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TREATING THE OPIOID EPIDEMIC: THE STATE OF COMPETITION IN THE MARKETS FOR ADDICTION MEDICINE

BEFORE THE HOUSE JUDICIARY SUBCOMMITTEE ON REGULATORY REFORM, COMMERCIAL AND ANTITRUST LAW

UNITED STATES HOUSE OF REPRESENTATIVES

SEPTEMBER 22, 2016

I am David Gaugh, Senior Vice President for Sciences and Regulatory Affairs at the Generic Pharmaceutical Association and a licensed pharmacist. GPhA is the nation's leading trade association for manufacturers and distributors of generic medicines. GPhA's core mission is to improve the lives of patients and the U.S. healthcare system by advancing timely access to affordable generic medicines. Generic pharmaceuticals fill 88 percent of all prescriptions dispensed in the U.S., but consume just 28 percent of the total drug spending for prescription medicines.

Introduction

I would like to begin by commending the Committee for your continued focus on the important issues we will examine today. I have worked in and around the generic industry for more than three decades and have witnessed firsthand the industry's remarkable growth and the vital role it plays in the lives of Americans every day.

GPhA is strongly committed to addressing the misuse of prescription medication and improving treatment options for patients suffering from addiction. We understand that the current treatments for people with life-threatening addictions are nothing short of miraculous, and should be within reasonable financial reach of any patient suffering from addiction. We are committed to combating drug abuse at every level of the health system, including supporting community anti-drug coalitions, encouraging safe disposal of unused drugs, and through the development of abuse deterrent drug formulations.

A key part of this response includes ensuring the availability of high quality, low-cost generic drugs for the treatment of addiction; and I commend you for your attention to this issue.

As a representative of GPhA, I am here to discuss our organization's conviction that the best way of achieving the goal of providing patients access to these lifesaving treatments is through the development of policy that promotes robust, competitive markets. As GPhA is a trade association representing multiple competing generic manufacturers, we focus entirely on promoting the common interests of our members and the general welfare of the generics industry through policy processes. As such, we are not privy to member company information about their individual products or any pricing decisions around those products. Those decisions are made internally by each company, and GPhA has no knowledge about them beyond what is in the public domain.

We can however provide some insight to what we believe is the proven solution to rapidly inflating brand prices: competition. For more than three decades, the generics industry has demonstrated that direct competition in the pharmaceutical marketplace lowers costs and increases patient access. There are a number of ways policymakers can encourage competition and ensure that millions of patients will continue to have access to safe, effective, and affordable medicines.

In order to best illustrate that point, we believe the best way to show how access to generics is achieved is to explain the market and regulatory framework for generics, which differs significantly from the branded drug industry.

Savings From Competition

Competition from and among generic drugs drives savings and access, not costs. As drug cost issues recently have been at the forefront of policy issues, a variety of healthcare stakeholders have examined the role of generics and found a trend of overall price decreases. Before addressing the specific mechanisms that have been developed to create competition in the pharmaceutical marketplace, it is worth noting that it is not just GPhA calling for greater competition. Stakeholders throughout the healthcare environment recognize the value generics and biosimilars bring to patients. Competition works, and voices throughout the patient community, drug supply chain, and federal government are recognizing it.

- Just last week, the Government Accountability Office (GAO) published a report examining generic drug pricing in Medicare Part D. The report echoes the findings of multiple previous independent reports – that generic drug prices continue to decrease. Specifically, the GAO reports that between 2010 and 2015 generic drug prices in Medicare Part D declined by 59%.[1]

- In January 2016, the Department of Health and Human Services (HHS) Office of the Assistant Secretary for Planning and Evaluation (ASPE) released a comprehensive report, Understanding Recent Trends in Generic Drug Prices, which concluded, "Our review of evidence strongly supports the conclusion that generic drug prices are not an important part of the drug cost problem facing the nation." The report also found that "about two-thirds of generic products appear to have experienced price declines in 2014."[2]

