S. HRG. 109–685

THE GENERIC DRUG MAZE: SPEEDING ACCESS TO AFFORDABLE LIFE-SAVING DRUGS

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BEFORE THE

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UNITED STATES SENATE

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THE GENERIC DRUG MAZE: SPEEDING ACCESS TO AFFORDABLE LIFE-SAVING DRUGS

THURSDAY, JULY 20, 2006

U.S. SENATE,
SPECIAL COMMITTEE ON AGING,
Washington, DC.

The Committee met, pursuant to notice, at 10:04 a.m., in room SD–106, Dirksen Senate Office Building, Hon. Herb Kohl presiding.

Present: Senators Kohl, Smith and Clinton.

OPENING STATEMENT OF SENATOR HERB KOHL

Senator KOHL. We will call this hearing to order at this time, and we welcome our witnesses. As always, I thank our Chairman, Gordon Smith, for the opportunity to put this hearing together today.

We will examine today the bureaucratic and legal barriers that stop new generic drugs from entering the market and what we can do about it. This is of particular interest to this Committee as we work to help seniors cope with the high costs of prescription drugs.

But rising drug prices don't only harm the elderly; they hurt us all as they undermine our private and public health systems. Health insurance premiums continue to skyrocket in large part due to escalating drug costs. The Federal Government, with the new Medicare prescription drug benefit, also feels the squeeze.

Yet, the pharmaceutical industry, as you know, remains one of the most profitable industries in the world, returning more than 15 percent on investment. As a businessman myself, I respect an industry's right to maximize profits. Nevertheless, I believe they are charging Americans the highest drug prices in the world—that is almost beyond dispute—and forcing many employers to drop health coverage for their employees and squeezing the budgets of State and Federal Governments as well.

As we will examine in this hearing today, government needs to consider action if companies unfairly and or evenly illegally manipulate the private market. According to the CBO, generic drugs save consumers $8 to $10 billion every year. Just last week, this Committee heard from Richard Wagoner, the CEO of General Motors, who stated how important using generic drugs are in reducing General Motors' health costs.

General Motors employees and retirees substitute generic drugs for brand name drugs in 90 percent of the cases in which a generic exists, and this has come about, this 90 percent, because General Motors pushes it with such great energy. General Motors estimates

savings of $400 million every year as a result of using generic drugs.

So we need to find every possible way to get government, companies and individuals to emulate what General Motors has done. If we could do that, health care savings in this country as a result of using generic drugs could be astronomical. One way to make that happen is for Congress to monitor more closely and adequately fund FDA's Office of Generic Drugs.

Earlier this year, the FDA had a backlog of more than 800 applications to bring new generic drugs to the market. That was an all-time high. This backlog continues to grow as more brand drugs lose their patent protection. According to FDA guidelines, the agency should take no longer than 6 months to review a generic application, and yet the wait averages nearly 2 years.

We have been working with the FDA to reduce this time. Earlier this year, we were able to add $10 million for generic drug review at FDA in the Ag appropriations bill, and we hope to keep these dollars in conference. While increasing funding for this program is just step one, we are pleased that the Director of the Office of Generic Drugs is here today to outline steps two, three and four so that we get generics to pharmacy shelves much more quickly.

Since passage of the Drug Price Competition and Patent Term Restoration Act, commonly known as Hatch-Waxman, we have seen a wider availability of generic drugs with little effect on the profitability of drug manufacturers and their ability to do research and development. Unfortunately, some brand name pharmaceutical manufacturers have learned to circumvent Hatch-Waxman using litigation and other means to extend the life of patents and keep generics from entering the market.

Courts and the FTC have determined that some brand name drug manufacturers have even colluded with generic drug manufacturers to delay the marketing of competing generic products. One form of collusion is to use payoff settlements. A drug company that holds a patent on a blockbuster brand name drug will pay off a generic drug maker to delay the sale of a competing generic drug. So while the brand name drug company and generic manufacturer make out extremely well, consumers, as we can readily understand, can lose out.

The FTC has taken a strong stand against these types of payoffs, but they still flourish because of recent court rulings which allow back-room deals to occur. I have introduced bipartisan legislation to prohibit these payoffs. We hope to talk about this bill today, as well as other ways to address practices used by the drug industry to delay generic drug entry into the market. In our effort to cut down the cost of health care in this country, there is nothing more important than making sure that consumers, employers and governments have full access to affordable generic drugs.

