DEPARTMENT OF HEALTH & HUMAN SERVICES

Food and Drug Administration
Silver Spring, MD 20993

The Honorable Joseph R. Pitts
Chairman
Subcommittee on Health
Committee on Energy and Commerce
House of Representatives
Washington, D.C. 20515-6115

JUN 19 2013

Dear Mr. Chairman:

Thank you for providing the opportunity for the Food and Drug Administration (FDA or the Agency) to testify at the April 25, 2013, hearing before the Subcommittee on Health, Committee on Energy and Commerce, entitled "Securing Our Nation's Prescription Drug Supply Chain." This letter provides responses for the record to questions posed by one of the Committee Members, Congresswoman Ellmers, which we received on May 24, 2013.

If you have further questions, please let us know.

Sincerely,

Michele Mital
Acting Associate Commissioner
for Legislation

cc: The Honorable Frank Pallone, Jr.
Ranking member

We have restated the Member's questions below in bold, followed by our responses.

**The Honorable Renee Ellmers**

1. **Dr. Woodcock, you mention that a breach in any point of the supply chain could lead to dangerous outcomes for patients. How critical is identifying and licensing all entities that manufacture, store, transport and distribute drugs in realizing visibility and security in the supply chain? And can you elaborate why?**

   It is essential that there is transparency and accountability in the drug supply chain. An important element of this is knowing the legitimate players in the supply chain that manufacture, store, transport, and distribute drugs and ensuring that they are licensed or otherwise accountable to Federal and state officials. This allows FDA to take swift action against those who are not legitimate and who may be bad actors. It is also important for other supply chain stakeholders to know who are the legitimate players and only do business with those entities. This creates a closed drug supply chain that further ensures the security of drug products and minimizes the chances of patients receiving an unsafe or ineffective drug.

2. **We all know that the most important goal of pharmaceutical supply chain track and trace legislation is to ensure that medicines are safely delivered to patients in North Carolina and the rest of the country. In the wake of recent high profile prescription drug counterfeiting cases in the U.S., can you share with us a summary of the discussions that you have had with patient groups regarding the importance of supply chain safety to combat these types of cases from occurring in the future?**

   Because recent incidents have involved injectable drugs purchased directly by medical practices from foreign or unlicensed suppliers, we have been focusing on educating the health care community about the risk of receiving drugs that may be counterfeit, contaminated, improperly stored and transported, ineffective, and/or unsafe. Medical practices that purchase and administer illegal and unapproved medications from foreign sources are placing patients at risk and potentially depriving them of proper treatment.

   To date we have not met with specific patient groups; however, we have issued public alerts and notices through FDA's MedWatch system about these incidents and the risks involved. Many patient organizations subscribe to Medwatch and further distribute these alerts and notices to their members.