- The Seventh Annual Generic Drug Savings in the United States report compiled by the IMS Institute for Healthcare Informatics on behalf of GPhA, generic drugs accounted for 88% of all prescriptions dispensed in the U.S., but equaled only 28% of total drug spending.[3]

- Express Script's 2015 Drug Trend Report[4] found that generic drug prices were 19.9% lower than a year earlier whereas brand drug prices were 16.2% higher. An index of commonly used generic drugs shows prices decreased by

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[1] *Generic Drugs Under Medicare: Part D Generic Drug Prices Declined Overall, but Some Had Extraordinary Price Increases.* GAO-16-706: Published: Aug 12, 2016. Publicly Released: Sep 12, 2016. http://www.gao.gov/products/GAO-16-706

[2] *Understanding Recent Trends in Generic Drug Pricing*. Office of the Assistant Secretary for Planning and Evaluation, January 2016. https://aspe.hhs.gov/sites/default/files/pdf/175071/GenericsDrugpaperr.pdf

[3] *Generic Drug Savings in the U.S. Seventh Annual Edition: 2015*. Generic Pharmaceutical Association, October 2015. http://www.gphaonline.org/media/wysiwyg/PDF/GPhA_Savings_Report_2015.pdf

[4] *Drug Trend Report*. Express Scripts, 2016. http://lab.express-scripts.com/lab/drug-trend-report

more than 70% from January 2008 through December 2015. During that same period, a brand drug price index increased in price by 164%.

- Another recent report[5] from AARP found that retail prices for generic drugs fell an average of 4% in 2013, marking nearly a decade of consecutive years of decreasing generic drug costs. The annual retail price decreased for 203 (73 percent) of the 280 most widely used generic drug products.

Looking forward, biosimilars present the same opportunity for high-cost specialty medicines. As more biosimilar drug applications are reviewed and approved by FDA, such products have the potential to save patients, insurers and the government billions of dollars each year in treatment costs. Estimates from various economic impact studies pin the projected savings from $42 billion on the low end to as high as $250 billion over the first 10 years of biosimilar market formation.

Taken together, and with other important studies, these data show that competition in pharmaceutical markets is effective, and that competition is fueled by the legal and regulatory framework that shapes the market.

The Hatch-Waxman and BPCIA Framework

For over 30 years, the foundation that has allowed the competitive market to work has been the Drug Price Competition and Patent Term Restoration Act, commonly referred to as "Hatch-Waxman," which was signed into law in 1984.[6] The law effectively established the modern generics industry by creating the abbreviated regulatory approval pathway for generic products, while simultaneously providing lucrative incentives for brand manufactures to continue to bring new treatments to the market.

Prior to enactment, manufacturers who wanted to compete with a brand product were forced to prove the safety and efficacy of their product in a very similar manner to the original brand product. Hatch-Waxman created a new "abbreviated" pathway that allows generics to instead demonstrate that they are the "same" as their branded reference product. By demonstrating sameness, generic drugs become eligible for automatic substitution at the pharmacy level, ensuring patients receive the most affordable treatment while also guaranteeing equivalent safety and effectiveness.

The law also created opportunities for generic manufacturers to challenge brand patents that they believed were improperly granted, artificially extending brand monopolies and costing patients. Generics are incentivized to invalidate those patents by receiving a short period of statutorily allowed time as the sole

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[5] *Trends in Retail Prices of Prescription Drugs Widely Used by Older Americans, 2006 to 2013*. February 2016. http://www.aarp.org/content/dam/aarp/ppi/2016-02/RX-Price-Watch-Trends-in-Retail-Prices-Prescription-Drugs-Widely-Used-by-Older-Americans.pdf

[6] 21 U.S.C. §355

competitor to the brand. As a counterbalance to that system, brands are also given valuable protections such as patent life extensions and guaranteed periods of market exclusivity in order to ensure that true innovation is properly rewarded.

