

SUMMARY OF THE GENERIC PHARMACEUTICAL ASSOCIATION TESTIMONY
BEFORE THE ENERGY AND COMMERCE SUBCOMMITTEE ON HEALTH
UNITED STATES HOUSE OF REPRESENTATIVES - FEBRUARY 9, 2012
“REVIEW OF THE PROPOSED GENERIC DRUG AND BIOSIMILARS USER FEES AND FURTHER
EXAMINATION OF DRUG SHORTAGES”

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, manufacturers and distributors of bulk pharmaceutical chemicals and suppliers of other goods and services to the generic industry. Generic pharmaceuticals fill 78 percent of the prescriptions dispensed in the U.S. but consume just 25 percent of the total drug spending.

Landmark User Fee Programs Will Provide Additional Resources

Currently, more than 2,000 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. The Generic Drug User Fee Act (GDUFA) will help alleviate the backlog and expedite consumer access to generic drugs, while also enhancing drug quality and safety. FDA will receive \$299 million per year over the five-year GDUFA program, or about \$1.5 billion in total. The new user fee program will also establish performance goals for the FDA. The agreement’s performance goals call for FDA to complete, by the end of year five, the review of 90 percent of all ANDAs that are pending on October 1, 2012 — effectively eliminating the current application backlog. 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. GDUFA also 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 API and finished dosage form manufacturers involved in each generic drug product sold in the U.S.

The Biosimilars User Fee Act will benefit both patients and industry by providing a higher degree of certainty in the timeliness of application reviews. The program creates a separate review platform for biosimilar sponsors that will be jointly financed annually by industry and the FDA through \$20 million in Congressional appropriations and then supplemented by user fees equivalent to those under the Prescription Drug User Fee Act. The program’s performance goals call for FDA, 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.

Addressing the Drug Shortage Crisis

GPhA is committed to working with the FDA and all stakeholders to minimize current drug shortages and prevent future shortages from occurring. Causal factors of drug shortages are numerous and do not apply in every case. They include everything from an insufficient supply of available raw materials, to increasing consumer demand, to decreasing available capacity, to inadequate and delayed communications about shortages — all within the supply chain and also within and among the FDA’s enforcement and drug shortages personnel. The manufacturing community has been extremely visible in working with all stakeholders, especially the FDA, to find suitable solutions that accelerate the availability of critical drugs in short supply. A group of generic manufacturers, including both GPhA and non-GPhA members, that represent approximately 80 percent of the generic sterile injectable products sold in the U.S. today, are proposing the **Accelerated Recovery Initiative (ARI)**, which is a private sector solution that is predicated on voluntary communication between stakeholders in the manufacture and distribution of generic injectable drugs in shortage.

Supply Chain Security

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. GPhA recommends that Congress adopt a federal drug tracking system with uniform standards across all states. As a member of the Pharmaceutical Distribution Security Alliance (PDSA), 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.



TESTIMONY OF DAVID GAUGH, R.PH.

VICE PRESIDENT FOR REGULATORY SCIENCES

GENERIC PHARMACEUTICAL ASSOCIATION

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Good morning Chairmen Pitts and Upton, Ranking Members Pallone and Waxman and Members of the House Energy and Commerce Subcommittee on Health. Thank you for inviting me to testify before your subcommittee on these very timely and important subjects.

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, 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 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 \$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. Though I am just beginning my time at GPhA, I have worked in and around the generic industry for more than two decades and 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 and continual efforts to address drug shortages we are discussing today, represents only a small measure of our ongoing collaboration.

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 safety and access to 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 the plate to help provide the FDA with resources to address the ongoing challenges caused by an increasingly global drug supply, the increase in the agency's workload and the regulation of new and complex technologies.

Throughout much of the last 12 months, 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 in this global age and 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 2,000 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, 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 down drug prices 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, also 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 important to emphasize that the funding provided by GDUFA is in addition to, not a substitute for, Congressional appropriations. And while the program provides an

excellent framework for industry to help support the growing global needs of FDA, it does not completely solve the problem. 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.

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, albeit with a portion of the application fee paid during the biosimilar development phase to support earlier resourcing for product reviews. Similar to GDUFA, the program also includes performance goals for the FDA, which call 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 the plate to do our part to help insure 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.

Addressing the Drug Shortage Crisis

GPhA believes strongly that the collaboration between industry, the FDA and other stakeholders shown during the development of the user fee programs should serve as a model for other areas, in particular as we work to eliminate existing shortages of critical drugs and minimize the potential for future shortages.

As members of the public who also are affected by shortages, the generic pharmaceutical industry is acutely aware of the distress caused to patients, families and clinicians by the shortage of critical drugs. Drug shortages represent a complex, multi-faceted issue and our industry has, and will continue, to work tirelessly to be part of the solution.

Before examining how best to respond to drug shortages it is important to understand why they are occurring. Contrary to some media reports, drug shortages are typically not caused by a manufacturer's decision to voluntarily discontinue supplying the product, and manufacturers do not — and would never — deliberately reduce the supply of essential medicines to push prices up. There can be no question that generic manufacturers are in the business of supplying quality medicines and assuring that consumers and patients have access to the drugs they need.

Causal factors of drug shortages, rather, are numerous and do not apply in every case. They include everything from an insufficient supply of available raw materials, to increasing consumer demand, to decreasing available capacity, to inadequate and delayed communications about shortages — all within the supply chain and also within and among the FDA's enforcement and drug shortages personnel.

GPhA also acknowledges that while factors contributing to drug shortages are many and complex, roughly half of the reported shortages have been attributed to difficulties associated with the manufacturing and release of generic sterile injectable products.

