



May 7, 2013

Chairman Joe Pitts
Subcommittee on Health
House Energy and Commerce Committee
420 Cannon House Office Building
Washington, DC 20515

Ranking Member Frank Pallone
Subcommittee on Health
House Energy and Commerce Committee
237 Cannon House Office Building
Washington, DC 20515

Dear Chairman Pitts and Ranking Member Pallone:

On behalf of the Healthcare Distribution Management Association (HDMA) and its 33 primary distributor members, I would like to express our support for the Latta-Matheson discussion draft on Pharmaceutical Distribution Supply Chain Legislation.

HDMA believes that a national approach to pedigree and traceability is the right approach to further strengthen our pharmaceutical supply chain, help ensure safe, efficient delivery of medicines and protect patients from the threats associated with counterfeit and diverted products. This bipartisan discussion draft contains the core elements necessary to establish a comprehensive, practical framework that increases safety, continues to promote efficiencies and minimizes inconsistencies among competing state requirements.

HDMA believes that any reform and modernization of the supply chain should raise national wholesaler licensing standards and include 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 of prescription drugs and product tracing.

Additionally, we appreciate the inclusion of a uniform national pedigree framework that incorporates the importance of a primary distribution model until such time that unit-level traceability activity is available and implemented. We believe this will provide immediate safety benefits, preserve an important enforcement tool, and assist distributors as they transition to unit-level product tracing.

The discussion draft sets out workable phases for each supply chain segment, clear guidance regarding implementation dates and timeframes, as well as feasible parameters for each stage of the process. 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 we finally may have an opportunity to enact federal pedigree legislation. 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.

HDMA thanks you for your leadership on this important issue and we look forward to supporting you in your efforts to advance this proposal this year. Should you have questions or need additional information, please contact me at 703-885-0234 or egallenagh@hdmanet.org.

Sincerely,

A handwritten signature in blue ink, appearing to read "E. Gallenagh".

Elizabeth A. Gallenagh, Esq.
Vice President, Government Affairs
and General Counsel

Cc: Members of the House Energy and Commerce Subcommittee on Health, Chairman Upton, Ranking Member Waxman, and Representative Latta.