In 2010, Congress passed the Biologics Price Competition and Innovation Act (BPCIA), which codified a new abbreviated pathway for new innovative medicines that were too complex to easily function under the old Hatch-Waxman framework. The new law provides biosimilar manufacturers and the FDA with a new standard of "biosimilarity" which requires biosimilar developers to show that they are highly similar to their reference product and that they have the same safety, purity, and potency as the original. While this initial biosimilarity determination does not allow for automatic substitution as expected in the generic industry, manufacturers can pursue an interchangeability designation by demonstrating the product has the same clinical effects in all patients and would not change outcomes in the event of switching between manufacturers. Interchangeable biosimilars are eligible for substitution by the pharmacist, in line with their state pharmacy practice laws.

The Generic Drug and Biosimilar User Fee Agreements

The overwhelming success of Hatch-Waxman in promoting a robust generics industry ultimately led to the approval of over 14,000 generic applications. With that incredible volume, however, came complications in FDA's ability to efficiently and effectively review the numerous generic applications being submitted every month. By 2011 there were over 2,700 generic applications pending at FDA and average approval times had begun to exceed 30 months, while Hatch-Waxman had never envisioned reviews taking longer than six.

In order to alleviate the burden on FDA, and begin to expedite generic approvals, the generic industry negotiated and agreed to the first-ever Generic Drug User Fee Program (GDUFA) in 2012. Since the approval of GDUFA, generic manufacturers have paid over one billion dollars in user fees to the FDA for the purposes of hiring and training new staff, updating outdated IT systems, increasing the manufacturing facility inspections necessary to grant approvals, improving the technical specifications of FDA's quality standards, and many other vital agency initiatives. Unfortunately, four years later, the number of pending generic applications has now ballooned to over 4,000 while median approval times exceed 45 months.

Nonetheless, there have been significant achievements under the GDUFA program. FDA has hired and begun to train over 1,000 new employees intended to increase its efficiency in reviewing generic applications, and it has issued a number of critical guidances providing insight into the data necessary in the approval of an applications. These are important steps forward, and we intend to continue to work with FDA to ensure it has the resources it needs to meet the GDUFA goals. We also will continue to seek sufficient clarity into the agency's approval process to ensure that generic manufacturers can submit applications that they reliably know meet the standards set.

Also included in the 2012 law was the inaugural Biosimilar User Fee Act (BSUFA), which provided biosimilar developers with the opportunity to engage FDA early in the development process to develop individualized applications that would meet the newly developing FDA standards. That process has led to 3 approvals thus far and over 50 biosimilar development programs being monitored at FDA.

Both GDUFA and BSUFA play an important role in giving follow-on manufacturers the opportunity to engaged with their regulatory overseer, and create accountability within the agency for meeting performance metrics that assure timely review of applications that leads to the earliest possible availability of affordable products for patients.

Portfolio Selection

The process by which generic and biosimilar manufacturers select which products they wish to pursue regulatory approval is a complex and highly confidential analysis. This calculation can include any number of variables that may come into play, including the complexity in reverse engineering the original product, the state of the intellectual property claimed by the brand manufacturer over the product, the size of the patient population served, the number of likely competitors for that product, the product development and manufacturing capabilities and costs.

Many of the largest generic manufacturers maintain portfolios of hundreds of different products that they manufacture and distribute throughout the country. Unlike brand manufacturers, who focus on a smaller number of high-margin products at any given time, generic manufacturers engage in a different type of portfolio management that is more similar to that of many other commodity markets.

Brand Abuses Delaying Patient Access to Generic Drugs

Generic and biosimilar manufacturers often face significant delay tactics from brand manufacturers looking to game the system in order prevent the massive loss of market share that follows the introduction of a competitive product.