The manufacturing community has been responsive to this issue and has been extremely active in working with all stakeholders, and especially the FDA, to find suitable solutions that accelerate the availability of critical drugs in short supply.

Collaboration Among Stakeholders is Needed

GPhA also believes it is critical that generic manufacturers, and all stakeholders, continue to work together in an effort to solve the problem. As an industry whose entire business model is to make quality medicines available and affordable to all, we are acutely aware that a lack of supply of a critical drug can be devastating, even if it impacts only one patient.

With this in mind, the generic pharmaceutical industry has spearheaded the development of an unprecedented multi-stakeholder tool, which we believe will accelerate the recovery of certain critical drugs in short supply to patients in need. This proposal, which we have labeled the Accelerated Recovery Initiative, or ARI, can be utilized by all stakeholders involved in the manufacturing and distribution of vulnerable drugs in shortage — including, but not limited to manufacturers, wholesalers, distributors, Group Purchasing Organizations (GPO's) and the FDA — in order to accelerate the recovery of critical drugs in short supply to patients in need. In addition, this multi-stakeholder approach will provide additional information to focus on decisions and actions proposed by regulatory agencies and their potential impact on critical supply.

Accelerated Recovery Initiative (ARI)

The goal of ARI is to put in place industry practices that provide a more accurate, timely and comprehensive view of the current drug shortage situation, provide greater visibility to potential shortages solutions and establish practices that allow for potential, voluntary production adjustments to lessen or eliminate the impact of a current shortage. Given that over 200 products are currently identified by the FDA Drug Shortage staff, the initial scope of the initiative will focus only on those products deemed most critical, sterile generic injectable products. We will continue to fine tune the inclusion criteria with a focus on products that have few manufacturing options and no therapeutic alternative.

As I noted, this initiative is predicated on voluntary communication between an independent third party and stakeholders involved in the manufacturing and distribution of generic injectable drugs in shortage. In addition, this multi-stakeholder approach will provide additional information focusing on real time decisions and actions proposed by regulatory agencies and their potential impact on critical supply.

In order for this type of initiative to work, each stakeholder involved in the manufacture, supply and distribution of critical drugs in shortage that is willing to participate will communicate necessary information to the independent third party and the FDA Drug Shortage staff. Safeguards will be put in place to ensure that market and manufacturing information is treated with appropriate care.

Further, this initiative will not limit or restrict competition, and will not in any way deal with pricing information. It will also require prior approval by the Federal Trade Commission and the Department of Health and Human Services.

The primary focus of the ARI is to gather the current and future supply information from stakeholders for those products identified as meeting the critical criteria. This will then be used to determine current and potential supply gaps, with a focus on those products where a shortage is expected to last longer than 90 days. This type of information will increase early visibility and communication between the FDA and industry relating to current and potential drug shortages.

Under the ARI, the impartial third party will gather and disseminate the supply information in compliance with all current market regulations and under terms of strict confidentiality. This independent third party will be supplied with data from manufacturers related to drugs currently in shortage or expected to go into shortage, including the name of the drug, the expected duration of the shortage and internal reviews of a product's production and release data to identify production capabilities that will allow us to respond to any market shortage. Wholesalers and distributors will also supply current product availability data to assure a complete review of all available inventories in their pipelines.

The independent third party will then aggregate the data to provide an overall view of the projected available supply by product, as defined by critical product criteria, compared to the total market need. If the data reveals gaps in market supply that require FDA intervention, the information will be provided by the independent third party to the FDA Drug Shortage staff so that they may help to develop solutions with the manufacturers.

In addition, GPO's also have an important role to play. Their focus will be to assure that timely and accurate information is readily available between all affiliated members, institutions and customers, and the independent third party.

The last step of ARI focuses on FDA. The agency deserves tremendous credit for the work it is currently doing to expedite regulatory reviews and work closely with manufacturers. However, there is still more that must be done, and manufacturers would be aided by a formal process specifically designed to facilitate communications related to drug shortage regulatory issues.

The formation of a FDA drug shortage management team could more effectively address current drug shortages and minimize future shortage events. The industry strongly encourages the establishment of this high-level FDA drug shortage management team, which would include representation from key agency offices; the FDA's Center for Drug Evaluation and Research medical staff, Office of Compliance, Drug Shortage staff and Office of Regulatory Affairs.

This team would provide an avenue for timely access to FDA decision makers by the pharmaceutical industry to review strategies for addressing or averting drug shortages. This high-level FDA team could provide the expertise and the appropriate level of authority to effectuate rapid decisions on steps to address drug shortages by being empowered to evaluate issues such as expediting reviews of pending supplements, which enable industry to address shortages of critical drug products.

Our industry is currently working with FDA and other stakeholders to implement the ARI in parallel with our other recommendations in order to increase the channels of communication and strengthen our collective ability to supply patients with the medicines they critically need.

Supply Chain Security

Finally, as we work to resolve these shortages of critical drugs and prevent future shortages from occurring, I would also like to mention briefly the vital importance of securing the supply chain that patients rely on to provide them with these medications.

GPhA and our member companies 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. 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.

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 a historic time for GPhA. The two user fee proposals now before the Committee will shape the future of our industry for years to come. And the unprecedented level of collaboration between industry, the FDA and other stakeholders that it took to reach these agreements will continue to serve us well as we work to minimize current drug shortages and prevent future shortages from occurring. Nothing is more important to our industry than ensuring patients have access to the lifesaving generic medications they require, and with a joint effort among all involved, we believe we can continue to make significant steps toward accomplishing this goal. Thank you.