

SUMMARY OF THE GENERIC PHARMACEUTICAL ASSOCIATION TESTIMONY
BEFORE THE ENERGY AND COMMERCE SUBCOMMITTEE ON HEALTH
UNITED STATES HOUSE OF REPRESENTATIVES – APRIL 18, 2012
“FDA USER FEES 2012: HOW INNOVATION HELPS PATIENTS AND JOBS”

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 80 percent of the prescriptions dispensed in the U.S. but consume just 27 percent of the total drug spending.

Today’s generic industry is one marked by diverse, innovative companies, who have grown to become global leaders both in providing equivalent medicines and pioneering new treatment options for patients. Generic competition also continues to play a vital role in driving pharmaceutical innovation. This growth in the generic industry has led to the creation of tens of thousands of new jobs across the country. We urge the Committee to approve Generic Drug User Fee Act (GDUFA) and Biosimilar User Fee Act (BSUFA) as negotiated and in a timely manner, so that patients, the FDA, and generic manufacturers can begin to see the many benefits of these agreements.

Landmark User Fee Programs Will Provide Additional Resources

Through the negotiation of GDUFA, the generic industry has stepped up to help provide the FDA with much-needed additional resources. GDUFA will help ensure U.S. drug safety, establish a more level playing field among the U.S. pharmaceutical supply chain, and make certain that Americans receive timely access to safe, effective and affordable generic drugs. Currently, more than 2,700 generic drug applications, or Abbreviated New Drug Applications (ANDAs), 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. GDUFA’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 also 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 sold in the U.S.

Biosimilar User Fee Act

BSUFA 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.

Additional Measures are needed to Ensure Access to Affordable Medicines

Drug Shortages – GPhA supports the proactive reporting and expedited review measures in the previously released discussion draft.

Forfeiture – GPhA urges the inclusion of the forfeiture proposal introduced by Rep. Pallone and Rep. Guthrie, the Generic Drug Application Review Fairness Act of 2012.

Supply Chain Security – GPhA supports a risk-based model for foreign inspections and urges the inclusion of the RxTEC drug tracking model outlined by the Pharmaceutical Distribution Security Alliance (PDSA)

Antibiotics - GPhA supports appropriate efforts to increase incentives to develop new novel antibiotics but has concerns regarding the increased filing moratorium in the previously released draft.



TESTIMONY OF DAVID R. GAUGH, R.PH.

VICE PRESIDENT FOR REGULATORY SCIENCES

GENERIC PHARMACEUTICAL ASSOCIATION

**FDA USER FEES 2012: HOW INNOVATION HELPS PATIENTS
AND JOBS**

BEFORE THE ENERGY AND COMMERCE SUBCOMMITTEE ON HEALTH

UNITED STATES HOUSE OF REPRESENTATIVES

APRIL 18, 2012

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 your subcommittee on this very timely and important subject.

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 27 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. 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.

Today's generic industry is one marked by diverse, innovative companies, who have grown to become global leaders not only in providing equivalent medicines, but in pioneering new treatment options for patients. At the same time, generic competition continues to play a vital role in driving pharmaceutical innovation. New life saving medicines can only help patients if they have access to them, and this is made possible through the savings generics create both directly and indirectly by bringing down the total drug costs for every household.

Since the enactment of the Hatch-Waxman Act, which created the modern day generic industry, there has been a multiple-fold increase in the innovation of new drugs — including the cholesterol drugs Lipitor and Zocor, antidepressants Prozac and Paxil, and antiulcerants Prilosec and Nexium, among others — while at the same time an

increased use in generic drugs. By creating a fair balance between innovation of new medicines and accessibility to lower cost generic medicines, the legislation established a win-win-win system for providers, payers and consumers.

This dynamic will only heighten as the industry moves toward the development of new, complex technologies such as generic versions of biologic drugs, or biosimilars. As the Federal Trade Commission (FTC) concluded in its report "Follow-On Biologic Drug Competition", market competition from biosimilars actually will spur biologic innovation and the introduction of new medicines.

