Statement of Ron Bone
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On Behalf of the Healthcare Distribution Management Association (HDMA)
Before the Health Subcommittee on Energy and Commerce Committee
United States House of Representatives
On the "Safeguarding America's Pharmaceuticals Act"
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Mr. Chairman, thank you for the opportunity to testify before the House Energy and Commerce Subcommittee on Health about the safety and security of the U.S. pharmaceutical supply chain. My name is Ron Bone and I am Senior Vice President of Distribution Support for McKesson Corporation, the largest pharmaceutical distributor in North America. I have worked for McKesson for 36 years with senior management positions in distribution, sales, finance and independent pharmacy management. Currently, I am responsible for overseeing McKesson's electronic tracking systems for pharmaceuticals and serve as a member of the leadership team of GS1 Healthcare, which is developing track-and-trace standards internationally and here in the U.S.

I am testifying on behalf of the Healthcare Distribution Management Association (HDMA), the national trade association representing primary pharmaceutical distributors. HDMA's member companies are responsible for storing, managing and delivering 80 percent of prescription medicines sold in the U.S.

Today, I am here to express HDMA's support for HR 5839, the "Safeguarding America's Pharmaceuticals Act," as introduced by Representatives Buyer and Matheson.

This comprehensive bipartisan legislation would establish a uniform, national requirement for the tracking and tracing of prescription medicines from the manufacturer, through the distributor, to the pharmacy.

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Role of Distributors in U.S. Pharmaceutical Supply Chain

HDMA's pharmaceutical distributor members typically purchase prescription medicines from more than 700 different manufacturers. We safely store these medicines in state-of-the-art distribution centers across the country and make daily deliveries to the nation's 144,000 pharmacies, hospitals, nursing homes, physician offices and other healthcare providers. Each day, HDMA member companies deliver 13 million prescription medicines and other healthcare products. This critical public health function is performed with tremendous efficiency, saving the nation's healthcare system nearly $34 billion each year.

Industry Efforts to Further Secure the U.S. Pharmaceutical Supply Chain

The U.S. pharmaceutical supply chain is extremely secure, providing an effective system for the safe and efficient delivery of medicines to patients nationwide. Manufacturers, distributors and pharmacies together share a responsibility to continuously monitor, protect and enhance this secure system against increasingly sophisticated criminals who may try to introduce counterfeit or diverted drugs into the legitimate supply chain.

HDMA members have a long history of working with Congress, the FDA, state legislatures and regulators, law enforcement and supply chain partners to identify business, policy and technology improvements that can be made to enhance patient safety.

The industry has promoted legislation in multiple states to tighten licensure requirements and to increase the criminal penalties for those who counterfeit or divert medicine. HDMA members also have a record of supporting current and emerging track-and-trace technologies such as those required in California.

In 2006, HDMA established Rx SafeTrack, an industry task force of manufacturers, distributors and pharmacies dedicated to identifying the operational and technical requirements for track-and-trace implementation. In addition, HDMA has led the development of track-and-trace research and education, as well as technical guidelines.

We are pleased the "Safeguarding America's Pharmaceuticals Act" includes provisions that build upon these innovations, as well as the work already underway in many states.

Industry Support for the "Safeguarding America's Pharmaceuticals Act"

HDMA members support this bill for three primary reasons.

First, the bill provides for a uniform, federal electronic pedigree standard that the national supply chain can implement. Today's pharmaceutical supply chain is regulated at both the federal and state levels of government. Federal law establishes minimum licensing and pedigree requirements as a baseline, while each state can enact additional requirements. The variability of these state requirements creates a patchwork of regulations that causes confusion, erodes efficiencies and disrupts the just-in-time availability of prescription medicines. These conflicting requirements slow the development and adoption of uniform approaches to pedigree implementation.

Second, this bill will allow the industry to focus on and invest in interoperable technologies to track and trace pharmaceuticals across the supply chain. One standard for the country, rather than 50 potentially conflicting state requirements, will be more efficient and less costly. The development of end-to-end systems based on the unique identification and tracking of individual prescription drugs will achieve true, long-term safety benefits for all Americans.

Third, the world is moving toward a unique identifier for each prescription drug. This legislation builds upon the standardized numerical identifier provisions of last year's Food and Drug Administration Amendments Act (FDAAA). These standards, mandated by Congress, are under development by the FDA.

Conclusion

As pharmaceutical distributors, our greatest priority is the security of the supply chain.

National, uniform pedigree requirements will support the existing national pharmaceutical inventory that enables the safe, reliable and efficient distribution of critical medicines and facilitates our rapid response in times of emergency.

This legislation strikes the right balance by providing the FDA with the authority to establish federal standards, while preserving a critically important role for states to license, regulate and enforce.

With a net industry profit margin of approximately one percent, HDMA member companies have every incentive to ensure the technology is right the first time. Pharmacies and hospitals will look to their distributors for assistance in implementing track-and-trace requirements. The distribution industry has pioneered innovative electronic ordering and other inventory management systems in the past, and we will continue to help ensure the success of our supply chain partners.

We urge the Committee to consider this important legislation, which we believe will successfully reduce the threat of counterfeit and diverted medicines in the legitimate pharmaceutical supply chain.