Specifically, there are two major policy areas that directly impact generic manufacturers' ability to get through the initial development stages and reach the market at the earliest possible date:

1.) Abuses of patient safety programs, like the Risk Evaluation and Mitigation Strategies (REMS) programs to delay the development and approval of generic drugs; and
2.) Attempts by brand manufacturers to exempt themselves from scrutiny of their Intellectual Property (IP) by the US Patent and Trademark Office.

The Growing Use of Abusive, Anticompetitive Barriers to Generic Drug Development

In spite of current law that clearly forbids the use of a REMS program to block or

delay approval of a generic drug application, certain brand companies continue to use REMS and other restricted access programs to delay competition. They delay the development of generic drugs by denying generic and biosimilars manufacturers access to samples of branded drug products, which are required to conduct the bioequivalence studies necessary for FDA approval. They have even begun applying restricted access programs to drugs for which the FDA has not required a REMS program in order to delay generic entry.

According to a July 2014 study conducted by Matrix Global Advisors, the ongoing abuse of REMS and REMS-like programs costs the U.S. health system $5.4 billion annually – $1.8 billion to the federal government[7]. But such abusive practices affect more than just payers – they have a direct impact on the costs borne by patients.

These abuses are clearly anticompetitive, and have attracted the interest of the Federal Trade Commission, which argued in one case: "If successful, conduct of the type alleged in this case threatens to undermine the careful balance created by the Hatch-Waxman Act and potentially preserve a brand firm's monopoly indefinitely".[8]

FDA has also expressed its concerns. FDA Office of New Drugs Director Dr. John Jenkins called the abuse a "growing major problem" for FDA. He went on to say, "I think companies have really gone to the extent of kind of abusing the system, because the system was designed to try to ensure the safe use of the drug and now it's become an evergreening system for avoiding generic competition." He added, "The problem is use of REMS to block generic competition and the innovators have really become very aggressive in using that strategy and hiring the best lawyers to back up that strategy."[9]

Presently, two pieces of legislation are pending before Congress that would address these abuses. Congressmen Stivers (R-OH) and Welch (D-VT) have introduced H.R.2481, the FAST Generics Act; and Senators Leahy (D-VT), Grassley (R-IA), Klobuchar (D-MN) and Lee (R-UT) have introduced S.3056, the CREATES Act. While the two bills take different approaches, GPhA is encouraged that each of them directly tackle this growing barrier to generic drug competition and the success of the Hatch-Waxman Act. GPhA encourages the Committee to closely examine these bills and support legislation that would reform pre-approval restrictions on generic and biosimilar drug development. Such legislation must:

1. Ensure that generic and biosimilar drug developers have timely access to brand samples on market-based terms

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[7] Brill, Alex, *Lost Prescription Drug Savings from Use of REMS Programs to Delay Generic Market Entry*, Matrix Global Advisors, July, 2014.
http://www.gphaonline.org/media/cms/REMS_Studyfinal_July2014.pdf

[8] Brief of Federal Trade Commission on Actelion Pharmaceuticals v. Apotex, Inc., No. 1:12-cv-05743 (New Jersey District Court, Mar. 11, 2013).

[9] Gingery, Derrick. REMS That Block Generics Are 'Major' Problem For FDA, Jenkins Says. "The Pink Sheet" Daily. January 8, 2015.

2. Ensure that generic and biosimilar drug developers can enter into a brand's REMS program on fair and equitable terms without unnecessary delay or automatically be allowed to create a comparable (approved by FDA) REMS after a designated time
3. Ensure that the bill applies to REMS-covered drugs as well as brand drug manufacturers who self-impose restrictions on the sale or distribution of their product absent a direct FDA mandate.

Ensuring Appropriate Oversight of Intellectual Property

This Committee has also played a key role in recognizing the *Inter Partes Review* (IPR) process as a critical consumer protection against abusive patent activity in the prescription drug market. The IPR process is an important consumer protection against abusive patent extensions. It plays a vital role in quickly, efficiently and accurately clearing the system of weak patents -- including those that artificially prolong drug exclusivity provisions in order to delay competition from generics. The IPR holds great promise in reducing anticompetitive "evergreening" practices that drive up health care costs for consumers.

