June 17, 2013

The Honorable Joseph Pitts
Chairman
House Energy and Commerce Subcommittee on Health
2125 Rayburn House Office Building
Washington, DC 20515

Dear Chairman Pitts:

Thank you for the opportunity to testify before the House Energy and Commerce Subcommittee on Health on April 25, 2013 at the hearing entitled "Securing Our Nation's Prescription Drug Supply Chain." I have attached my response to the Questions for the Record.

HDMA supports H.R. 1919, the Safeguarding America's Pharmaceuticals Act and 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 legislation 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.

Thank you for your leadership on this important issue and we look forward to continuing to work with you and your staff as this issue moves through the legislature.

Sincerely,

Elizabeth Gallenagh
Vice President, Government Affairs and General Counsel

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The Honorable John D. Dingell

1) **Do you agree that a traceability system would help to better secure our drug supply chain from counterfeits, theft, and intentional adulteration? If no, please explain why.**

   Yes. The approach captured in H.R. 1919 requires members of the supply chain to verify suspect and illegitimate product and provides for greater assurances than under current law that the product is not counterfeit, stolen, or adulterated.

2) **Do you agree that a traceability system would help to identify and detect illegitimate pharmaceuticals? If no, please explain why.**

   Yes. H.R. 1919 requires manufacturers to include a product identifier on each package, which will assist supply chain partners in verifying if a product is legitimate.

3) **Do you agree that a traceability system would help to ensure the safety of pharmaceuticals for patients and consumers? If no, please explain why.**
   Yes. The application of product identifiers and a national approach to pharmaceutical traceability allows supply chain stakeholders to provide greater assurances to patients and consumers that prescription medicines are safe.

4) **Do you agree that a traceability system would improve the efficiency and effectiveness of recalls or returns? If no, please explain why.**

   Yes. A national approach to pedigree and traceability will help facilitate more efficient identification of recalled product and faster removal from the supply chain. Additionally, unique identification of products will add more security and certainty to the returns process. Under the current legislation, wholesale distributors will be verifying all returns to ensure legitimacy.

5) **Do you agree that a traceability system should be based on uniform, national standards? If no, please explain why.**

   Yes. The current patchwork of varying state laws 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 and based on uniform, national standards.

6) **Do you agree that a traceability system should include participation from everyone in the supply chain? Please explain why.**

Yes. HDMA believes that all stakeholders - including manufacturers, distributors, and dispensers - should have a role in any traceability system. HDMA has been a leader in industry task forces and working groups that bring together manufacturers, distributors and pharmacies dedicated to identifying the operational and technical requirements for traceability implementation. HDMA is also an active member of PDSA, the Pharmaceutical Distribution Security Alliance, which has included members of the entire supply chain in the formulation, development and implementation of a traceability proposal.

7) **Do you agree that a traceability system should take a phased-in approach? If no, please explain why.**

Yes. Once product is serialized, it is believed that product traceability initially can be achieved at the lot level, with potential for traceability at a more discrete level as systems mature. A system that works for all supply chain partners across all 50 states cannot be achieved with the flip of a switch. The industry believes in working to achieve this goal but it needs to be accomplished in a measured, practical way, over time.

8) **Do you agree that a traceability system with a phased-in approach should include clear requirements and a clear timeframe for a second phase? If no, please explain why.**
Yes. HDMA supports a migration toward traceability at unit level that includes deliberate, careful evaluation and assessment by FDA and stakeholders at each step. 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.

9) **Do you believe that a unit level traceability system is feasible at this time for all members of your industry? Please explain why.**

No. It is critical that federal legislation be enacted to provide the appropriate targets and parameters for longer-term electronic solutions that HDMA members can then work to implement over the period of several years. Without a uniform, national pedigree and traceability law for all supply chain participants, it would not be feasible to implement a unit level traceability system.

10) Do you believe that a lot level traceability system is feasible at this time for all members of your industry? Please explain why.

No. Currently lot numbers on pharmaceutical products are not applied uniformly. Because of the complexities of a national supply chain, without federal standards, it would not be feasible for pharmaceutical distributors to implement a lot level traceability system.

11) Do you agree that the goal of any federal traceability system should be unit level tracing? If no, please explain why.

Yes. Currently, there is no mechanism to identify a unique bottle of medicine or distinguish one from another. H.R. 1919 will require manufacturers to apply a unique identifier to prescription drugs at the unit and case levels. This will facilitate improved ability to identify non-legitimate items and help protect the supply chain from counterfeit, adulterated or substandard products. Prescription drugs will be identified and traced at the unit and case level using a serial number (SNI), lot number and expiration date.

12) Do you believe that it is imperative that traceability legislation be passed this year? If no, please explain why.

Yes. 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 access to safe medicines in the U.S.