Senator Tom Harkin, Chairman
Senator Michael Enzi, Ranking Member
Senate Committee on Health, Education, Labor and Pensions
428 Dirksen Office Building
Washington, DC 20510

Representative Fred Upton, Chairman
Representative Henry Waxman, Ranking Member
House Committee on Energy & Commerce
2125 Rayburn Office Building
Washington, DC 20515

November 7, 2012

Dear Chairmen Harkin and Upton and Ranking Members Enzi and Waxman:

As national organizations dedicated to improving and protecting public health, we appreciate the opportunity to comment on the Pharmaceutical Distribution Supply Chain draft legislation to improve drug distribution security. Americans rely on safe and effective drugs to promote their health by preventing and treating diseases. Before drugs can be marketed in the U.S. they are approved by the Food and Drug Administration (FDA) who determines whether they are, in fact, safe and effective. FDA oversees that these drugs are manufactured under Good Manufacturing Practices to ensure that the ingredients in these products are produced in conditions that minimize the risk of adulteration and contamination.

However, FDA does not oversee the drug distribution chain. The rules that govern drugs and other medical products as they move from the manufacturer to the wholesaler to the pharmacy and to the patient vary from state to state. This creates an uneven system that leaves some patients better protected than others from the risks of counterfeit and diverted drugs.

This legislation presents a number of options that would create a strong national system that would be a meaningful advance for patient safety and public health. We would like to highlight what would be the most important elements to include in any legislation to address drug distribution security:

1. Legislation must outline a clear path to a unit-level system. We recognize that it is not feasible to immediately require that all drugs be checked at the unit-level. However, a national system to track drugs will not adequately protect patients from the risk of counterfeit and stolen products unless it ultimately requires that these products are checked at the unit-level.

2. A robust unit-level system must include proactive and real-time authentication of drugs. Ultimately, participants in the supply chain have to routinely check the authenticity of the drugs they are passing through the chain. They cannot simply be required to check drugs in cases where a problem is suspected or has been identified. A passive system will not prevent counterfeit drugs from entering the supply chain. It may only detect them after the fact, putting patients at risk.

3. An interim, lot-level system should be as robust as possible in order to establish a platform for the development of a unit-level system.

4. Both the interim and the unit-level system must be implemented as quickly as is feasible.

The draft legislation contains a number of policy options. From our perspective, the most important provisions are the following:

1. Section 3—Enhanced Drug Distribution Security.

This section establishes FDA's authority to create a robust unit-level tracking system. This system is essential to achieve a meaningful advance for drug distribution security and patient safety. We urge Congress to retain this section in order to ensure a clear path to an enhanced, unit-level tracking system. We recommend Congress choose the following options in this section:

- The language gives FDA the authority to issue proposed regulations for a unit-level system, but does not *require* that FDA issue proposed regulations. Congress should not leave the development of these regulations up to the discretion of FDA. Instead, the legislation should require that FDA issue these regulations within a specified timeframe. The elements of the regulations are strong and should be maintained.

- Congress should not indefinitely exempt pharmacies from full participation in a unit-level tracking system. This exemption is unjustified and would leave patients at risk from counterfeit, stolen, and diverted drugs.

- The legislation proposes a "trigger" mechanism that will create a unit-level tracking system if FDA does not finalize regulations. This is a very important provision which would ensure stakeholder and FDA commitment to developing a strong unit-level system, and should be maintained in the final legislation.

2. Section 2—Pharmaceutical Distribution Supply Chain

This section establishes an interim lot-level tracking system that requires supply chain participants to pass a drug's transaction history ("pedigree") as the drugs move through the distribution chain. This section contains some good concepts on the identification and investigation of suspect products, as well as an alert system for industry and FDA in case there are unsafe products that threaten patients in the distribution chain. It is important that this system is as robust as possible in order to be a meaningful step toward a unit-level system. Specifically, we recommend Congress choose the following options in this section:

- The legislation should ensure strong verification requirements are established for suspect products. We support the requirements for companies to verify returned products, particularly as returns have been identified as a weakness in the security of the distribution chain. We also support the requirements for companies to verify suspect products. However, those requirements should include unit-level verification.

- The draft legislation would require companies to have systems to issue, receive and terminate alerts about suspicious and illegitimate products. These provisions are generally strong. We urge Congress to require pharmacies to issue alerts and not just receive them. Pharmacies should also have the same requirements to alert the Secretary and affected trading partners about illegitimate products within 24 hours that other members of the distribution chain have.

- The legislation should ensure that the returns process does not create a gap in a drug's pedigree. Erasing a product's prior transaction history when it is returned and resold makes it more difficult for a purchaser to determine a drug's provenance. It also makes returns a vulnerable link in the supply chain and a point at which illegitimate, counterfeit or diverted drugs could enter the supply chain.

3. Timelines

The legislation has a number of options for timeframes. We urge Congress to adopt the shortest of those options in order to ensure swift implementation of these patient safety provisions. In fact, we would like to see the proposed timeframes shortened because even the lower end of the proposed time lines raise some concerns that this legislation will not be implemented as expeditiously as possible. Track and trace technology is already widely used in numerous industries and is required of pharmaceutical manufacturers, distributors and pharmacies operating in California with implementation beginning in 2015.

Thank you again for your work in drafting this legislation and for the opportunity to provide comments. We look forward to working with you to enact this legislation, which is critical to improving patient safety.

Sincerely,

American Public Health Association
Association of State and Territorial Health Officials
National Association of County and City Health Officials
Trust for America's Health