So we look forward to this hearing today, and at this time I turn to our esteemed Chairman, Gordon Smith.

OPENING STATEMENT OF SENATOR GORDON H. SMITH, CHAIRMAN

The CHAIRMAN. Thank you, Senator Kohl.

Senator Kohl is our Chairman for this day. We have a relationship on this Committee that allows us to pass the gavel back and forth, and I want to thank Senator Kohl for his leadership on this issue. We jointly share a real concern about affordable prescription drugs.

Clearly, the biggest problem we have in health care today is just simply the skyrocketing cost that far outpaces overall inflation for other goods and services. In fact, from June 2004 to 2005, prices for health care grew at a rate double other types of consumer goods. Obviously, driving much of this growth in costs are prescription drugs. Prices for brand name prescription drugs have grown 4 percent since January of this year alone.

For some medications like the sleeping aid Ambien, increases have been in the double digits. Frankly, if this trend continues, drug therapies important to seniors will just simply be undermined. The gains we have achieved with the implementation of Medicare Part D will just simply be lost.

Generic drug alternatives do hold some promise in helping to provide consumers more affordable options. The CBO estimates that generic drugs save health care consumers $8 to $10 billion a year. With a number of popular brand name drugs soon going off patent, Americans and the Federal Government could save billions of dollars by choosing to purchase generic alternatives.

Such savings will only be realized if the drugs get to market in a timely manner, and as Senator Kohl has just indicated, we are very concerned about the practice of paying by brand to keep generics off the market. This is of great concern to us. Obviously, we want the market to work, but it is not working when it is done in that way.

So given the potential cost savings that could be gained by getting more generic drugs to market, Congress needs to carefully consider whether it is appropriately funding the FDA's approval activities. An even greater impediment to generic drug access is this practice of paying off. That simply needs to stop. As Senator Kohl noted, Congress is already taking steps to prohibit brand name drug companies from entering into these kinds of agreements so they can delay less expensive alternatives from coming to market.

So I look forward to learning more about this important topic and I appreciate very much the effort that our Committee is making on this. Senator Kohl has assembled an excellent group of witnesses today and I know they will provide us with useful information on this issue.

Senator KOHL. Thank you, Senator Smith.

We are very pleased to welcome our first panel here today. The first witness will be Gary Buehler. Mr. Buehler has been the director of the FDA's Office of Generic Drugs, Center for Drug Evaluation and Research, since July 2001. Besides working for FDA for the past 10 years, Mr. Buehler has compiled a great deal of experience with various aspects of the issues that we will be examining today. Mr. Buehler's testimony, I believe, will help us understand

some of the factors that slow the approval of generic drug applications.

After him, we will hear from Jon Leibowitz, who has been an FTC commissioner since 2004. Before joining the executive branch, Mr. Leibowitz served in a variety of different offices in the Congress, including my own as my chief counsel on Judiciary from 1989 to 2000. Additionally, he has prior experience on the U.S. Senate Antitrust Subcommittee as the Democratic chief counsel and staff director from 1997 to 2000. Mr. Leibowitz will discuss current efforts by the FTC to protect consumers from anti-competitive practices of the pharmaceutical industry.

We welcome you both here today and we look forward to your testimony.

Mr. Buehler.

STATEMENT OF GARY BUEHLER, DIRECTOR, OFFICE OF GENERIC DRUGS, CENTER FOR DRUG EVALUATION AND RESEARCH, FOOD AND DRUG ADMINISTRATION, ROCKVILLE, MD

Mr. BUEHLER. Good morning, Mr. Chairman and Ranking Member Senator Kohl. I am Gary Buehler, Director of the Office of Generic Drugs in the Center for Drug Evaluation and Research at the U.S. Food and Drug Administration. Thank you for the opportunity to testify about FDA's efforts to expedite the approval of generic drug products.

FDA understands that Congress and the public are concerned about the high cost of prescription drugs. Generic drugs play an important role in granting access to affordable products that will benefit the health of consumers and especially seniors. Generic drugs typically cost 50 to 80 percent less than their brand name counterparts, and prompt approval of generic drug product applications, also known as abbreviated new drug applications, or ANDAs, is imperative in making generic products available to American consumers at the earliest possible date.

