April 28, 2014

[Submitted electronically to www.regulations.gov]

Drug Enforcement Administration
Federal Register Representative/ODW
8701 Morrissette Drive
Springfield, Virginia 22152

Re: Pharmacy Profession Comments to DEA Notice of Proposed Rulemaking on the Rescheduling of Hydrocodone Combination Products From Schedule III to Schedule II

Dear Sir/Madam:

The undersigned pharmacy organizations would like to thank the Drug Enforcement Administration for the opportunity to offer our comments on Federal Register Notice of Proposed Rulemaking (NPRM), Docket No. DEA–389, Schedules of Controlled Substances: Rescheduling of Hydrocodone Combination Products (HCPs) From Schedule III to Schedule II. Collectively, our organizations represent over 100,000 pharmacists across the full spectrum of practice settings.

We recognize the significant public health concerns associated with the abuse, misuse and diversion of prescription drugs. In 2011, the Centers for Disease Control and Prevention (CDC) declared prescription painkiller overdose an epidemic in the United States, estimating that 75 opioid-related deaths occur daily. Our organizations are dedicated to the development of effective solutions to address this public health crisis. Despite our unified commitment to patient safety and the prevention of prescription drug abuse, we have concerns that rescheduling HCPs will not solve the problem and, will actually negatively affect those we are trying to help – patients. Additionally, we believe this change will further burden an already strained health care system.

DEA's Analysis

DEA asserts in the NPRM that rescheduling of HCPs is warranted because these products are chemically similar to Schedule II oxycodone and have similar abuse potential and includes studies to support that assertion. While our organizations are concerned with the current abuse of HCPs, we question the merits of rescheduling to reduce prescription drug abuse. The studies DEA uses to support rescheduling actually demonstrate that hydrocodone is abused at a lesser rate than oxycodone – a Schedule II product – despite being prescribed almost four times more often.

Moreover, the NPRM includes data highlighting oxycodone's significantly higher rates of diversion and related deaths compared to HCPs. While our organizations are devoted to finding workable and effective solutions to our Nation's prescription drug abuse problem, the data DEA uses to justify rescheduling of HCPs confirms that stricter scheduling does not reduce abuse.

Adverse Policy Effects

We appreciate DEA's efforts to develop solutions to curtail the issue of prescription drug abuse, misuse and diversion. However, we believe that in identifying and developing solutions, and weighing the costs and benefits of each approach, it is important to remember that the vast majority of patients taking hydrocodone do so legitimately.

Patient Access

The Institute of Medicine (IOM) estimates that 100 million Americans live with chronic pain, and the Centers for Disease Control and Prevention's (CDC) estimates that an additional 46 million individuals suffer from acute pain associated with surgery. HCPs play a key role in acute and chronic pain management and helping patients engage in the activities of daily life.

Rescheduling HCPs will have far-reaching consequences for millions of Americans who legitimately rely on them for short-term and chronic pain. Schedule II drugs have stricter requirements related to prescribing and dispensing, which can restrict patient access. Prescriptions for Schedule II medications cannot be refilled nor can they be telephoned or faxed to a pharmacy. Therefore, rescheduling will result in patients requiring doctor's visits for the purposes of seeking refills for HCPs. And while a prescriber's written instructions to postpone the filling of multiple Schedule II prescriptions up to a ninety-day supply can help with issues of patient access in some jurisdictions, it is not the overall solution.

Furthermore, patients with a legitimate clinical need could be forced to endure pain while waiting for an appointment or the ability to take time off work. These stricter prescription/ refill requirements could also impose additional hardships on patients who have physical limitations or live in rural or medically underserved areas – cases in which traveling to a health care provider is not a simple task.

Health Care Costs

Rescheduling HCPs will unnecessarily introduce inefficiencies into the health care system and increase costs at a time when policymakers are seeking ways to streamline processes and reduce costs. Patients living with chronic pain will see costs rise due to more frequent clinician visits required to obtain a new HCP prescription. In addition to the direct costs associated with increased visits (e.g. copays and cost of the services), there are the costs associated with time off from work and transportation to and from health care providers (e.g. physician's office, pharmacy, etc). These additional burdens are particularly troublesome for some of our Nation's most vulnerable citizens, such as patients who have access issues (e.g. limited resources, physical challenges or geographically restricted).

In addition to the costs to the patient, rescheduling will add substantial costs and workload to the health care delivery system as a whole. As noted, the increased prescribing requirements will warrant additional patient visits. There are currently primary care provider shortages across the country and the shortage is predicted to worsen. With approximately 50 million patients taking HCPs, meeting the new demands associated with the rescheduling HCPs may cripple an already overtaxed system. Moreover, pharmacies and distributors will have to comply with stricter storage and handling laws for Schedule II controlled substances, and such requirements may cause delays in maintaining an adequate supply of HCPs.

While we appreciate the concerns and effort that DEA and FDA put forward to address our Nation's significant prescription drug abuse problem, our organizations believe rescheduling will have a substantial and negative impact on patients with legitimate medical need for these products, while negligibly impacting the issue. Furthermore, rescheduling will strain our already burdened health care system. Again, we thank DEA for considering our views on this critical issue and our organizations look forward to working together on solutions to address this public health concern.

Sincerely,

American Association of Colleges of Pharmacy

American College of Clinical Pharmacy

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