



September 24, 2013

The Honorable Tom Harkin  
Chairman  
Committee on Health, Education, Labor and Pensions  
U.S. Senate  
Washington, DC 20510

The Honorable Fred Upton  
Chairman  
Committee on Energy and Commerce  
U.S. House of Representatives  
Washington, DC 20510

The Honorable Lamar Alexander  
Ranking Member  
Committee on Health, Education, Labor and Pensions  
U.S. Senate  
Washington, DC 20510

The Honorable Henry Waxman  
Ranking Member  
Committee on Energy and Commerce  
U.S. House of Representatives  
Washington, DC 20510

**VIA ELECTRONIC DELIVERY**

Dear Chairman Harkin, Ranking Member Alexander, Chairman Upton and Ranking Member Waxman:

You are currently working in a bipartisan fashion to address two patient safety issues: pharmaceutical compounding and drug distribution security, both of which are important to the safety of our drug supply. This letter focuses on implementation of sweeping safeguards of the nation's pharmaceutical distribution supply chain – policy that our organizations have engaged on together for close to two years.

The risk to consumers when the supply chain is porous can be significant. A gaping hole in the system could permit a counterfeiter to insert bogus “medicines” – perhaps containing useless substances like talcum or sugar; or harmful substances such as rat poison or formaldehyde – into the chain. And thefts of legitimate medications may culminate in their sale on the black market. As representatives of multiple stakeholders deeply committed to the goal of a stronger supply chain, we urge you to act as quickly as possible on a reconciled bill that can be sent to the President for his signature.

The pharmaceutical distribution supply chain is a complex and wide-ranging system that moves finished medicines from a manufacturing facility to the pharmacy shelf or other health care facility. The United States has one of the safest pharmaceutical supply chains in the world and most patients don't need to think twice about the safety and purity of their medicine. However, news of vulnerabilities in the form of illicit, counterfeit and life-threatening products make clear the benefit of establishing a uniform national solution that provides greater safeguards for consumers by placing unique serial numbers on each drug package, and tracking them as they move through the distribution system.

Because a product may travel through multiple states with the help of several parties before arriving at a pharmacy, the most effective safeguard is a single, strong national supply chain policy so all healthcare consumers receive the same level of protection regardless of where they live. Recognizing these threats, some states enacted their own laws in recent years to strengthen the supply chain. While state lawmakers should be commended for recognizing this problem and proposing solutions, a state-by-state approach to a national problem could cause weak links in the chain that can be exploited by bad actors who shop for lax venues. As each state enacts its own supply chain laws and standards, we would be left with a system of kinks and chinks that unnecessarily burden supply chain stakeholders who rely on uniform and efficient regulation to move products safely to the consumer. To comply with 50 varying state laws, stakeholders would need to implement systems that may not mesh with the standards of other states. The result would be gridlock that ultimately hinders consumer access to needed medications.

Under a single, uniform and national supply chain solution, federal legislation will establish one rigorous standard for all supply chain participants that will extend from coast to coast. The law and ensuing regulatory standards will govern all elements of the chain: product manufacturers, primary and secondary wholesale distributors, logistics providers and pharmacies.

Leaders in Congress have been working on a bipartisan basis for two years to craft a national supply chain solution. A bill to do so passed the House of Representatives by voice vote in early June, and a similar measure has cleared a key Senate committee with no objections. Now is the time for both chambers to act so a final bill can be signed into law as quickly as possible to provide the stronger level of protection our healthcare consumers deserve.

Sincerely,

**Vince Ventimiglia**  
**Pharmaceutical Distribution Security Alliance**

**Allan Coukell**  
**The Pew Charitable Trusts**