FDA has taken a number of significant steps to provide greater access to affordable prescription medicines. In 2003, FDA published a final rule to improve access to generic drugs and lower prescription drug costs for millions of Americans. This rule was first proposed in response in part to FTC recommendations and other changes that the agency identified as being useful in improving generic competition.

The rule limits an innovator drug company to only one 30-month stay of a generic drug applicant's entry into the market for resolution of a patent challenge. These changes will save Americans over $35 billion in drug costs over the next 10 years, and will also provide billions in savings for the Medicare and Medicaid programs. We were pleased that elements of this rule are prominent in part of the Medicare law, and that with FDA's technical assistance, the law added additional mechanisms to enhance generic competition in the marketplace.

In addition, since fiscal year 2001, the administration and Congress have increased funding for FDA's generic drug program by 66 percent—a clear sign of the important role played by the Office of Generic Drugs. These increases have enabled FDA to hire addi-

tional expert staff to review generic drug applications more quickly and initiate targeted research to expand the range of generic drugs available to consumers.

While there remains work to be done, as I will discuss, we have been able to produce significant reductions in approval times for generic drugs since 2002. These reductions, coupled with changes to reduce the time for developing generic drugs and making them available, will save consumers billions.

Much concern has been raised from the public and Congress about a backlog of pending ANDAs currently under OGD review. OGD generally maintains a first in, first reviewed policy for ANDAs to ensure the integrity of the approval process. A number of factors govern the timing of generic drug approvals, including whether the application is of high quality, meets the inspection standards and the scientific and technical requirements for approval, and whether patent protection and exclusivity periods have expired on the innovator drug.

Over the last 5 years, the number of applications submitted to OGD has increased by 150 percent, which is shown in detail on the graph to my right. The receipts are in yellow and the tentative approvals are in green. You can see the receipts from 1995 through 2001 remained at around 300. They were very, very static at that point. In the year 2002, they increased to 364, and continued to increase in 2003 to 449; in 2004, 563, and then in 2005, 766 applications. This year, since we are three-quarters of the way through the year, I can report that we expect to receive almost 800 applications for generic drug applications by the end of September.

Just last month, we approved 45 applications, but received 92. Clearly, this rate of increase in applications resulted in a dramatic increase in the workload. It is important to stress that the ANDAs in the backlog are not all unreviewed, but may be applications that have had an initial review and are now waiting a second or subsequent review of the company's attempts to satisfy our approval requirements.

Although OGD still has a backlog, the graph demonstrates that we have managed to increase the number of approvals each year, and in 2001 OGD approved or tentatively approved 310 ANDAs, and this number increased to 467 in fiscal year 2005. OGD's efforts are also evident when looking at the median approval time. The median approval times have decreased from the 18.4 figure in fiscal year 2001 to 16.3 months in fiscal year 2005. Some of these applications were approved in less than a year.

FDA has taken significant steps to improve our resources. With additional resources each year, FDA has increased its generic drug FTE positions from 134 in fiscal year 2001 to 201 in fiscal year 2006. In addition, OGD has taken actions to streamline the ANDA review process, which includes addition of a third chemistry review division and a fifth review team in OGD's division of bioequivalence. Also, a number of new review practices have been implemented to improve interactions with the generic drug companies. Other new efficiencies to the application review process are described in detail in my written statement.

Because of these efforts, on the very day that the last patents or exclusivities expire on an innovator product, OGD has been able to

approve at least one generic application in most cases. Recently, FDA approved applications for generic versions of the popular brand names Pravachol, Zoloft and Zocor on the day the innovator protections expired. Just yesterday, OGD approved 13 applications for Meloxicam, the generic equivalent for Mobic, a popular analgesic used for osteoarthritis. These applications were approved in just over 9 months from the date they were submitted. The approvals of these four products should produce savings measured in the billions of dollars per year. We will work to continue our success in staying ahead of the curve on first-time generics and responding to all pending applications.

An issue of particular focus in OGD is streamlining the citizen petition review process. Citizen petitions may be submitted at any time, requesting FDA to impose new criteria for approval of ANDAs. These petitions often make serious challenges to whether or not a generic product can be approved; that is, whether a specific application or group of applications would meet the statutory requirements for approval.