Unfortunately, brand manufacturers have sought to delay generic competition and extend their patent life by limiting the opportunity for the appropriate review and challenge of patents. These tactics run counter to the goals of promoting a viable and competitive health care market for consumers, small and large businesses, and taxpayers. As branded specialty drug costs continue to increase and outpace overall health care cost growth, any attempt to weaken a viable, administrative process that helps expedite patient access to more affordable medicines should be rejected.

The ability of generic and biosimilar manufacturers to utilize the IPR process to challenge patents plays a critical role in weeding out weak branded drug patents and bringing generics to market quickly. Proposals to carve out pharmaceuticals from the IPR process have been estimated to cost the federal government $1.4 billion over the course of the next decade.

The FDA Approval Process

Once a manufacturer has acquired the necessary product samples and navigated the various IP claims on any given product, it is still subject to regulatory review processes by FDA in order to ensure patient safety and outcomes. The process used by FDA for evaluating generic products is notably different from that of brand products. Generic and biosimilar manufacturers typically provide very different evidence to demonstrate their bioequivalence than the safety and efficacy studies conducted by brands.

In order to obtain approval, generics are required to provide bioequivalence studies to demonstrate sameness to the reference product. These products typically do not require any clinical trials like the ones used by brands as the drug has already been proven to be safe and effective. Certain "complex" products (I.E., inhalation, extended release, drug-device combinations, etc.) and biosimilars use

technologically advanced analytical analyses that provide in depth characterizations of the drug substance demonstrating their sameness to the original brand product. In addition to the analytical analyses package provided, complex generic and biosimilar manufacturers are required to provide clinical data to demonstrate that patients taking either the reference product or the follow-on product demonstrate the types of similar clinical outcomes that should be expected from the innovator products. Similar to brands, generic manufacturers are also subject to stringent regulatory standards and inspections to ensure their products are safe and effective.

Ultimately, the approval process leads to the issuance of a final generic label from the FDA that is identical to that of the original brand drug. The ability to maintain the same label between all generic products is a fundamental part of the system that promotes such high generic utilization rates among product classes that have seen generic entry. It assures patients and providers that the generic product they are getting will not produce any different result than the products they have grown accustomed to.

For that reason, we have significant concerns regarding a 2013 proposal from FDA to change the process for updating generic labels with new safety information. The proposal would allow for different labels among equivalent products, and likely cause significant confusion among patients and providers. Fortunately, the agency has to date been mindful of the wide range of stakeholders who have expressed similar concerns, including a number of members of this committee. We appreciate the committee's continued engagement on this issue, and hope that FDA will soon abandon this harmful proposal that will only harm competitive markets.

Conclusion

In conclusion, Mr. Chairman, and in light of the extremely complex competitive and regulatory forces that shape generic manufacturer behavior, GPhA continues to believe that the best way to control drug costs generally, whether that be in the drug addiction treatment market or otherwise, is through the promotion of policies that incentivize competition. There are clear opportunities for Congress to support greater development and availability of generic drugs. Specifically, Congress should act quickly to:

- Ensure a fully-resourced Food and Drug Administration (FDA) that can address the backlog of more than 4,000 generic drug applications and shorten FDA median generic drug approval timelines.
- Pass the bipartisan CREATES Act or the FAST Generics Act to curb some brand drug company abuses of FDA safety programs such as Risk Evaluation and Mitigation Strategies (REMS) used to keep generics off the market, an estimated savings of $2.4 billion - 3.2 billion over 10 years.

GPhA looks forward to continuing its work with Congress, the Food and Drug Administration (FDA) and others to accelerate access to safe, effective and more affordable generic drugs. Thank you and I look forward to taking your questions.