This growth in the generic industry has led to the creation of tens of thousands of new American jobs in dozens of states across the country. It 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 complex technologies.

Throughout much of last year, GPhA and our member companies worked closely with the FDA to negotiate a generic drug user fee program 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 program will make certain that all Americans receive timely access to safe, effective and affordable generic drugs, and will provide a level playing field for U.S. and foreign manufacturers.

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, 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. Any finished dose or active pharmaceutical ingredient manufacturing facility that is referenced or listed in a generic drug application — commonly referred to as an Abbreviated New Drug Application, or ANDA — will pay a facility fee under GDUFA.

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 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 of submission — 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. 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 believes that the FDCA should be amended to ensure that all facilities, foreign and domestic, are held to the same inspection frequency and prioritized on a risk basis.

This 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. It will also benefit foreign manufacturers, who are likewise disadvantaged through delayed approval times, as a recent inspection history is required for new product approval.

These important updates to the law will result not only in a safer drug supply with consistent oversight for all players in the U.S., but will also help reduce approval times of new drugs undergoing FDA review and help expedite the availability of new medicine, as all facilities will be subject to routine FDA inspection.

GPhA has also long-maintained that, in light of 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.

To that end, a critically important metric of the GDUFA program is that FDA will conduct risk-adjusted biennial current Good Manufacturing Practice, or cGMP, surveillance inspections of generic finished-dose and API manufacturers, with the goal of achieving parity of inspection frequency between foreign and domestic firms in FY 2017.

Achieving this inspection parity will provide significant value to industry participants, as the majority of outstanding inspections delaying ANDA approvals are associated with foreign facilities. These applications are currently disadvantaged by having to wait for an inspection before approval.

Further, the disparity in the degree of oversight experienced by domestic versus foreign facilities creates an uneven playing field between those that are receiving regular GMP inspections and those that are not. The GDUFA program will help ensure that any noncompliant players within the drug supply chain, wherever they are based, are identified in order to ensure the safety of drugs and protect the reputation of our industry around the world.

Through the novel and landmark generic drug user fee agreement, the generic industry has truly stepped up 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 program to spread fees across multiple stakeholders and sources to keep individual amounts as low as possible, the program 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.

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 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.

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. With this in mind, we urge the Committee to address additional

areas — outside the scope of the user fee agreements — that would further increase access to safe and effective generic medicines.

This is particularly true in regard to the Committee's important work to address drug 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.

The Committee's previously released discussion draft of the user fee legislation contains a proposal to formalize the process for proactively reporting drug shortages to the FDA — as many generic manufacturers now do voluntarily — and allow the FDA to expedite regulatory reviews. We believe this proposal would enable both the agency and industry to mitigate the damage a shortage can cause. We also applaud the inclusion in the discussion draft of a provision to expedite the review of major manufacturing changes in order to prevent or alleviate a drug shortage.

In conjunction with these efforts, the generic pharmaceutical industry is spearheading the development of an unprecedented multi-stakeholder collaboration, which we believe will accelerate the recovery of certain critical drugs in short supply to patients in need.

This solution, which we have labeled the Accelerated Recovery Initiative (ARI), is designed to provide a more accurate, timely and comprehensive view of critical drugs in drug shortage situation, provide greater visibility to potential shortages of these critical drugs and establish practices that allow for potential, voluntary production adjustments to lessen or eliminate the impact of a current shortage.

The ARI is predicated on voluntary communication between an Independent Third Party and stakeholders involved in the manufacturing and distribution of generic injectable medications currently in shortage. It is designed to use real-time supply and distribution information to give the FDA a better understanding of current conditions and expand the supply of critical medications.

This voluntary initiative will take place in conjunction with the excellent work currently being done by the FDA and members of Congress. The type of information gathered and disseminated will increase early visibility and communication between the FDA and industry relating to current and potential drug shortages.

