TESTIMONY OF

GORDON JOHNSTON

SENIOR ADVISOR FOR REGULATORY SCIENCES

GENERIC PHARMACEUTICAL ASSOCIATION

SECURING THE PHARMACEUTICAL SUPPLY CHAIN

BEFORE THE

COMMITTEE ON HEALTH, EDUCATION, LABOR AND PENSIONS

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Good morning Chairman Harkin, Ranking Member Enzi and Members of the Senate Committee on Health, Education, Labor and Pensions. Thank you for asking me to participate in this very timely and important hearing.

I am Gordon Johnston, Senior Advisor for Regulatory Sciences at the Generic Pharmaceutical Association. GPhA represents the manufacturers and distributors of finished dose generic pharmaceuticals, manufacturers and distributors of bulk pharmaceutical chemicals and suppliers of other goods and services to the generic industry. Generic pharmaceuticals now fill 78 percent of all prescriptions dispensed in the U.S., but consume just 25 percent of the total drug spending.

According to an analysis by IMS Health, the world's leading data source for pharmaceutical sales, the use of FDA-approved generic drugs in place of their brand counterparts saved U.S. consumers, patients and the health care system more than $824 billion over the past decade — $137 billion in 2009 alone — which equates to one billion dollars in savings every three days.

Prior to joining GPhA, I was with the U.S. Public Health Service, where I served in a number of pharmacist and health care management positions. In 1987, I was assigned to the Food and Drug Administration and, in 1994, became the Deputy Director of the FDA's Office of Generic Drugs (OGD). While at the FDA, my duties required that I interfaced with a number of foreign governments on drug safety and regulatory standards.

Introduction

I would like to make two brief points in my testimony today, before providing comments on securing the pharmaceutical supply chain.

First, we commend the Committee for your focus on ensuring the safety of America's pharmaceutical supply — brand and generic. For nearly a quarter of a century America's generic drug industry has been developing, manufacturing and marketing generic versions of brand-name prescription drugs. Last year, approximately 78 percent of the more than 3 billion new and renewal prescriptions dispensed in the U.S. were filled with generics, saving patients and consumers billions of dollars. We are committed to doing everything possible to work with Congress and the FDA to ensure that adequate oversight of the nation's drug supply is in place to ensure its safety.

Second, the generic pharmaceutical industry is among the most highly regulated in the world, with strict rules governing the development, manufacture, approval, packaging, marketing and post-marketing surveillance of prescription drugs by the FDA. These stringent regulations apply equally to all pharmaceutical products — brand or generic, approved by the FDA.

Securing the nation's pharmaceutical supply chain is of vital importance to the Generic Pharmaceutical Association and to our member companies. Given that more than 78 percent of all prescription drugs dispensed in this country are generic drugs, we have a

keen interest in making sure the supply chain is safe for American consumers who rely on our medicines. We also have a keen interest in a level, competitive and accountable playing field among all participants in the U.S. pharmaceutical supply chain.

Current Landscape

As the Committee begins to look closer at this important issue, it is critical to understand the fundamental underpinnings of the current system that ensures drug safety in our country and acknowledge the global dynamics of our current branded and generic pharmaceutical supply here in the United States.

While much of the responsibility of ensuring safe drugs rests with industry, the FDA plays a critical role in making sure all players participating in the pharmaceutical supply chain meet FDA's rigorous standards, including compliance with current Good Manufacturing Practices ("GMP"). With a mission to protect and promote the public health, the FDA is charged by Congress to ensure the safety, efficacy and security of the U.S. drug supply and to address threats to public health.

Background on FDA's Authority

FDA's authority to carry out this responsibility originated some seven decades ago when President Franklin Roosevelt signed into law the Federal Food, Drug and Cosmetic Act of 1938 following the death of more than 100 people as a result of ingesting Elixir Sulfanilamide, which contained the deadly poison diethylene glycol. In an effort to avoid future tragedies, this landmark legislation of 1938 became the

foundation on which the FDA oversees our nation's pharmaceutical supply today. Among other authorities, this law authorized FDA to demand evidence of safety and conduct facility inspections, two critical authorities of the world's most robust drug authority.

The Problem

The pharmaceutical marketplace FDA oversees in today's global age, however, looks drastically different than it did in 1938 when FDA's guiding statute was enacted. And several unfortunate tragedies in the pharmaceutical world since 1938 have prompted further enhancements to FDA's authority under the FDCA to ensure the agency is equipped to carry out its mission of protecting the public health. A few pivotal events have led to an enhancement of FDA's original 1938 authority since the law's original passage. This included the thalidomide tragedy in Europe, which strengthened the rules for drug safety and required manufacturers to prove their drugs' effectiveness in the U.S. in 1962. In 1976, additional amendments were made to apply safety and effectiveness safeguards to new devices following a U.S. Senate finding that faulty medical devices had caused 10,000 injuries, including 731 fatalities.

