

Statement from  
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For the U.S. House of Representatives  
Energy and Commerce Committee  
Subcommittee on Health

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Good morning Chairman Pitts, Ranking Member Pallone and Members of the Energy and Commerce Subcommittee on Health. I am Elizabeth Gallenagh, Vice President, Government Affairs and General Counsel of the Healthcare Distribution Management Association (HDMA). Thank you for the opportunity to inform the Subcommittee regarding the critically important issue of prescription drug pedigree and pharmaceutical supply chain safety. I would also like to thank Congressmen Bilbray and Matheson for their leadership in this area.

HDMA represents the nation's primary pharmaceutical distributors that purchase prescription drugs and other healthcare products from manufacturers and deliver them every day to 200,000 pharmacy and provider settings across the country.

Our 34 member companies are responsible for storing, managing and delivering nearly 90 percent of all prescription medicines sold in the U.S. This critical public health function is performed with tremendous efficiency, saving the nation's healthcare system nearly \$42 billion each year.

The pharmaceutical distribution industry's primary mission is to operate the safest, most secure and efficient supply chain in the world. As part of this mission, HDMA's members work to eliminate counterfeit and

diverted medicines by capitalizing on the technological innovation and constant improvements in efficiency that are the foundation of our industry.

Today, I am here to express HDMA's strong support for a national, uniform approach to the pedigree and traceability of medicines throughout the supply chain. HDMA believes that reform should have tighter wholesaler licensing standards and a new federal ceiling for traceability requirements to improve safety and uniformity across the country, while establishing targets and parameters for longer-term electronic solutions. In addition to fundamentally addressing counterfeit and diverted medicines, federal pedigree may be a useful tool in discouraging gray market activities associated with drug products in short supply.

After many years of debate, 2012 is the best window of opportunity to enact federal pedigree legislation. This is, in large part, due to a broad consensus among supply chain partners as well as the possibility of attaching a federal pedigree provision to the Prescription Drug User Fee Act (PDUFA) reauthorization.

Because of the unique role HDMA members play in the supply chain between manufacturers and providers, including pharmacies, they see firsthand the complexities of dealing with the current 50-state wholesaler

licensing and pedigree laws (see attached map of state pedigree legislation and regulations).

Basic guidelines for pedigree were set forth nearly 25 years ago with the enactment of the federal Prescription Drug Marketing Act (PDMA). Since that time, activity at the state level has varied with some enacting complex electronic pedigree laws and others never going further than the original 1988 guidelines. Based on our experience, the complexities of dealing with multiple approaches in the states will only get worse if we fail to solve this problem at the federal level.

Since Florida's first foray into raising pedigree and licensure requirements in 2003, we have seen dramatic variations across the country in both legislative activity and regulatory interpretation. This variation has occurred despite HDMA's attempts to work in every state along with fellow stakeholders and interested legislators and regulators to achieve more uniformity. Today, for example, 29 states have acted beyond the federal PDMA standards. The states of Florida and California are viewed as leaders in this arena. However, they take completely different approaches with Florida considered to be the most stringent in terms of today's requirements and California the most complex once its electronic pedigree law is implemented in 2015.

This patchwork not only creates operational challenges, but also creates openings for bad actors to shop around for more lenient state rules — openings that could mean the difference between a fake or diverted medicine being dispensed or administered to an innocent patient in need of treatment. Because of this state-by-state variation, we believe that pedigree and traceability should be under the purview of Congress and the FDA.

HDMA has been a leader in this area, forming and participating in industry task forces and working groups that bring together manufacturers, distributors and pharmacies dedicated to identifying the operational and technical requirements for electronic pedigree, track-and-trace and traceability implementation. We are currently part of an industry alliance, the Pharmaceutical Distribution Security Alliance (PDSA), which is dedicated to working on a consensus approach to pharmaceutical traceability. PDSA has developed a consensus model that includes support from manufacturer, distributor and pharmacy stakeholders.

This comprehensive, practical approach would result in increased safety, continued efficiencies and minimal inconsistencies among competing state requirements — all of which will enable HDMA distributors

and our supply chain partners to continue to deliver prescription drugs safely and efficiently every day.

This consensus model includes:

- National Uniformity

Adoption of national requirements for wholesaler licensing standards and for direct-purchase and standard pedigree (documentation of product distribution history) upon the effective date of the legislation (or shortly thereafter). Taking this immediate first step would help to ensure the efficient flow of prescription drugs between states, raise the bar for states that have not gone beyond the current federal PDMA “floor” and enhance protection for the most secure prescription drug supply chain in the world — further ensuring patient safety and just-in-time access to lifesaving medicines.

- Unit-level Serialization

Currently, there is no mechanism required to identify a unique bottle of medicine. This proposal would require manufacturers to apply a unique identifier to prescription drugs at the unit and case levels. This would be the first in a series of steps designed to help protect the supply chain against counterfeit, adulterated or other substandard

product by facilitating improved ability to identify non-legitimate products. Products would be identified at the unit and case level with GTIN and serial number (SNI), lot number and expiration date for the product. (This is referred to as “RxTEC”.)

- Data Exchange and Systems Development

Once product is serialized, it is believed that product traceability initially can be achieved at the lot level, with potential for traceability at more discrete levels as systems mature. As a result, exchange of transaction data will be possible and can be leveraged to provide additional efficiency and safety benefits within the supply chain.

HDMA supports a path toward traceability that includes deliberate, careful evaluation and assessment by FDA and stakeholders at each step.

- Prescription Drug Traceability

A migration to traceability must include appropriate transition time and development phases for each segment of the supply chain.

Further use of product information should be determined based on the current state of industry, proven technologies, as well as potential to enhance patient safety.

Federal legislation must preserve the critically important role for states to license and enforce. There is no single element that will protect the supply chain from every threat but rather, a comprehensive solution should incorporate each of the elements above.

We urge the Subcommittee to consider this important issue for inclusion in the PDUFA legislation. The integrity of the supply chain is dependent on commitment and participation by all supply chain partners and any workable solution must include manufacturers, distributors, pharmacies and other healthcare providers who dispense medications. Now is the time for Congress to act to bring cohesion and consistency to our national drug supply chain.

Thank you.

# 2012 HDMA Map of State Pedigree Legislation/Regulations

As of March 5, 2012

