriers create serious medical and financial hardships, and any program to prevent drug abuse should be tailored narrowly to protect legitimate users.

Additionally, rescheduling hydrocodone will create new burdens for an already overtaxed health care system. Following the rollout of the Affordable Care Act, providers, including pharmacists, are already stretching thin resources to provide required services to new enrollees. Rescheduling hydrocodone will create additional administrative and logistical issues, causing providers to lose even more valuable time for patient care.

Pharmacies stock dozens of different hydrocodone products and rescheduling will impose new requirements, including the provision of additional secure storage, recordkeeping, and inventory management. 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 tablet in storage on a regular basis. Further, ordering requirements for Schedule II products are much more burdensome than non-Schedule II products, and Federal law also requires that separate files be kept in the pharmacy for these products. In addition, rescheduling carries logistical considerations. For example, if rescheduling occurs, many pharmacies would likely be forced to purchase and install significantly larger safes, which are costly and consume a large amount of the limited space within a pharmacy. Pharmacies would be willing to work with the FDA, HHS, and DEA to implement these new measures if clear evidence shows that rescheduling hydrocodone would solve the prescription drug abuse problem.[2] However, there is no indication that rescheduling will solve the problem, and every indication that it will create new patient access and administrative burdens.

There are more narrowly tailored options for handling prescription drug abuse, some of which have been shown to be effective. Almost all states already have electronic prescription drug monitoring programs (PDMPs) and tracking systems, which allow for appropriate identification, tracking and investigation of potential overprescribing or abuse. Several states with serious prescription drug issues have seen significant decreases in prescription drug abuse

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[1] Because prescriptions of Schedule II drugs cannot be refilled without a new prescription, patients would be required to schedule office visits with their physicians to obtain a new prescription. Thus, the number of office visits would increase exponentially, pushing up costs and exacerbating scheduling and access issues created by the physician shortage. Additionally, it is possible that patients will turn to emergency rooms when they cannot schedule an appointment with a physician, which would also drive up health system costs.

[2] According to recent research, the vast majority of prescription drug abusers obtain the medications from family and friends, not through personal prescriptions. *See* Substance Abuse and Mental Health Services Administration, Results from the 2011 National Survey on Drug Use and Health: Summary of National Findings, NSDUH Series H-44, HHS Publication No. (SMA) 12-4713 (2012), *available at* http://www.samhsa.gov/data/NSDUH/2k11Results/NSDUHresults2011.htm.

after implementing PDMPs.[3] Likewise, CMS has moved forward through its program integrity unit with programs aimed at identifying and tracking overprescribing, overdispensing, and misuse within the pharmacy community and the prescribing community. Federal and state governments should focus resources and funding on these programs that really do curb inappropriate utilization and abuse, and not implement burdensome measures that will produce little benefit and prevent patients in need from accessing and receiving the appropriate care.

We share the FDA and DEA's concerns regarding diversion and abuse of hydrocodone products, but we do not believe that rescheduling will adequately address the problem. As stated above, moving all hydrocodone products to Schedule II will result in significant barriers for patients who have a legitimate need for these products and add to the nation's health care costs with no assurance of a reduction in diversion and abuse. We believe that there are more effective solutions to the prescription drug abuse problem and we pledge to work with you and other policymakers to develop viable alternative proposals.

Sincerely,

Academy of Managed Care Pharmacy
American Pharmacists Association
American Society of Consultant Pharmacists
National Alliance of State Pharmacy Associations
National Association of Chain Drug Stores
National Community Pharmacists Association

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[3] *See* White House, *Epidemic: Responding to America's Prescription Drug Abuse Crisis* (2011), *available at* http://www.whitehouse.gov/sites/default/files/ondcp/policy-and-research/rx_abuse_plan.pdf.