Unfortunately, as this Committee is aware, the U.S. experienced another tragedy recently when tainted brand Heparin was distributed in the U.S., leading to 81 deaths and shedding additional light on some notable shortcomings of the 1938 law, which makes it more difficult for FDA to carry out its mission in the now very globalized U.S. pharmaceutical supply chain. FDA traced the adulteration of the Heparin product to a

manufacturing facility in China, which the agency had never inspected. As globalization of drug supply increases, so do concerns about drug safety and demands to preserve the stringent quality standards Americans deserve, regardless of where their medicines are produced.

Today, nearly 40 percent of all prescription drugs dispensed in the United States are manufactured outside of the country, and nearly 80 percent of the ingredients in our drugs are manufactured abroad. The Food and Drug Administration is charged with ensuring the safety of all medicine sold in the United States no matter where these products are made. According to FDA estimates, the number of drug products made outside of the U.S. doubled from 2001 to 2008. The growth in the number of facilities requiring FDA oversight has grown substantially, particularly in foreign facilities that supply the U.S. marketplace. In 2010, nearly 20 million shipments of food, drugs and cosmetics arrived at U.S. ports of entry. A decade earlier, that number was closer to 6 million and, a decade before, just a fraction of that figure. Unfortunately, this growth has outpaced the law's reach as well as the funds needed to allow FDA to hold all participants in the pharmaceutical supply chain to the same high quality standards.

More Foreign Inspections Needed

One of the most critical ways FDA ensures continued compliance with the high quality standards required of prescription drugs sold in the U.S. is conducting on-site inspections of facilities where drugs are manufactured. These important surveillance inspections ensure that facilities are continuing to meet their obligation of producing

safe products in accordance with a rigorous set of standards known as Good Manufacturing Practices, or GMP, and serve as a critical tool of ensuring continued safety and GMP compliance — separate and distinct from other supply chain controls.

The FDCA of 1938 requires American manufacturers associated with pharmaceutical production to undergo a surveillance inspection every two years to ensure that these facilities are complying with strict GMP standards. However, the FDCA does not impose the same biennial GMP inspection requirement on foreign facilities. According to FDA, foreign facilities have grown by 185 percent, while at the same time FDA inspection rates have decreased by nearly 57 percent. Meanwhile, the FDA inspected just 11 percent of the 3,765 foreign establishments in its database in 2009, according to the Government Accountability Office.

This disparity in the degree of oversight experienced by domestic versus foreign facilities reduces American competitiveness by creating an uneven playing field, while at the same time threatening the safety of the U.S. drug supply.

This disparity in inspections between foreign and domestic facilities is also causing notable delays in introducing new prescription drugs to consumers, including delays in approving products that serve an unmet medical need or offer a more affordable alternative in the case of generic drugs. This is because new product approvals, such as those facing drug shortages, require an inspection history of the relevant

manufacturing facility and, given the number of facilities awaiting inspection, many of the facilities producing new drugs are waiting to be inspected.

The Solution

FDA does indeed need, in the words of Health and Human Services Secretary Kathleen Sebelius, "additional tools from Congress to move its oversight capabilities into the 21st century." And more recently, the agency noted that it is "looking to Congress to modernize its antiquated authorities so that FDA's legal tools keep pace with globalization."

GPhA is in agreement with FDA on this matter. Without modernization of the law governing the U.S. drug supply and increased authority and resources to carry out FDA's oversight of today's complex and global drug supply, the significant challenges facing the U.S. pharmaceutical marketplace will continue and likely compound. Earlier this year, the President signed into law legislation intended to globalize FDA to help protect the nation's food supply and equip the agency to carry out its twin mission of ensuring food safety in an increasingly globalized food supply. When it comes to drugs, however, FDA still operates in accordance with the FDCA of 1938, the scope and provisions of which are largely domestic. This law needs to be globalized to ensure FDA is equipped for the global age and to ensure competitiveness.

GPhA is pleased the Committee is holding this hearing to begin efforts to equip FDA with the necessary legal authority and tools to carry out its critical public health mission in the globalized U.S. pharmaceutical marketplace.

Ensuring that all contributors to the U.S. drug system, both foreign and domestic, are held to the same quality standard is a critical issue for the entire pharmaceutical industry — brand and generic alike. Amending the FDCA of 1938 and, in particular, ensuring foreign facilities are held to the same standards as U.S. facilities, will improve quality, consistency and availability within the drug supply chain and create a level playing field, allowing U.S. pharmaceutical manufacturers to be more competitive. These important updates to the law will not only result in a safer drug supply with consistent oversight for all players in the U.S. system, the changes will also help reduce approval times of new drugs undergoing FDA review and help expedite the availability of new medicine.

GPhA further supports a “risk-based” model for inspections that prioritizes inspections according to a company’s safety and compliance track record. This system would ensure that questionable or problematic facilities receive a comprehensive review and evaluation sooner, rather than later, or not at all as is the case under the current system. Facilities with strong records of compliance and positive inspections would be placed further down on the inspection schedule, allowing the agency to prioritize its immediate attention on companies that have never had an inspection or that have a history of compliance issues.

Generic Drug Industry Steps Up to Help Address this Industry-Wide Issue

As I noted in my opening remarks, the responsibility of ensuring safety is a shared one that rests with all of us in industry, though, not just the FDA.

