

SUMMARY OF THE GENERIC PHARMACEUTICAL ASSOCIATION TESTIMONY
BEFORE THE ENERGY AND COMMERCE SUBCOMMITTEE ON HEALTH
UNITED STATES HOUSE OF REPRESENTATIVES – MARCH 8, 2012
“FDA USER FEES 2012: HEARING ON ISSUES RELATED TO ACCELERATED APPROVAL, MEDICAL GAS, ANTIBIOTIC DEVELOPMENT AND DOWNSTREAM PHARMACEUTICAL SUPPLY CHAIN”

I am Shawn Brown, Vice President of State Affairs at the Generic Pharmaceutical Association. GPhA represents the manufacturers and distributors of finished dose generic pharmaceuticals, bulk pharmaceutical chemicals, and suppliers to the generic industry. Generic pharmaceuticals fill 80 percent of the prescriptions dispensed in the U.S. but consume just 25 percent of the total drug spending.

For many years, GPhA has worked closely with multiple stakeholders across the supply chain to ensure that U.S. consumers will continue to benefit from the safest and most secure prescription drug supply chain in the world. Our commitment to this issue is evidenced by the historic Generic Drug User Fee Act currently being considered by the Committee, under which FDA will receive \$1.5 billion over five years from the generic industry, which will hold all players contributing to the U.S. generic drug system, foreign or domestic, to the same inspection standards. As the Committee further considers downstream pharmaceutical supply chain issues, it is vital to ensure that any national system developed is practical, focused, and uniform across the country.

Previous Efforts to Regulate the Pharmaceutical Supply Chain

Several Members of Congress have introduced legislation in recent years that would urge the establishment of national standards for an electronic prescription drug tracking system, and we look forward to working with them to achieve our shared goal of ensuring the safety of the U.S. drug supply. On the state level, California has passed a law requiring manufacturers to implement a unit-level, interoperable electronic track-and-trace system. GPhA believes that adoption of the California model will cost the industry billions of dollars over time, would be prone to error, and would have, at best, similar results to the less-expensive, more efficient model we propose. GPhA has helped lead an effort to develop an alternative approach to increase the security of the U.S. drug supply.

The PDSA Model

The Pharmaceutical Distribution Security Alliance (PDSA) is a multi-stakeholder initiative whose membership spans the U.S. pharmaceutical distribution system, including manufacturers, wholesale distributors, third-party logistics providers and pharmacies. PDSA’s mission is to develop a federal policy that enhances the security and integrity of the domestic pharmaceutical distribution system for patients and ensure patients have uninterrupted access to safe, authentic, FDA-approved medicine.

As a member of PDSA, GPhA strongly supports the Alliance’s proposed electronic traceability system known as the Pharmaceutical Traceability Enhancement Code (RxTEC), which would increase patient access to safe medicines while improving the security of our country’s drug distribution system. The RxTEC system would aid state and federal agencies in tracing the distribution history of suspect products, replace the inconsistent and inefficient patchwork of state laws, increase efficiency throughout the drug distribution system, and establish foundational technology for future enhancements.

As part of the RxTEC system, manufacturers have committed to serializing individual saleable units of medicine and maintaining and managing data in their systems that would associate the serial numbers on individual bottles of medicine with the lot numbers of products. This system would help identify and prevent the introduction of suspect product through full lot traceability and allow regulatory authorities to validate the serial number of a product at the unit level. And unlike a full track-and-trace system, which is not technologically feasible in the near term, the RxTEC system would provide immediate measures to increase supply chain security.

The system would additionally provide regulators with new authorities and penalties to address counterfeit products, cargo theft, illegal online drug sellers, and new rules regarding e-labeling that will increase patient safety. It would also create more stringent federal standards and state licensing for wholesale distributors.