April 25, 2014

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

To Whom It May Concern:

Re: Docket No. DEA-389 Rescheduling Combination Hydrocodone Products from Schedule III to Schedule II

On behalf of the undersigned patient and health professional groups, we wish to convey to the Drug Enforcement Administration (DEA) our serious concerns with the proposed rule rescheduling combination hydrocodone products from schedule III to schedule II controlled substances. This scheduling change will significantly impede patient access to medication that is used legitimately by millions of Americans to manage chronic pain. Although we support DEA’s underlying goal of reducing misuse and abuse of combination hydrocodone products, rescheduling these prescription drugs is a misguided course of action.

Combination hydrocodone products are often prescribed for acute pain, but these medications also play a key role in helping patients manage chronic cancer and non-cancer pain over time. They are effective for a wide range of painful conditions and diseases, providing patients with the relief necessary to complete their disease-directed treatments, sleep through the night, or continue to work and otherwise engage in and enjoy activities of daily life.

The vast majority of patients who use combination hydrocodone products do so legitimately; these medications are as essential to their health as any other medication. According to the Institute of Medicine and Centers for Disease Control and Prevention respectively, there are 100 million Americans living with chronic pain and 46 million patients with acute pain following surgery. Rescheduling combination hydrocodone products would have far-reaching consequences for these individuals, resulting in serious medical and financial hardships, but would have a negligible impact on drug abuse.

There is no evidence to suggest that reclassifying hydrocodone will curb misuse and abuse of pain medications. Notably, Oxycodone is a Schedule II medication, and it remains one of the most heavily abused prescription drugs. However, there is evidence that rescheduling medications to higher classifications can reduce patient access to medications and cause harm. Thus, while it is highly unlikely that DEA will achieve the desired outcome of reducing abuse of combination hydrocodone products through this rescheduling action, patients who rely on these medicines for chronic pain will face obstacles to care.

A better approach than the proposed rescheduling action would be to maintain combination hydrocodone medications in Schedule III and to instead establish targeted
controls around these products. As an alternative to the rescheduling action, DEA should pursue limits on the total amount of medication available through an original hydrocodone combination product prescription plus refills to no more than a 90-day supply; and establish that new telephone prescriptions for hydrocodone-containing combination products shall not exceed a ten day supply (based on the directions for use) and cannot be refilled. This solution would address concerns related to prescribers providing many months’ supply with one prescription, minimize the increased number of office visits necessary, and increase control over subsequent prescription fills on the part of prescribers and dispensers, without imposing the burdens of moving these medications into Schedule II.

More broadly, prescription drug misuse and abuse is a complex problem. To effectively curb misuse and abuse of controlled substances (including combination hydrocodone products,) DEA should take a more holistic approach to addressing the problem. Balanced policies designed to curb misuse and abuse of pain medications, which also preserve patient access to medications, are imperative. Policies including targeting illegitimate drug sellers, better educating prescribers and youth, better utilizing prescription drug monitoring programs, and establishing permanent medication disposal programs would better serve the goal of reducing abuse of combination hydrocodone products.

Given the serious implications for patients who take combination hydrocodone products to manage chronic pain, we urge the agency not to proceed with the rulemaking to reschedule these products. Instead, DEA should pursue targeted policies that address the root problems of misuse and abuse of these medications. We thank DEA for considering our views on this matter.

Sincerely,

American Academy of Pain Management
American Pharmacists Association
American Society for Pain Management Nursing
The Center for Practical Bioethics and PAINS (The Pain Action Alliance to Implement a National Strategy)
Global Healthy Living Foundation
Interstitial Cystitis Association
Massachusetts Pain Initiative
National Association of Chain Drug Stores
US Pain Foundation
Virginia Cancer Pain Initiative

CC: Joseph Rannazzisi
   Deputy Assistant Administrator and Deputy Chief of Operations for Diversion Control
   Office of Diversion Control, Drug Enforcement Administration
   United States Department of Justice