

April 24, 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: Manager's Amendment to the "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 manager's amendment to the FDA Safety and Innovation Act, released on Monday April 23, 2012. We commend you and your staff for all the hard work that has gone into the process of developing this amendment. NCPA represents the owners and operators of 23,000 independent community pharmacies in the United States. Our pharmacies provide about 40 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 Committee for tackling the issue of prescription drug shortages. While most of the reported drug shortages to date have come from the institutional setting, community pharmacies have also experienced shortages of certain medications, primarily in drugs that 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.

We recognize that these quotas may be important to guard against prescription drug abuse and diversion. However, we urge that Congress include in any final FDA reform bill, provisions that would require the DEA to act more favorably 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.

This past year, we heard from many of our pharmacists that they were forced to turn away patients because they could not obtain sufficient supplies of these medications. Moreover, third party payers – including Medicare Part D and Medicaid – were not responding quickly enough to increase their reimbursement after the remaining manufacturers of these drugs increased their prices to take advantage of the shortage situation. The lag in reimbursement rates meant that pharmacies had to absorb the increased costs of these medications once their prices spiked. We believe that the rigidity of the DEA quota system is creating drug shortages that are adversely affecting patient care and this situation should be addressed in any final FDA reform bill.

Providing Prescription Information to Visually-Impaired and Blind Consumers: We support language included in the amendment that would create voluntary “best practices” for pharmacists regarding the provision of 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. Having said that, we especially appreciate the inclusion of language in the amendment that would consider the potential financial or technical issues that small pharmacies could face in adopting these best practices. We look forward to helping to develop these best practices.

Impact on Small Business from Enhancing Supply Chain Security: The manager’s amendment does not include the RxTEC program, which has been under development by a diverse group of provider and pharmaceutical stakeholders for many months. This program would create a lot-level tracking program for prescription drugs, but would also require that each prescription drug container include a unique serial number for possible tracking purposes. These modifications could further enhance pharmaceutical supply chain security. While we support the general framework of the RxTEC proposal, NCPA’s view is that the nation’s pharmaceutical supply chain is already very safe.

It is important for us to note, however, that we believe the RxTEC proposal can be implemented effectively without placing new burdensome requirements on small business community pharmacies to verify individual units of prescription drug product. As a result, we can only support the overall framework of the RxTEC proposal as long as it does not impose these additional unnecessary burdens.

Estimates are that the average independent community pharmacy purchases anywhere from 65,000 to 150,000 individual prescription drug units each year. This does not include the pharmacy’s management of pharmaceutical product returns or recalls, which must be sent back to wholesalers or manufacturers. Requiring pharmacies to manage and purchase new data storage capacity for the new RxTEC system, scan every product that enters the pharmacy, and integrate the RxTEC system with their existing inventory systems would be extremely expensive, and likely require each pharmacy to hire one new full time employee just to handle these new government mandates. These are costs that a small pharmacy – already operating on 2 percent net profit margins – can simply not absorb. At the same time, we support other proposals to enhance supply chain security – such as Federal standards for wholesaler licensure – that may prove just as effective, without creating the costs on the supply chain. We want to continue to work with the Committee to implement cost effective solutions to enhance supply chain security.

We appreciate the opportunity to provide these views to the Committee on these important issues. We look forward to working with you to assure a FDA bill is enacted into law this year. Thank you for your support of community pharmacy.

Sincerely,



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