THE COMMITTEE ON ENERGY AND COMMERCE

MEMORANDUM

April 23, 2013

To: Energy and Commerce Committee Members

From: Majority Staff

Re: Hearing Entitled "Securing Our Nation's Prescription Drug Supply Chain"

On Thursday, April 25, 2013, at 10:00 a.m. in 2322 Rayburn House Office Building, the Subcommittee on Health will hold a hearing entitled "Securing Our Nation's Prescription Drug Supply Chain." The following provides background on the witnesses and securing the pharmaceutical supply chain.

I. WITNESSES[1]

Panel I

Janet Woodcock, M.D.
Director
Center for Drug Evaluation and Research
Food and Drug Administration (FDA)

Panel II

Elizabeth A. Gallenagh, J.D.
Vice President, Government Affairs and General Counsel
Healthcare Distribution Management Association

Christine M. Simmon
Senior Vice President, Policy & Strategic Alliances
Generic Pharmaceutical Association

Michael Rose
Vice President
Supply Chain Visibility
Johnson and Johnson Health Care Systems, Inc.

Tim Davis, PharmD.
Owner, Beaver Health Mart Pharmacy
On behalf of:
National Community Pharmacists Association

[1] Additional witnesses may be added.

Allan Coukell
Director
Medical Programs
Pew Health Group, The Pew Charitable Trusts

Carmen A. Catizone, MS, RPh, DPh,
Executive Director and Secretary
National Association of Boards of Pharmacy

II. BACKGROUND

Pharmaceutical Supply Chain

The hearing will focus on the importance of securing the downstream pharmaceutical supply chain, which includes manufacturers, wholesale distributors, pharmacies, repackagers and third-party logistics providers. In order to ensure that counterfeit or stolen drugs do not enter the supply chain and harm patients, States have passed laws that require, or will require, those involved in the downstream supply chain to keep pedigrees or transaction histories of drugs. Some believe that these differing State requirements should be replaced with a reasonable, practical and feasible Federal policy.

Latta- Matheson Discussion Draft

The Latta-Matheson discussion draft would enhance the security of the pharmaceutical distribution supply chain for America's patients while preventing duplicative Federal and State requirements. It also would establish a collaborative, transparent process between FDA and stakeholders in order to better understand how and when to move to unit-level traceability. Below is a summary of the discussion draft.

Section 1: Short Title

Section 2: Pharmaceutical Distribution Supply Chain – This section would increase the security of the supply chain by establishing lot-level tracing requirements for manufacturers, wholesale distributors, pharmacies and repackagers based on changes in ownership. It also would require the members of the supply chain, including third-party logistics providers, to undertake verification and notification activities regarding suspect or illegitimate products. Further, it would require that members of the supply chain only transact with registered or licensed entities. Finally, the section would require manufacturers to serialize prescription drugs at the unit level.

Section 3 – Enhanced Drug Distribution Security – This section would require FDA to establish pilot projects and hold biannual public meetings in order to foster collaboration with stakeholders regarding how and when to build on the requirements in the bill and move to unit-level traceability. The section also would require that the Government

Accountability Office (GAO) and FDA submit reports to Congress on those same subjects.

Section 4 – National Standards for Wholesale Distributors – This section would establish national standards for wholesale distributors, but States would continue to license wholesale distributors and retain their ability to charge fees.

Section 5 – National Licensure Standards for Third-Party Logistics Providers – This section would establish third-party logistics provider licensure standards. It would not prevent a State from licensing third-party logistics providers in accordance with the section.

Section 6 – Penalties – This section would establish penalties for violations of the requirements of the bill to ensure bad actors are held accountable.

Section 7 – Uniform National Policy – This section would preempt, upon enactment, State laws on tracing drugs through the distribution system. It also would preempt State laws regarding standards for wholesale drug distributors and third party logistics providers. This preemption would not affect the authority of states to collect fees from wholesale drug distributors or third-party logistics providers.

Section 8 – Electronic Labeling Requirement – This section would allow prescription drug labeling to be provided by electronic means.

III. STAFF CONTACTS

Should you have any questions regarding the hearing, please contact Paul Edattel or Carly McWilliams at (202) 225-2927.