May 30th, 2012

The Honorable Fred Upton, Chairman
Committee on Energy and Commerce
United States House of Representatives
Washington D.C. 20515

The Honorable Henry Waxman, Ranking Member
Committee on Energy and Commerce
United States House of Representatives
Washington D.C. 20515

Subject: Opposition to Rescheduling Hydrocodone Combination Products

Dear Chairman Upton and Congressman Waxman:

The pharmacy groups listed below regretfully oppose the language that was included in the Food and Drug Administration Safety and Innovation Act (S. 3187) that would reclassify hydrocodone-containing combination products as Schedule II. We ask that it not be included in the final bill. While we share the concerns regarding the abuse and diversion of these prescription drugs, these concerns must be balanced with the impact on patients who legitimately need access to these products. There are numerous hydrocodone-containing combination products that patients need to treat moderate to severe pain from various conditions, such as cancer. We have significant concerns about the patient care impact and the impact on pharmacy operations that will result from this language.

States Can Reschedule Controlled Substances: With all due respect, we do not believe that this language is needed. 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.

Products Will Be Harder to Obtain to Treat Pain: If these products are reclassified into Schedule II, prescribers will no longer be able to phone in prescriptions to pharmacies for their patients. In addition, products in Schedule II cannot be refilled. As a result of needing a new prescription for each fill, there is a greater chance that patients with a legitimate clinical need would be unnecessarily forced to endure symptoms of pain for a longer period of time. Many states already have electronic prescription drug monitoring programs and tracking systems, which allow for appropriate identification, tracking and investigation of potential overprescribing or abuse. 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.

Burdens 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, every pharmacy in the U.S. would likely be forced to purchase and install significantly larger safes which are expensive and consume a large amount of limited space within a pharmacy. 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.

Pharmacy ordering requirements for these products are much more burdensome and have more paperwork requirements than non-Schedule II products. Federal law also requires that separate files be kept in the pharmacy for these products. These are costs that are not typically covered in reimbursements received from benefit managers.

We understand the concerns about diversion and abuse of these products and we share 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. There are better strategies to address this issue and we pledge to work with you and other policy makers to develop these viable alternative proposals. Thank you for considering our views.

Sincerely,

American Pharmacists Association
Food Marketing Institute
International Academy of Compounding Pharmacists
National Association of Chain Drug Stores
National Community Pharmacists Association

Cc: The Honorable John Boehner, Speaker of the House
The Honorable Eric Cantor, House Majority Leader
The Honorable Nancy Pelosi, House Minority Leader
The Honorable Joseph Pitts, Chairman, Energy and Commerce Subcommittee on Health
The Honorable Frank Pallone, Ranking Member, Energy and Commerce Subcommittee on Health