I am proud to say that the generic drug industry has been a leader in this area, developing supply-chain security measures independently and with the FDA to provide the necessary oversight to maintain the nation's drug supply.

For example, one new initiative is the FDA's border control policy, which is being developed in an attempt to cut the number of poor standard medicines that enter the supply chain from outside the U.S. The new initiative, which is called PREDICT — Predictive Risk-based Evaluation for Dynamic Import Compliance Targeting — will be a border-based scheme that assesses drugs at the point of import. Barcodes on cases of medicines will be scanned at the U.S. borders and linked to a central database. The results will be able to tell the FDA agents at the border whether or not the producer has a license to ship and sell their drugs in the U.S. If the products do not meet FDA compliance they will not be allowed into the country.

The pharmaceutical industry also provides multiple layers of testing and oversight to build in quality and supply chain security from the ground up. Suppliers of inactive and active ingredients are carefully evaluated to assess their facilities, manufacturing capabilities and supply chain practices and controls. These initiatives provide the foundation of drug product quality, as well as taking all necessary steps to help

eliminate potential contamination or adulteration in the shipment channels. Next, manufacturers test the incoming raw materials for quality, purity and potency in accordance with FDA-approved analytical methods. These testing methods are designed to assure that all raw materials meet their predetermined quality attributes. Finished dosage form manufacturers have sophisticated testing procedures during the manufacturing process and for the final product, which are all intended to assure that the product received by patients meets all standards for quality, purity and potency.

As drug products are shipped to wholesalers, pharmacies or other intermediaries, the pharmaceutical industry utilizes multiple forms of controls within the supply chain to mitigate the potential risk of contamination or adulteration. Careful planning of drug shipments, along with strict supply chain custody and controls, are part of the advanced logistical operations that provide accountability and oversight of the products before they ever reach a patient's hands. By following these standards, manufacturers are able to determine any deviation from a product's predetermined shipment and custody program, and stop problems before they occur.

As my colleagues at Pew noted in their recent report, it is also critical that we as manufacturers continue to go beyond current GMP standards in our own facilities to ensure appropriate supplier qualification, through risk-based assessments, quality agreements and physical audits, where appropriate. By working together as an industry to share the results of these audits, as well as new technologies, we can further develop harmonized standards and best practices to ensure that all stakeholders in the

pharmaceutical supply chain are utilizing the most current and effective methods for providing patients with safe and effective medications.

Landmark User Fee Program Will Provide Additional Resources

Even with these significant efforts in place, however, the generic pharmaceutical industry has realized that more needs to be done. That is why the industry, which accounts for 78 percent of all prescription drugs dispensed in the U.S., has stepped up to the plate to help provide FDA with resources to address the challenges caused by the global drug supply and the increase in the FDA's workload. The industry has been working closely with FDA to negotiate a generic drug user fee program to help the agency obtain additional resources in this global age to ensure all participants in the U.S. generic drug system, whether U.S.-based or foreign, comply with all U.S. strict quality standards and to make certain Americans get timely access to low cost, high quality generic drugs.

The generic drug user fee program being finalized now with FDA recognizes that while providing earlier access to effective medicines is critical — and the key aim of all other existing user fee programs — an equally important pillar of FDA's mission is ensuring drug safety. The overall goal is to hold all players, foreign or domestic, contributing to the U.S. generic drug system to the same GMP inspection standards, while expediting access to more affordable, high quality generic drugs; and, enhancing FDA's ability to identify, track and require the registration of all contributors involved in each generic

drug product sold in the U.S. Final recommendations are expected be submitted to Congress in January 2012.

While the generic drug user fee program provides an excellent framework for industry to help support the growing global needs of FDA and to level the playing field between foreign and domestic facilities through inspection parity, it does not completely solve the problem, nor does it have the reach of the entire pharmaceutical industry. To globalize FDA's authority, eliminate the inspection disparity and better ensure the safety of the global supply chain, it is paramount that a bill is introduced to expand FDA's authorities to achieve its mission in this global age.

The safety of our nation's pharmaceutical supply is only as good as our weakest link, and the responsibility rests upon all of us. GPhA encourages Congress and our counterparts throughout the pharmaceutical industry to work together to ensure FDA is equipped to keep our consumers safe in a 21st century global drug supply environment.

Federal Pedigree Standard Should Replace State-by-State Patchwork

Finally, as we look at the broader issue, GPhA also recommends that Congress adopt a federal pedigree system with uniform standards across all states, as opposed to a patchwork of more state-enforced regulations that are starting to arise in the absence of federal leadership mandating one uniform standard. Given that products are distributed throughout interstate commerce and across all states lines, having what could potentially be a 50 state patchwork of different standards will be a mess without a

federal mandate setting a reasonable, uniform standard. The challenge to implementation will be to ensure that the technology is reasonable and feasible in light of numerous economic, technical and logistical factors so that the end product does not result in an increase to consumer and payer cost.

Conclusion

In conclusion, Mr. Chairman, the Generic Pharmaceutical Association stands ready to support Congress and the FDA in strengthening its oversight, updating the law and investing more resources to ensure we continue to lead the world in safety while maintaining competitiveness.

Thank you. I would be happy to address any questions of the Committee.