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FDA USER FEE AGREEMENTS: STRENGTHENING FDA AND THE MEDICAL PRODUCTS INDUSTRY FOR THE BENEFIT OF PATIENTS

BEFORE THE UNITED STATES SENATE

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 timely and important hearing.

I am David Gaugh, Vice President for Regulatory Sciences at the Generic Pharmaceutical Association and a licensed pharmacist. GPhA represents the manufacturers and distributors of finished dose generic pharmaceuticals, bulk pharmaceutical chemicals, and the suppliers of other goods and services to the generic industry. Generic pharmaceuticals now fill 80 percent of all prescriptions dispensed in the U.S., but consume just 25 percent of the total drug spending for prescription medicines.

According to a recent 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 $931 billion over the past decade — $158 billion in 2010 alone — which equates to $3 billion in savings every week.

Prior to joining GPhA, I was Vice President and General Manager for Bedford Laboratories, the generic injectable division of Ben Venue Laboratories, I have also served as Senior Director, Pharmacy Contracting and Marketing, for VHA/Novation, one of the largest Group Purchasing Organizations in the U.S., and was System Director of Pharmacy for a regional referral tertiary-care healthcare system in the Midwest.

Introduction

I would like to begin today by commending the Committee for your continued focus on the important issues we will examine today. As someone who has worked in and around the generic industry for more than two decades, I have witnessed firsthand the industry's remarkable growth and the vital role it plays in the lives of Americans every day. By providing consumers access to safe and effective medicines at an affordable price, the generic industry fills an essential role not only for patients, but for our health care system and, indeed, our national economy.

This growth in the generic industry has also served to underscore the critically important role of the Food and Drug Administration (FDA). As I will highlight, the level of cooperation between industry and the FDA has never been greater. The two historic user fee agreements we are discussing today represent only a small measure of our ongoing collaboration. It is our hope that this collaboration will continue and extend throughout all of our interactions with the agency.

As evidenced by these accomplishments, the FDA's work during this period of growth for the generic industry has been extraordinary. Thanks to their efforts, the U.S. drug supply remains the safest of anywhere in the world, and the FDA's drug approval and inspection processes represent the gold standard for regulatory agencies worldwide.

However, the agency remains underfunded, and the responsibility of ensuring access to safe and affordable medicines is a shared one that rests with the entire pharmaceutical industry, not just the FDA. That is why the generic industry has stepped up to help provide the FDA with additional resources to address the ongoing challenges caused by an increasingly global drug supply-chain, the increase in the agency's workload and the regulation of new and complex technologies.

Throughout much of last year, GPhA and our member companies worked closely with the FDA to negotiate two separate user fee programs designed to help the agency obtain additional resources to ensure all participants in the U.S. generic drug system, whether U.S.- based or foreign, comply with all of our country's strict quality standards. Most importantly, the programs will make certain that all Americans receive timely access to safe, effective and affordable generic drugs. Let me provide some more details.

Landmark User Fee Programs Will Provide Additional Resources

Currently, more than 2,700 generic drug applications are awaiting approval from the FDA's Office of Generic Drugs (OGD), and the average approval time for an application is now stretching beyond 30 months, more than five times longer than the statutory six-month review time called for by Hatch-Waxman. Unfortunately, this backlog keeps safe, low-cost generic drugs off the market and reduces competition that may drive drug prices down further.

The proposed Generic Drug User Fee Act, or GDUFA, that we are discussing today will help alleviate the backlog and expedite consumer access to generic drugs, while also enhancing drug quality and safety by ensuring inspection parity among both foreign and domestic manufacturing sites.

Specifically, FDA will receive $299 million per year over the five-year GDUFA program, or about $1.5 billion in total. Of that funding, 80 percent, or about $240 million, will come from finished-dose manufacturers, and the remaining 20 percent will be paid by manufacturers of active pharmaceutical ingredients. Thirty percent of the funding will stem from application fees and 70 percent will be derived from fees on manufacturing sites, or facility fees.

Splitting the fees in this manner will provide the FDA with a predictable source of annual income, as the number of facilities manufacturing generic drugs on a yearly basis provides a more consistent figure than the number of generic drug applications submitted. Finished dose facilities that manufacture both generic and brand medications will be required to pay both a Prescription Drug User Fee Act facility fee and a GDUFA facility fee.