We also urge the inclusion in the user fee legislation of a proposal introduced by Ranking Member Pallone and Representative Guthrie, H.R. 4332, the Generic Drug Application Review Fairness Act. As I mentioned earlier, the average approval time for a generic drug application is now stretching beyond 30 months, five times longer than the statutory six-month review time called for by the Hatch-Waxman Act. While GDUFA will help to lower this approval time to 10 months over the next five years, in the short

term this delay is causing certain generic manufacturers to forfeit the 180-days of market exclusivity period they would gain by successfully challenging a brand drug's patent.

This is happening because, under a provision included in the Medicare Modernization Act (MMA) of 2003, a first filer of a generic drug application must forfeit its 180-day exclusivity if it does not receive a tentative approval from the FDA within 30-months of the date its application is received. The intent of the provision was to encourage first filers to submit quality applications. If the application was not sufficiently complete to be eligible for approval upon review, it would have the threat of losing the 180-days of exclusivity.

When Congress passed MMA, the average review and approval time for an ANDA was 16 months. FDA median review and approval time of ANDAs, however, has slowly increased since 2003 and is now approximately 30 months. This unprecedented increase in approval time has caused several first filers to forfeit the 180-days of exclusivity, which was clearly not the intent of Congress. The proposed solution provides temporary relief from this unintended consequence by temporarily increasing the 30-month period to reflect the increase in median ANDA approval time in 2012. As GDUFA goes into effect, the average approval time for ANDAs will eventually be reduced. The proposal is therefore tied to the GDUFA timeline and will sunset at the end of 2017. Additionally, this relief would be available on a prospective basis only and would only apply to those first-to-file applications that have not hit their 30 months from

filing date at the time of enactment. By providing this temporary relief, the legislation will ensure that generic manufacturers can continue to challenge patents and bring generic drugs to the market sooner.

As this user fee legislation moves forward, GPhA also respectfully urges the Committee to consider including a measure to ensure the security of the U.S. pharmaceutical supply chain.

As noted previously, we strongly support 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 follows the model established by GDUFA. This model prioritizes inspections according to an establishment’s inspection, safety and compliance track record and whether an establishment is associated with ANDAs that are otherwise approvable, or eligible for tentative approval, except for an outstanding inspection. Establishments associated with ANDAs that have not been inspected previously, as well as facilities in need of a recent inspection history, also would gain priority.

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, unless awaiting an inspection for an application approval, 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 also 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.

Finally, I would like to note briefly our concerns with the Committee's proposal in the previously released discussion draft to incentivize new antibiotic development.

GPhA supports appropriate efforts to increase incentives to develop new novel antibiotics. Market exclusivity is a powerful tool, however, that Congress should judiciously use as an incentive to spur the development of new products. An increase in market exclusivity for specific classes of drugs is a slippery slope and prioritizes certain medical conditions over others.

Moreover, an increase in market exclusivity for certain classes of drugs could have the unintended consequence of pharmaceutical manufacturers overly focusing efforts on those classes of drugs that have larger market exclusivity periods at the expense of developing new cures for other diseases that have shorter market exclusivity periods.

GPhA has always been supportive of ensuring that innovator companies receive an appropriate amount of time to recoup their investment into research and development. The 10 years of market exclusivity that this bill affords accomplishes this balance. However, we must also be mindful of the public health aspect of antibiotics. Thus, it is important that Congress strike a delicate balance between affording market exclusivity to manufacturers and providing patients timely access to low-cost generic versions of these products. Increasing the filing moratorium to nine years, which, due to an

automatic 30-month stay and the likely six months of exclusivity for pediatric testing, would represent a de facto 12 years of market exclusivity, overlooks this balance.

Additionally, Hatch-Waxman, the Orphan Drug Act, and the Biologics Price Competition and Innovation Act all have four-year filing moratoriums. Increasing the filing moratorium for novel antibiotics to nine years would create a new and separate filing standard solely for this specific class of drugs.

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.