



June 14, 2013

The Honorable Joseph R. Pitts
Chairman
Subcommittee on Health
420 Cannon House Office Building
Washington, DC 20515

The Honorable Frank Pallone, Jr.
Ranking Member
Subcommittee on Health
237 Cannon House Office Building
Washington, DC 20515

Dear Chairman Pitts and Ranking Member Pallone,

GPhA would like to submit the following in response to your recent additional questions for the record for the hearing before the Subcommittee on Health on Thursday, April 25, 2013, entitled "Securing Our Nation's Prescription Drug Supply Chain."

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

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

Yes

- 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

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

Yes

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

Yes

- 6. Do you agree that a federal traceability system should include participation**

from everyone in the supply chain? Please explain why.

Yes. In order to prevent the introduction of counterfeit or adulterated products into the supply chain and ensure patient safety, it is vital that a federal traceability system is practical, focused, and uniform across the country and includes participation from everyone in the supply chain. It is for this reason that GPhA is a member of the Pharmaceutical Distribution Security Alliance, a multi-stakeholder initiative whose membership spans the entire spectrum of the U.S. pharmaceutical distribution system, including manufacturers, wholesale distributors, third-party logistics providers, and pharmacies.

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

Yes

8. Do you agree that a federal 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

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. At the present time, the technology to support a unit-level traceability system is unreliable and underdeveloped, and the costs associated with such a model would be billions of dollars. An attempt to implement such a system hastily and before the technology is developed would lead to confusion in the supply chain, aggravate product shortages, and dramatically increase costs for all prescriptions, particularly generic medicines.

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

Yes. A lot-level traceability system is feasible and achievable for our industry in the near-term. Generic manufacturers have committed to identifying individual saleable units of medicine with labels, and maintaining and managing data in their systems that would associate the identifiers on individual bottles of medicine with the lot numbers of products. Such a building-block approach would ensure orderly implementation and avoid unintended consequences, while allowing the industry to apply the knowledge and experience gained over time to refine the system as public health threats, interoperability standards, and technologies evolve.

11. Do you agree that the goal of any federal traceability system should be unit

level tracing? If no, please explain why.

Yes

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

Yes

Thank you again for the opportunity to testify before the Subcommittee.

Sincerely,

A handwritten signature in black ink, appearing to read 'C. M. S.', with a stylized flourish at the end.

Christine Simmon
Senior Vice President, Policy and Strategic Alliances

cc: The Honorable John D. Dingell