Testimony before the

House Energy and Commerce Committee

Subcommittee on Health

United States House of Representatives

April 25, 2013

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Vice President, Government Affairs and General Counsel

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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 for 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 also would like to thank Chairman Upton, Congressman Latta and Congressman Matheson for their leadership in this area.

HDMA represents the nation's primary pharmaceutical distributors that deliver more than nine million prescription drugs and other healthcare products every day to 200,000 pharmacy and provider settings across the country.

Our 33 member companies purchase products from manufacturers and 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, resulting in nearly $42 billion in annual savings to the nation's healthcare system.

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 pedigree and the traceability of medicines throughout the supply chain. We support the core elements of the Latta-Matheson proposal and look forward to working with you and your Senate colleagues to enact federal legislation.

HDMA supports enhanced national wholesaler licensing standards and a new federal ceiling for pedigree and traceability requirements to improve safety and uniformity across the country, while establishing the foundation for longer-term electronic solutions, such as unit-level serialization and product tracing.

In addition to fundamentally addressing counterfeit and diverted medicines, a national approach to pedigree and traceability may be a useful tool in discouraging gray market activities associated with drug products in short supply. More importantly, it will put the U.S. on par with countries around the world engaging in serialization and traceability efforts.

After many years of debate, it appears that Congress finally may be poised to enact federal pedigree legislation. This is, in large part, due to a broad consensus among supply chain partners as well as growing support from Members of Congress and the leadership of Congressmen Latta and Matheson. While Congress, FDA and industry stakeholders have been working at this diligently for several years, it is critical that Congress act now due to the uncertainties faced by the industry, the need for uniformity across the supply chain and to ensure patient safety.

Because of the unique role HDMA members play in the supply chain between manufacturers and providers, they witness firsthand the complexities of dealing with the current 50-state patchwork of 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 now, at the national 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's law thought to be the most complex, with track-and-trace and electronic pedigree implementation beginning in 2015.

This patchwork not only creates operational challenges, but also leaves 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. HDMA is also an active member of PDSA, the Pharmaceutical Distribution Security Alliance.

A 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.

HDMA commends Congressmen Latta and Matheson, along with the committee leadership, on continuing the dialogue and moving this effort forward with the release of the Latta-Matheson discussion draft. We believe that the framework of the draft is consistent with the basic foundation HDMA has supported through the years.

The bipartisan proposal includes the following core elements:

- National Uniformity

  Adoption of national requirements for wholesaler licensing standards while preserving the states' ability to license and enforce, as well as uniform direct-purchase and standard pedigree (documentation of product transaction history) requirements. Taking this immediate first step will help to ensure the efficient flow of prescription drugs in

interstate commerce, raise the bar for states that have not gone beyond the current federal PDMA "floor" and enhance protections for the most secure prescription drug supply chain in the world — further ensuring patient safety and access to lifesaving medicines.

- Unit-level Serialization

  Currently, there is no mechanism required to identify a unique bottle of medicine. This proposal will 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 products by facilitating improved ability to identify non-legitimate items. Prescription drugs would be identified at the unit and case level with a serial number (SNI), lot number and expiration date.

- 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 migration toward traceability that includes deliberate, careful evaluation and assessment by FDA and stakeholders at each step.

  There is no single element that will protect the supply chain from every threat but rather, a comprehensive solution should incorporate each of these elements.

We applaud the work that has been done to date and urge the Subcommittee to act on this important issue this year. Now is the time for Congress to act to bring cohesion and consistency to our national drug supply chain.

Thank you.