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GENERIC PHARMACEUTICAL ASSOCIATION

"SECURING OUR NATION'S PRESCRIPTION DRUG SUPPLY CHAIN"

BEFORE THE ENERGY AND COMMERCE SUBCOMMITTEE ON HEALTH

UNITED STATES HOUSE OF REPRESENTATIVES

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Good morning Chairman Pitts, Ranking Member Pallone and Members of the House Energy and Commerce Subcommittee on Health. Thank you for inviting me to testify before the subcommittee on the important topic of securing our nation's pharmaceutical supply chain.

I am Christine Simmon, Senior Vice President, Policy & Strategic Alliances at the Generic Pharmaceutical Association. GPhA represents the manufacturers and distributors of finished dose generic pharmaceuticals, bulk pharmaceuticals and suppliers of other goods and services to the generic industry. Generic pharmaceuticals now fill 80 percent of all prescriptions dispensed in the United States, but account for only 27 percent of the total spending for prescription medicines. 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 has saved U.S. consumers, patients and the health care system more than $1 trillion over the past decade and $192.8 billion in 2011 alone — which equates to $1 billion in savings every other day. The quality and affordability of generic medicines is vital to public health and the sustainability of the health care system.

Introduction

For many years, GPhA has worked closely with multiple stakeholders across the supply chain to ensure that American consumers will continue to benefit from the safest and most secure prescription drug supply in the world. Both industry and the FDA are

exceptionally vigilant against the distribution and sale of counterfeit and adulterated medicines.

Any presence of counterfeit and adulterated pharmaceuticals in our supply chain threatens both the health of patients and the integrity of our industry. As the makers of 80 percent of the prescriptions dispensed in the United States, the generic pharmaceutical industry is deeply committed to ensuring the security of our country's drug supply. GPhA believes that the problem of counterfeit medicines raises a significant public health concern that must be addressed systemically on a range of levels — from local to global, and throughout the drug supply chain.

Our commitment to this issue is further evidenced by our industry's strong support of last Congress' historic Generic Drug User Fee Act, which recognizes that while providing earlier access to effective medicines is critical — and the key aim of all other existing user fee programs — FDA's central mission is ensuring drug safety. We also applaud the efforts of this Committee in enacting the user fee program into law. The program holds all players, foreign or domestic, contributing to the U.S. generic drug system to the same Good Manufacturing Practices (GMP), and inspection standards, while expediting access to more affordable, high quality generic drugs; the generic drug user fee program also enhances FDA's ability to identify, track and require the registration of all contributors involved in each generic drug product sold in the U.S.

We also are members of the Pharmaceutical Distribution Security Alliance, or PDSA:

a multi-stakeholder and interdisciplinary initiative whose membership spans the entire spectrum of the U.S. pharmaceutical distribution system, including manufacturers, wholesale distributors, third-party logistics providers and pharmacies.

The PDSA's mission is to develop, and help enact, a federal policy proposal that enhances the security and integrity of the domestic pharmaceutical distribution system for patients, and to articulate a technical migratory pathway to implement such a policy. The coalition's primary goal is to ensure patients have uninterrupted access to safe, authentic, FDA-approved medicine.

It is worth noting that low-cost generic drugs are rarely, if ever, targeted by counterfeiters. And in general, as the FDA acknowledges, "counterfeiting is quite rare within the U.S. drug distribution system." Nevertheless, the generic industry has been a leader in supporting numerous anti-counterfeiting efforts and developing methods to further protect the integrity of the pharmaceutical supply chain. The generic industry is committed to ensuring the safety of the millions of consumers nationwide who use safe, affordable generic medications. As such, we support a system built on the core principles of: a uniform, federal standard; technical requirements that support achievability; and a building-block approach to ensure an orderly implementation and avoid unintended consequences.

Last year, the effort to enact a national solution received strong support from key members in both the House and Senate but unfortunately was not enacted into law. We

applaud this Committee for picking up where the previous effort left off, and we recognize and appreciate the dedicated attention to this issue given by Congressman Matheson and Congressman Latta.

Uniform Federal Standard

As these efforts move forward, however, it is vital to ensure that any system is practical, focused, and uniform across the country. A uniform system founded on reliable technology and business practices would preclude the unintended consequence of erecting cost barriers to the distribution of safe and effective medicines.

For example, some anti-counterfeiting efforts, such as the drug pedigree model currently set to take effect in 2015 under California law, would require implementation of full electronic "track-and-trace" capabilities, where the entire distribution history, and the location, of every unit in the supply chain can be determined at any time. At present, the technology to support such a system is unreliable and underdeveloped, and the costs associated with such a model would be billions. Considering the myriad of manufacturers, packaging operations and potential exceptions, this is not a realistic expectation. An attempt to implement such a system would lead to confusion in the supply chain, aggravate product shortages and dramatically increase costs for all prescriptions, including generic medicines. The California law does include language providing for preemption of its requirements in the event that federal legislation is enacted, which we support.

Achievability

As the Committee begins its consideration of legislation to address this important issue, it is critical to understand how previous efforts at regulating the pharmaceutical supply chain — at both the state and federal level — have led us to where we stand today.

