June 7, 2012

The Honorable Tom Harkin, Chairman  
Senate Health, Education, Labor and Pensions Committee  
Washington, DC 20510-6300

The Honorable Fred Upton, Chairman  
House Energy and Commerce Committee  
Washington, DC 20515-6115

The Honorable Michael Enzi  
Senate Health, Education, Labor and Pensions Committee  
Washington, DC 20510-6300

The Honorable Henry Waxman  
House Energy and Commerce Committee  
Washington, DC 20515-6115

Subject: Community Pharmacy Views on House-Senate FDA Bill Reconciliation

Dear Chairman Harkin, Chairman Upton, Senator Enzi and Congressman Waxman:

The National Community Pharmacists Association (NCPA) commends the work of the House and the Senate on developing this critically important legislation and the transparency with which the process has been conducted. NCPA represents the owners and operators of 23,000 independent community pharmacies in the United States. Our pharmacies provide approximately 41 percent of all outpatient prescriptions dispensed in the U.S., and they will certainly be affected by many provisions in this bill. We would like to offer the following recommendations to the Conference Committee on the reconciliation of S.3187, the Food and Drug Administration Safety and Innovation Act and H.R. 5651, the Food and Drug Administration Reform Act of 2012:

Enhance Supply Chain Security (RxTEC Proposal): NCPA’s view is that the nation’s pharmaceutical supply chain is very safe. Independent community pharmacies take special pride in assuring the reputation and credibility of their pharmaceutical suppliers. However, we can support additional measures to further enhance the security of the supply chain. The RxTEC related provisions included in the Senate bill are the result of many months of work and collaboration by many interested parties. The provisions will create a lot level tracking program for all prescription drugs, including new requirements for all supply chain participants including pharmacies to use the new RxTEC data that will appear on each prescription unit.

We will continue to oppose any additional burdensome requirements on the country’s small business community pharmacies to verify individual units of prescription drug product. Estimates are that such a unit level tracking and tracing requirement would require pharmacies to hire an additional person, or take an existing employee away from patient care responsibilities. A 2008 study by Accenture found that it would cost the average community pharmacy between $84,000 and $110,000 to implement a track and trace system for prescription drugs. Those costs are likely higher today. Implementing a system of this type would also require expensive new investments in computer systems and records storage capacity. At this time as our nation’s small businesses struggle to stay vibrant and create jobs, we are opposed to any new unfunded government mandates.

Address Drug Shortages: NCPA commends Congress for tackling the difficult issue of prescription drug shortages. NCPA encourages the Committee to combine both bills’ provisions in this area, and especially the sections which require the Drug Enforcement Administration (DEA) to be more flexible and transparent with its quota system. While most of the reported shortages to date have affected the institutional settings in the sterile injectables area, community pharmacies have also experienced shortages of certain medications, primarily drugs which treat ADD and ADHD.
We believe that these controlled substances are in short supply, in part, because of the inflexibility of the current DEA quota system, which limits the quantity of certain medications that manufacturers can make in any given year. Please accept all the good work included in both bills, including the studies to determine if any government policies have led to drug shortages in the areas regulated by the DEA.

**Eliminate Rescheduling of Hydrocodone Products:** We have real concerns about the patient care impact and the pharmacy operations impact of the Manchin amendment (S. 2151) to reschedule hydrocodone-containing products from Schedule III to Schedule II. We sympathize and share the concerns of those in Congress about drug diversion and drug abuse. But this amendment will make it more difficult for prescribers, patients and pharmacies to access these medications. The impact is significant because there are dozens of hydrocodone-containing combination products in pharmacies. Moreover, Federal law already permits states to place greater restrictions around the prescribing and dispensing of controlled substances.

If implemented, this change would create serious logistical issues for pharmacies with respect to storage since we would have to keep all these products in safes, and larger safes are expensive to buy. Depending on state law, we would have to do a perpetual inventory on these products, which would mean literally counting each pill in storage. In addition, the pharmacy ordering requirements are much more burdensome and have more paperwork requirements than other products. Pharmacists would also have to keep separate files for these prescriptions. Moreover, e-prescriptions for these products will not be able to be generated in many states, and this could pose a large problem in rural areas. We would like to work with Congress to find a more viable solution that will not increase the number of patients in pain or overly burden the small independent pharmacist. We urge that this language not be included in the final bill.

**Address Monitoring Program Interoperability Standards:** NCPA supports this requirement included in the Senate bill for coordination between HHS and the Attorney General to facilitate the development of recommendations on interoperability standards. This will help inform and facilitate the exchange of prescription monitoring program information across state lines. This could help reduce the opportunities for prescription drug abuse and obviate the need for more extreme measures like reclassifying hydrocodone products as Schedule II.

**Curb Prescription Drug Abuse:** At a time when drug diversion and abuse is on the rise in this country, NCPA strongly encourages the FDA’s review of current initiatives and to identify gaps and opportunities with respect to ensuring the safe use and disposal of prescription drugs with potential for abuse. We also support the report by the FDA and the issuance of guidance on development of abuse-deterrent drug products.

**Provide Prescription Information to Visually-Impaired and Blind Consumers:** We support the Senate’s provision that would create voluntary “best practices” for enhanced prescription information for visually impaired and blind individuals.

**Enhance Access to REMS Generic Drugs:** NCPA supports the language clarifying a provision in the Food and Drug Administration Amendments Act of 2007 with respect to restricted access drugs. We fully support the Senate language in this area, and urge its inclusion in any final package.

**Adopt Online Pharmacy Report to Congress:** NCPA supports this critical study about internet pharmacies, and strongly encourages the Committee to include the Senate’s GAO Report in the final legislation.

Thank you for the opportunity to provide our views on this important legislation. We look forward to working with you to ensure that the bill enhances patient care as well as protects and enhances the role of community pharmacy in our health care system. Thank you.
Sincerely,

John M. Coster, Ph.D., R.Ph.
Senior Vice President, Government Affairs

Cc: Members of the Senate HELP Committee
    Members of the House Energy and Commerce Committee
    The Honorable Harry Reid, Senate Majority Leader
    The Honorable Mitch McConnell, Senate Republican Leader
    The Honorable John Boehner, Speaker of the House
    The Honorable Eric Cantor, House Majority Leader
    The Honorable Nancy Pelosi, House Minority Leader