The new user fee program will also establish performance goals for the FDA. As part of these goals, GDUFA calls for the agency to complete, by the end of year five, the review of 90 percent of all generic drug applications — commonly referred to as

Abbreviated New Drug Applications, or ANDAs — that are pending on October 1, 2012 — the proposed start date for the program. By achieving this goal, the GDUFA agreement will effectively eliminate the current application backlog.

In addition, by the end of the program's fifth year, GDUFA calls on the FDA to review 90 percent of ANDAs within 10 months after they are submitted — almost two years faster than today's average review time.

These are great strides that will go a long way toward ensuring patients have timely access to safe and effective generic medicines for years to come. But GPhA also 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 and industry's mission is ensuring drug safety.

Since the enactment of the Federal Food, Drug and Cosmetic Act in 1938, the core public health mission of the FDA has been to protect and promote the public's health. As part of that mission, the FDA has a critical responsibility to ensure the safety, efficacy and security of the entire U.S. drug supply, both brand and generic. Ensuring a safe and effective drug supply, however, is significantly more challenging today than it was in 1938 due to the increasing globalization of drug manufacturing, supply and testing and an increase in FDA-regulated drug products.

GPhA has long-maintained that, in light of this increasing globalization and with nearly 40 percent of all the prescription drugs in the U.S. being imported, the FDA needs more resources to ensure adequate oversight of the nation's drug supply.

A 2010 Government Accountability Office (GAO) report found that FDA was able to conduct Good Manufacturing Practice, or GMP, inspections at only 11 percent of the foreign establishments in its database, compared to 40 percent of the domestic sites it inspected. According to the GAO, in the absence of a paradigm shift, it would take FDA nine years to inspect all foreign facilities.

That is why GDUFA takes the unprecedented step of holding all players contributing to the U.S. generic drug system, foreign or domestic, to the same inspection standards, and enhances FDA's ability to identify and require the registration of active pharmaceutical ingredient and finished dosage form manufacturers involved in each generic drug product sold in the U.S. The program will significantly improve the resources the FDA has to do this important work, ensuring that it can be done with increasing speed, but without any sacrifice to today's high quality standards.

It is paramount that, as we work to shape the future of our country's generic drug industry, we also work to bring the FDA into the 21st century and ensure that the agency's authorities to achieve its mission in this global age are up to date.

In many ways, this process is already underway. Perhaps the best and most immediate example rests with the other user fee program we will discuss today — for generic biologic drugs, or biosimilars.

Biosimilar User Fee Act

Biologic medicines are often the only lifesaving treatments for many of the most severe diseases encountered by patients today. In many respects, they represent the future of medicine. Their high price tag, however, can keep them out of reach for many patients. The cost of biologics is increasing annually at a faster pace than almost any other component in health care. As proven with chemical prescription drugs, competition from generic biologic drugs will be the most important factor in holding down the future costs of these lifesaving medicines.

With the FDA still working to determine the process by which these products will be approved, GPhA continues to stress the importance of creating a workable regulatory mechanism that does not serve as a barrier to competition, but rather ensures the robust competition needed to lower costs and spur future innovation. If such a system is not put in place, it is our fear that the exponential growth of biologics over the next 10 to 20 years, without adequate generic alternatives, could bankrupt our health care system and the national economy. Moreover, the lack of lower-cost generic biologics will keep vital treatments away from the patients who need them most.

Within our organization, we represent manufacturers who currently produce high-quality, safe and effective biosimilars approved in Europe and other regulated markets around the world. These member companies are dedicated to bringing the same level of access and affordability for these critical medicines to U.S. patients.

During the biosimilar user fee negotiations, GPhA expressed its support for user fee funding to provide FDA with adequate resources to apply consistent regulatory standards to all biologics, and review new applications as they are filed. Both industry and patients will benefit from this user fee program by gaining a higher degree of certainty in the timeliness of application reviews.

