November 7, 2012

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

Re: Draft Proposal to Improve Drug Distribution Security

Dear Chairman Harkin:

As members of the Patient, Consumer, and Public Health Coalition, we thank you for the opportunity to provide comments on the discussion draft of legislation to improve the safety of our drug distribution system.

We write on behalf of millions of consumers, patients, scientists, and public health advocates to express our strong support for a robust U.S. pharmaceutical distribution system that will protect patients and the public health from unsafe, diverted and counterfeit medicines. We are deeply concerned about the current and growing risk to the U.S. pharmaceutical supply, a threat that can best be addressed through a meaningful national system to track and authenticate pharmaceutical products as they move from manufacturer to wholesaler to pharmacy to patient.

As you consider the various policy options laid out in the current draft, we urge you to make choices that will address the existing weaknesses in the system in a timely and comprehensive way. Our detailed comments follow:

Timelines
Even the shortest timelines proposed in this draft will result in delays of up to a decade before a comprehensive system is in place to protect patients and consumers. That is too long. Industry has extensive experience piloting track and trace programs and operating them in other countries. We recommend that timelines in this section be shortened.

Section 2. Pharmaceutical distribution supply chain

The legislation would create an interim lot-level system. This is a reasonable approach as long as it is part of a clear and established path to achieving a system that will track drugs at the unit-level. A meaningful system that will protect patients from the risks of counterfeit, stolen or diverted drugs must include the placement of a unique serial number on each package, or unit, of medicine as well as the ability to track those medicines at the unit-level. We note that any counterfeit drug product that copies an existing lot number will not be routinely detected under this interim system, since it entails no proactive responsibility on any entity within the distribution system to verify serial numbers. On its own, a lot-level tracking system alone is not a sufficiently significant advance in patient safety to warrant the preemption of existing state laws that go further to protect patients from counterfeit, diverted or stolen drugs.

Returns

Returns have been identified by regulators and enforcement officials as a significant area of risk for the insertion of counterfeit, diverted or stolen drugs into the legitimate supply chain. Erasing a product's prior transaction history when it is returned and resold removes a purchaser's ability to determine a drug's origin, representing a major weakness in the distribution chain. Furthermore, regulators require a full transaction history to fully and appropriately investigate a breach in the supply chain. Therefore, we recommend that any legislation forbids a break in a drug's pedigree when it is returned.

Verification

We support the requirement for companies to verify returned products. Ensuring that returned units are authentic will help to secure the returns process, which can be an entry point to the distribution chain for suspicious products. We also support the requirement for companies to verify suspect products, but this requirement must include the ability to determine whether the unique serial number on a unit or case of pharmaceutical product corresponds to the information applied by the drug manufacturer.

Alert system

We also support the proposed alerts system for the industry and FDA, but urge that this policy require that the alert system created under Section 2 is comprehensive. Pharmacies should have the same responsibility as other members of the supply chain to issue alerts when they encounter credible evidence of a suspect or illegitimate product that could cause serious health implications for consumers or threats to the public health.

Section 3. Enhanced Drug Distribution Security

Section 3 should be made as strong as possible in order to evolve and expand consistent with Congressional intent to significantly advance patient safety and justify the preemption of strong existing state laws. The policy must establish a clear path to achieving the steps described in Section 3, including mechanisms for all participants in the U.S. pharmaceutical system to proactively authenticate medicines at the unit level. A unit-level system is essential to achieving a meaningful advance for drug distribution security and to protect the public health. Without a clear and assured path to a unit-level system in the shortest timeframe possible, the policy would fail to adequately protect patients and consumers, and it would also cause significant harm by replacing strong, current state standards with a weaker national system.

FDA regulations for a unit-level system
The draft legislation would allow but not require FDA to issue regulations to create a unit level system. We strongly recommend that the development of regulations not be left to the discretion of FDA. Rather FDA should be required to write regulations within a specific timeframe. The proposed elements of the regulation are strong and should be maintained.

Pharmacies cannot be exempted
We recommend that Congress remove the exemption on requiring pharmacies to participate in the enhanced unit-level system. A strong national system cannot exempt pharmacies because to do so would leave consumers and patients at risk from counterfeit or stolen drugs introduced into the chain at the point of dispensing or inserted into distribution through pharmacy sales. The distribution security of the pharmaceutical supply cannot be assured without the participation of all members of the distribution chain, including pharmacies.

Default statutory mechanism to create a unit-level system
To ensure that FDA and stakeholders move to a unit-level system in a timely way, the default statutory provision in Section 3 that takes effect absent a final regulation is essential. We recommend that this language remain in its entirety because it creates a strong incentive to develop and release the regulations.

Pilot programs
Experience in California shows that industry will develop pilot programs in response to regulations or statutory requirements. That model is preferable to putting the burden for pilots on the FDA, which has neither budget nor authority to compel companies to participate in pilots. Therefore we recommend that the pilot language should be struck and development of future regulations not be contingent on the completion, or outcome of, pilots.

Avoid Preempting Strong State Protections
In a number of provisions in the legislation, Congress runs the risk of not only failing to protect patients, but also causing further harm. Enacting a weak national system could preempt stronger state protections currently in place in some states, and also prevent states from seeking more effective or stronger safeguards in the future. We recommend that in every area possible, Congress create federal standards that are a floor, so as to create no barriers to a state that seeks to respond quickly to address future risks from counterfeit or adulterated drugs entering the supply chain.

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