May 22, 2012

The Honorable Tom Harkin
Chairman, Senate HELP Committee
Washington, D.C. 20510

The Honorable Mike Enzi
Ranking Member, Senate HELP Committee
Washington, D.C. 20510

Subject: NCPA Views on S. 3187, the revised "Food and Drug Administration Safety and Innovation Act"

Dear Chairman Harkin and Senator Enzi:

The National Community Pharmacists Association (NCPA) is writing to provide our views regarding the final FDA Safety and Innovation Act, released on Monday May 21, 2012. We commend you and your staff for all the hard work that has gone into the process of developing this legislative package, 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 about 41 percent of all outpatient prescription dispensed in the United States, and will be affected by many provisions in this bill.

Addressing DEA Issues Regarding Drug Shortages: NCPA commends the Congress for tackling the difficult issue of prescription drug shortages. While most of the reported shortages to date have come from the institutional settings in the sterile injectable area, community pharmacies have also experienced shortages of certain medications, primarily in 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.

While we recognize that these quotas may be important to guard against prescription drug abuse and diversion, we were very pleased that this new Senate draft includes provisions aimed at investigating whether any government actions have caused or exacerbated drug shortages. Further, we are encouraged by the development of the task force (which we believe should certainly include enhanced communication with the DEA), as well as the third party study and the study on market factors. We would simply encourage that the final FDA legislation include a further recommendation that the DEA act more transparently and expeditiously on manufacturer requests to increase quotas for certain controlled substances that are in short supply. We also recommend that the DEA be more flexible regarding manufacturer timing of these requests.

Providing Prescription Information to Visually-Impaired and Blind Consumers: We support the legislation's development of voluntary "best practices" for pharmacists regarding providing enhanced prescription information to visually impaired and blind individuals. Many independent community pharmacies – who know their patients' needs better than any other pharmacy provider – already take various steps to help these patients better understand how to take their medications. We especially appreciate the inclusion of considerations "whether there are technical, financial, manpower, or other factors unique to pharmacies with 20 or fewer retail locations which may pose significant challenges to the adoption of the best practices." We look forward to helping to develop these best practices.

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Enhancing Supply Chain Security: We wanted to provide our views regarding the inclusion of the RxTEC program in the final legislation. This proposal has been under development by a diverse group of pharmaceutical stakeholders for many months. This program would create a lot level tracking program for all prescription drugs and would create new requirements for all supply chain participants – including pharmacies – to use the new RxTEC data that would be included on each prescription unit.

NCPA's view is that the nation's pharmaceutical supply chain is very safe. However, we can support other measures to further enhance the security of the supply chain. We support the overall framework of the RxTEC proposal as long as it is not subsequently changed to impose overly burdensome requirements on America'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 person away from patient care responsibilities. At this time as our nation's small businesses struggle to stay vibrant and create jobs, we are opposed to new unfunded government mandates. We look forward to continuing to work with the Congress and the other stakeholders to strike the right balance between enhancing the integrity of the supply chain and ensuring the continuing viability of small business community pharmacies.

We appreciate the opportunity to provide these views to the Senate on this critical package of legislation. We look forward to working with you to assure a FDA bill is enacted into law this year. Thank you.

Sincerely,

John M. Coster

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Senior Vice President, Government Affairs

Cc: The Honorable Harry Reid, Majority Leader
The Honorable Mitch McConnell, Republican Leader