The proposed program creates a separate review platform for biosimilar sponsors, to be financed annually through $20 million of the funds appropriated to the FDA and supplemented by user fees equivalent to those under the Prescription Drug User Fee Act. A portion of the application fee paid during the biosimilar development phase will be used to support earlier resourcing for product reviews. Similar to GDUFA, the program also includes performance goals for the FDA, which calls for the agency, by the end of the program's fifth year, to review 90 percent of the original biosimilar applications it receives within 10 months of their submission.

We applaud the FDA for recognizing the importance of biosimilars, and the need to apply state-of-the-art science in all agency activities governing the review and approval of these important drugs.

Through both of these user fee agreements, the generic industry has truly stepped up to do our part to help ensure U.S. drug safety, establish a more level playing field among all participants in the U.S. pharmaceutical supply chain and significantly reduce the time needed to commercialize a generic drug.

By designing the programs to spread fees across multiple stakeholders and sources to keep individual amounts as low as possible, the programs will help assure that American consumers continue to receive the significant cost savings from generics that, over the past dozen years, have provided more than $1 trillion in savings to the nation's health care system.

Additional Measures are needed to Ensure Access to Affordable Medicines

It is important to emphasize that the funding provided by both of these user agreements is in addition to, not a substitute for, Congressional appropriations. And while the programs provide an excellent framework for industry to help support the growing global needs of FDA and speed the entry of generic drugs to market, they do not completely solve the problem. As the user fee legislation moves forward, we urge Congress to address additional areas — currently outside the scope of the user fee acts — that would further increase access to safe and effective generic medicines.

For example, a concern related to Hatch-Waxman that warrants Congress' attention involves the law's "Section viii" process. Under a federal court's interpretation of current law, brand-name drug manufacturers are able to block generic competition by providing the FDA with misleading and overbroad descriptions of their patents.

While "Section viii" allows generic manufacturers to market their products for FDA-approved uses not covered by any patent, brand manufacturers have circumvented this process by changing their product's "use code" — a description of the patent required to be filed by the FDA. Because the FDA is not institutionally equipped to question brands' use codes by reading their patents, the agency has had no choice but to deny the approval of generic competition in such cases. And the Federal Circuit held that there is no judicial remedy for the problem. Though the U.S. Supreme Court is now considering reversing that ruling, clarity of the legislative language is needed and would be beneficial even if the appellate ruling is overturned.

Additionally, as noted previously, GPhA strongly supports the unprecedented steps taken in GDUFA to ensure that all contributors to the U.S. drug system, both foreign and domestic, are held to the same quality standard.

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 can be 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 facilities that have never had an inspection or that have a history of compliance issues.

GPhA recommends that Congress adopt a federal drug tracking system with uniform standards across all states. Given that products are distributed throughout interstate commerce and across state lines, having multiple standards will be problematic. The challenge to implementation will be to ensure that the technology is reliable and feasible in light of numerous economic, technical and logistical factors, so that the end product delivers patient safety and does not result in increased costs to consumers and payers.

As a member of the Pharmaceutical Distribution Security Alliance (PDSA), a multi-stakeholder group working to develop a national model for drug tracking, GPhA, in consensus with other supply chain partners, supports the RxTEC model, which will increase patient safety and help to achieve the goals we share with the FDA.

We believe this model will help prevent the introduction of counterfeit drugs, facilitate their identification, provide accountability for the movement of drugs by supply chain participants and improve the efficiency and effectiveness of recalls. Establishing a national uniform drug tracking system, as opposed to a system based on a patchwork of state laws and regulations, is critical to achieving these goals.

Conclusion

In conclusion, Mr. Chairman, this truly is an historic time for GPhA. The user fee proposals are the culmination of months of negotiations between FDA and industry, and the final product as transmitted to Congress represents a careful balance among all the stakeholders involved. We respectfully urge the Committee to approve GDUFA and BSUFA as negotiated by FDA and industry, without any changes to the underlying agreements. It is also vital that the agreements be approved in a timely manner so that patients, the FDA, and generic manufacturers can begin to see the many benefits of these agreements. Nothing is more important to our industry than ensuring patients have access to the lifesaving generic medications they require, and these historic agreements provide a critical step toward accomplishing this goal. Thank you and I would be happy to address any questions you may have.