FDA must consider and address the merits of the challenges to generic drug approvals. It is not required that FDA respond to citizen petitions before approval of a related ANDA, and it is very rare that petitions present new issues that CDER has not fully considered. But the agency must nevertheless assure itself of the fact by carefully reviewing these citizen petitions.

A high percentage of the petitions to OGD are denied. While the citizen petition process is a valuable mechanism for the agency to receive information from the public, it is noteworthy that very few of these petitions on generic drug matters have presented data or analyses that significantly altered FDA's policies. CDER's recent efforts to improve the process for responding to citizen petitions are described in detail in my written statement.

An issue garnering discussion among many stakeholders is that of authorized generics. The term "authorized generic" is generally used to describe an instance when an innovator company, in the face of pending generic competition, repackages its own product and markets it as a generic. Generic drug companies, through citizen petitions and lawsuits, have sought FDA's intervention to halt the marketing of authorized generics, especially during the 180-day exclusivity period. FDA determined, and the courts have upheld, that the Federal Food, Drug and Cosmetic Act does not give FDA authority to intervene in this matter.

Thank you for the opportunity to highlight some of the areas that OGD is working diligently to address. FDA appreciates the Committee's interest and concern about expediting the approval of generic drug products and the opportunity to discuss these important issues. In spite of an increasing workload, be assured that there is a sense of purpose and knowledge among my staff and the administration that we are working to fulfill an important public health mission.

FDA will continue to work toward greater efficiency in ANDA review and attempt to deal with the issues discussed today and the many emerging challenges ahead. We are committed to continue to make additional generic products available to the American public as soon as legally possible.

I would be pleased to respond to your questions.
[The prepared statement of Mr. Buehler follows:]

DEPARTMENT OF HEALTH & HUMAN SERVICES

Food and Drug Administration
Rockville MD 20857

STATEMENT OF

GARY BUEHLER, R.PH

DIRECTOR OF THE OFFICE OF GENERIC DRUGS

CENTER FOR DRUG EVALUATION AND RESEARCH

FOOD AND DRUG ADMINISTRATION

BEFORE THE

SPECIAL COMMITTEE ON AGING

UNITED STATES SENATE

"IMPROVING ACCESS TO GENERIC DRUGS"

JULY 20, 2006

Release Only Upon Delivery

INTRODUCTION

Mr. Chairman and Members of the Committee, I am Gary Buehler, R.Ph, Director of the Office of Generic Drugs (OGD), in the Center for Drug Evaluation and Research (CDER), at the U.S. Food and Drug Administration (FDA or the Agency). Thank you for the opportunity to testify about FDA's efforts to expedite the approval of generic drug products.

FDA understands that Congress and the public are concerned about the high cost of prescription drugs. Generic drugs play an important role in granting access to affordable products that will benefit the health of consumers, especially seniors – who often are on a fixed income. Prompt approval of generic drug product applications, also known as abbreviated new drug applications (ANDA), is imperative to making generic products available to American consumers at the earliest possible date.

Statutory Provisions

Prior to the passage of the Drug Price Competition and Patent Term Restoration Act (Hatch-Waxman Amendments) of 1984, FDA's primary statute, the Federal Food, Drug, and Cosmetic (FD&C) Act, did not provide for the approval of generic drugs. The Hatch-Waxman Amendments established the ANDA approval process, which permits FDA to approve generic versions of previously approved innovator drugs without the submission of clinical studies and other kinds of data that are required in a full new drug application (NDA). An ANDA refers to the previously approved NDA of the innovator drug and relies upon the Agency's finding of safety and effectiveness for that drug. Also, with respect to each

unexpired patent submitted to FDA by the owner of the innovator drug and published by FDA in the Orange Book[1], an ANDA contains a certification that the ANDA applicant either will wait for the patent to expire before marketing the drug or that the applicant challenges the patent as invalid or not infringed.

The Hatch-Waxman Amendments have been very successful and have provided for the approval of over 8,000 generic drug products. These products are lower cost, high quality products that have saved the American public and the government billions of dollars.

