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June 10, 2013

The Honorable Joseph R. Pitts
Chairman, Subcommittee on Health
2125 Rayburn House Office Building
Washington, DC 20515-6115

Dear Representative Joseph Pitts,

First, let me thank you for your follow up questions regarding my testimony to the Subcommittee on Health on April 25, 2013 at the hearing entitled "Securing Our Nation's Prescription Drug Supply Chain."

If Congress fails to act and the California law goes into effect, there will remain "numerous holes" and opportunities for bad actors to introduce "counterfeit or fraudulent product" into the nation-wide pharmaceutical supply chain. Prescription pharmaceutical products that are approved by the FDA for sale in the United States are manufactured and packaged to be sold anywhere in our nation through our authorized distributors of record (ADR's) and entities licensed by the state. Specifically, prescription pharmaceutical products are not manufactured or labeled for one specific state.

When a manufacturer sells a product to a wholesaler, pharmacy, hospital, or clinic for distribution and ultimately dispensing to the patient, the ownership, title and control of the product moves from the manufacturer to the commercial entity who purchased the product from the manufacturer. This commercial entity can distribute the product anywhere across the United States to other entities licensed by the state. Counterfeit product is introduced into the US supply chain through these entities, all of whom are beyond the manufacturer's control.

It is important that all entities engaged in the manufacturing, distributing, repackaging, and dispensing of prescription pharmaceutical products across the entire country be held accountable to ensure that all patients receive genuine product

If Congress fails to act and only the California law goes into effect, we will code our products accordingly and sell them in all states. Outside of California, if the downstream supply chain entities do not participate in the in system, the product identifiers will have little effect or benefit in protecting the public. Within California, patients will still be at risk due to the national scope of the drug supply. For example, the counterfeit Avastin situation could still occur again with counterfeit product being distributed into the state of California from another state, thereby, placing all patients at risk – including patients in California.

A single uniform, national standard for serialization and traceability will help protect the US prescription pharmaceutical supply chain. A patchwork of inconsistent state regulations is an ineffective means to protect the citizens of all states – including patients in California – from counterfeit product. Serialization and traceability will provide an additional deterrent against bad actors from trying to introduce counterfeit or fraudulent product into our nation's drug supply.

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I hope the above detail has satisfactorily answered your questions. If not, I would be glad to provide further information.

Again, thank you for your personal interest in this matter. We look forward to Congress' action on this vital issue of patient safety.

Mike Rose
VP Supply Chain Visibility
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June 11, 2013

The Honorable John D. Dingell
Energy and Commerce Committee
2328 Rayburn House Office Building
Washington, DC 20515-6115

Dear Representative 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

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. YES

The necessary standards, technologies and know how have advanced sufficient to make a unit level traceability system feasible. However, all supply chain stakeholders will need to make significant investments to implement unit level traceability.

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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

Manufacturers control their production and product inventory by lot today. Lot control is an accepted and well understood practice by the FDA. Manufacturers include product lot information on the shipping documentation that accompanies every shipment made by a manufacturer to their customer. When a problem(s) is identified with a product, the specific lots affected by the problem are identified. If the problem(s) is significant enough to warrant a recall, then only these specific lots would be withdrawn or recalled from the market. However, it is important to note that, currently, wholesalers and pharmacies do not control their inventories by lot. Therefore, wholesalers and pharmacies would have to make significant investments to implement lot level traceability.

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

Best regards,

Mike Rose
VP Supply Chain Visibility
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