In 1988, Congress passed the Prescription Drug Marketing Act, or PDMA, requiring drugs to be tracked when they passed outside of the normal chain of distribution, which begins at the manufacturer, goes to authorized distributors and finally to the pharmacy. Congress found this necessary because the majority of drugs that were counterfeit, stolen, expired or obtained through fraud were handled by secondary wholesalers, who were not authorized to distribute a manufacturer's product. Manufacturers and their authorized distributors were exempted from these requirements, because the introduction of counterfeit medicines would rarely, if ever, occur in this link of the supply chain. However, the law was stayed by the FDA, and finally enjoined in 2006 by a federal district court in New York, in large part because the creation of a national drug tracking system including all supply chain participants had not been mandated, making the requirements potentially too difficult or impossible to fulfill for many legitimate distributors.

Since that time, this Committee and the Congress passed the Food and Drug Administration Amendments Act of 2007 (FDAAA), which directs the FDA to develop standards for the identification, validation, authentication and tracking of prescription drugs, as well as a standard numerical identifier to be applied to a prescription drug at

the point of manufacturing and repackaging. While most of these standards have yet to be established, the FDA envisions a full track-and-trace system similar to that in California. We believe that the technology and processes necessary to achieve full track-and-trace are not fully mature at this time.

Additional federal legislation also has been introduced in recent years that would urge the establishment of national standards for an electronic tracking system. These proposals pursue the worthy goal of a single, uniform national standard for supply chain security, as opposed to a patchwork of differing state-by-state laws. However, the measures proposed would ultimately require an extensive track-and-trace model for each individual saleable unit of medicine that is simply unachievable within the proposed timeframes. GPhA believes that adoption of the California model, or one with very similar features, would raise the cost of medicine by billions of dollars over time, would be prone to error, and would have, at best, similar results to a less-expensive, more efficient model.

Building-block Approach

GPhA recognized the shortcomings of the California-type approach early on and proposed its own alternative model in 2011 by publishing a white paper on an end-point authentication model. At that time, we began to work in PDSA with representatives from all sectors of the supply chain and helped create an industry consensus model that we believe makes large safety strides in incremental steps over time. We believe that a building-block approach enables the industry to achieve the necessary interoperability in

achievable steps, all the while applying the knowledge and experience gained over time to refine the model. While our member companies are still reviewing the recently-released House draft, many elements of that draft are consistent with our proposed approach.

Specifically, as outlined in Phase I of the Latta-Matheson discussion draft, generic manufacturers have committed to identifying individual saleable units of medicine with labels, and maintaining and managing data in their systems that would associate the identifiers on individual bottles of medicine with the lot numbers of products. Verification that a specific unit was indeed identified by a manufacturer within a given production lot can provide information and security that is a major step forward from current practices. Unit-level identification provides greater granularity of a lot and improves the visibility of its distribution throughout the supply chain, and also provides unit-level data as an additional check. This system would help identify and prevent the introduction of suspect product through full lot traceability and allow regulatory authorities to validate the identifier of a product at the unit level.

And unlike a full track-and-trace system, which we do not believe is technologically feasible in the near term, the House language would provide immediate measures to increase supply chain security. The system established under the proposal will improve the efficiency and effectiveness of drug recalls and returns. In planning for the future, it would provide critical building blocks that can be expanded as public health threats, interoperability standards, and technologies evolve, and establish connectivity and

infrastructure throughout the supply chain that will enable a variety of other capabilities and efficiencies. We also strongly support the e-labeling requirement in the discussion draft to provide more standardized, electronic prescription drug information that would increase patient safety and provide significant quality improvements and cost reductions to patients, manufacturers, prescribers and providers of pharmaceuticals by developing a more accurate, cost-effective and sustainable alternative to existing paper inserts. The discussion draft would also create more stringent federal standards and state licensing for wholesale distributors, and streamline requirements for manufacturers who also operate as distributors.

In keeping with many years of existing law, GPhA agrees with the Latta-Matheson discussion draft that intravenous (IV) products must be exempted from these regulations and urges that this exemption be maintained.

In short, the House proposal will replace the patchwork of inconsistent state laws, while increasing patient safety and enhancing our ability to identify and prevent the introduction of suspect products. It is important to recognize the limitations of technology and the necessity of other means of vigilance to address the issues of counterfeiting and diversion of drugs. There is no technology or tracking system that will stop all thieves and counterfeiters from attempting to divert products, or profit illegally.

GPhA supports the development of pilot programs to explore and evaluate methods to enhance the safety and security of the pharmaceutical distribution supply chain as well as the inclusion in the discussion draft of report mandates for the Government Accountability Office and Food and Drug Administration to assess implementation and pilot programs, respectively.

Conclusion

In conclusion, Mr. Chairman, GPhA and the industry share the concerns of the Committee with regard to maintaining the security of our country's drug supply and preventing the entry of counterfeit, diverted, stolen or other substandard medicines. The development of a uniform, national system is needed to give regulatory authorities another tool for enforcement, make it more difficult for criminals to breach the supply chain and enhance the ability of the supply chain to respond quickly when a breach has occurred. We believe the model proposed by the House includes many elements to achieve these goals. We look forward to working together with the House and Senate to develop a consensus measure on this important issue that can be enacted into law. Thank you and I would happy to answer any questions you may have.