VIA ELECTRONIC SUBMISSION: http://www.regulations.gov

February 1, 2013

Margaret A. Hamburg, M.D.
Commissioner of Food and Drugs
Division of Dockets Management (HFA-305)
Food and Drug Administration
5630 Fishers Lane, Room 1061
Rockville, MD 20852

Dear Commissioner Hamburg:

RE: Docket No. FDA-2012-N-0548

On behalf of the patient and health professional groups listed below we would like to share our strong concerns about the January 25 vote of the Drug Safety and Risk Management Advisory Committee in favor of rescheduling combination hydrocodone products into Schedule II.

As patient advocacy and health professional organizations, we are committed to combating illegal use of prescription drugs. However, it is also important to consider the unintentional consequences of policy changes that can cause serious difficulties for patients, and even result in harm and further suffering.

Medications containing hydrocodone in combination with other pain relievers are often prescribed for acute pain, but these products 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. Often, these medications are the ones that allow patients 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 Institute of Medicine (IOM) has documented that there are 100 million Americans living with *chronic* pain. That number does not count Americans with acute pain annually estimated by the CDC to be 46 million from surgery alone. Rescheduling these medications is a drastic measure that would have far-reaching consequences; chief among them would be loss of pain control for millions of Americans.

No evidence currently exists to show that reclassifying hydrocodone will curb misuse and abuse of pain medications. In contrast, there is evidence that rescheduling medications to higher classifications can reduce patient access to medications and cause harm. Prescriptions for Schedule II medications cannot be transmitted by telephone or fax, nor can they be refilled. The proposed policy change would require patients to see their doctor for office visits with greater frequency simply to refill a prescription. This would impose burdens on patients and caregivers in terms of having to forego hours, days, or even weeks of work. There would be a much greater chance that patients with a

legitimate clinical need would be unnecessarily forced to endure symptoms of pain for longer periods of time. This requirement also could impose a hardship for patients in rural areas who travel long distances for doctor office visits.

There would be increased costs to patients, state and federal government healthcare expenditures, and to the healthcare delivery system for the much more frequent office visits. Rescheduling these medications would unnecessarily introduce inefficiencies and increase healthcare costs at a time when policymakers are seeking ways of increasing efficiencies and reducing costs.

Oxycodone is already a Schedule II medication, and it is one of the most heavily abused medications. It is difficult to believe that moving combination hydrocodone products into the same federal Schedule as oxycodone would have a measurable favorable impact.

Although we appreciate DEA's rule to allow a prescriber to issue multiple Schedule II prescriptions at the same time, up to a 90 day supply, pharmacies rarely encounter prescriptions that have been written pursuant to this DEA rule. Prescribers lack knowledge of the rule, are confused by differing state laws in this area, and fear law enforcement scrutiny.

We strongly support policy changes that strike the necessary balance to curb the misuse and abuse of pain medications in the U.S., while also preserving patient access to medications. Drug control policies should pursue equitable solutions such as targeting illegitimate drug sellers, better educating prescribers and youth, better utilizing prescription drug monitoring programs, and establishing permanent medication disposal programs.

The prescription drug abuse problem can be successfully curbed. However, we urge FDA not to recommend unworkable provisions, such as moving all combination hydrocodone products into Schedule II. Combating prescription drug abuse must take a holistic approach. All affected stakeholders must work proactively to tackle and resolve this complex problem.

Thank you for considering our views on this issue.

American Academy of Pain Management (AAPM)
American Association of Nurse Assessment Coordination (AANAC)
American Cancer Society Cancer Action Network (ACS CAN)
American Society of Consultant Pharmacists (ASCP)
Amputee Coalition
CarsonCompany, LLC
Citizen Advocacy Center (CAC)
Interstitial Cystitis Association
Long Term Care Pharmacy Alliance (LTCPA)
Massachusetts Pain Initiative
NADONA

National Association of Chain Drug Stores (NACDS)
National Community Pharmacists Association (NCPA)
National Fibromyalgia & Chronic Pain Association
National Hospice and Palliative Care Organization
Pain Treatment Topics
US Pain Foundation
Wisconsin Pain Initiative