FDA has taken a number of significant steps to provide greater access to affordable prescription medications, including unprecedented steps to lower drug costs by helping to speed the development and approval of low-cost generic drugs after legitimate patents have expired on branded drugs. Generic drugs typically cost 50 to 70 percent less than their brand-name counterparts. In 2003, FDA published a final rule to improve access to generic drugs and lower prescription drug costs for millions of Americans. This rule was first proposed in response, in part, to Federal Trade Commission recommendations and other changes the Agency identified as being useful in improving generic competition. The rule limits an innovator drug company to only one 30-month stay of a generic drug applicant's entry into the market for resolution of a patent challenge. These changes will save Americans over $35 billion in drug costs over the next 10 years, and will also provide billions in savings for the Medicare and Medicaid programs. We were pleased that elements of this

[1] The publication, "Approved Drug Products with Therapeutic Equivalence Evaluations" (commonly known as the Orange Book) identifies drug products approved on the basis of safety and effectiveness.

rule were codified as part of the Medicare law and that, with FDA's technical assistance, the law added additional mechanisms to enhance generic competition in the marketplace.

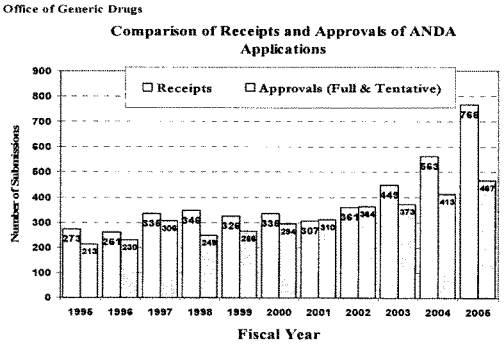
In addition, since FY2001, the Administration and Congress have increased funding for FDA's generic drug program by 66 percent, a clear sign of the important role played by OGD. These increases have enabled FDA to hire additional expert staff to review generic drug applications more quickly and initiate targeted research to expand the range of generic drugs available to consumers. While there remains work to be done, as I will discuss, we have been able to produce significant reductions in approval times for generic drugs since 2002 that consequently will save consumers billions by generally reducing the time for developing generic drugs and making them available.

The Office of Generic Drugs' Workload

Much concern has been raised from the public and Congress about a "backlog" of pending ANDAs, currently under OGD review. FDA has received an increased number of ANDAs in the last few years. OGD generally maintains a "first-in, first-reviewed" policy for ANDAs. FDA instituted this generic drug review priority to ensure the integrity of the approval process. A number of factors govern the timing of generic drug approvals, including: whether the application is of high quality, meets inspection standards and the scientific and technical requirements for approval, and whether patent protection and exclusivity periods have expired on the innovator drug.

There are several contributing causes to the increased number of generic applications FDA is receiving. Among these are the approvals of many new innovator drugs in the 1990s with patents that are now expiring, as well as the burgeoning number of new generic firms entering the market. Over the last five years, the number of applications submitted to OGD has increased by 150 percent. In fiscal year (FY) 2001, OGD received 307 ANDAs. In FY 2002 submissions increased 17.6 percent to 361. In FY 2003, they increased 24.3 percent to 449. In FY 2004, they increased 25.3 percent to 563. And, in FY 2005, they increased 36 percent to 766 applications submitted for review (see figure 1). Just last month, June 2006, we approved (or tentatively approved, meaning an application is technically ready for approval, but patent or exclusivity prevents immediate approval) 45 applications, however, the number of pending applications grew substantially because we received 92 applications. Clearly, this rate of increase in applications results in a dramatic increase in the workload for the review staff in OGD.

Figure 1



Although OGD still has a backlog, figure 1 also demonstrates that we have managed to increase the number of approvals each year. In FY 2001, OGD approved (or tentatively approved) 310 ANDAs and increased the annual number of approvals to 467 (or tentative

approvals) in FY 2005. OGD's efforts are also evident when looking at the median approval time. The median approval times have decreased from 18.4 months in FY 2001 to 16.3 months in FY 2005. In FY 2003, OGD approved (or tentatively approved) 132 applications in less than 15 months after receipt. In FY 2004, that number increased to 146 in less than 15 months and increased further to 174 in FY 2005 (102 of which were approved in less than 12 months). Despite these challenges, FDA has managed to maintain its rate of approval of more than one generic drug application a day.

It is important to understand that a pending ANDA has not been reviewed. When a pending ANDA is initially reviewed and deficiencies are communicated to the company, the application is no longer considered pending. However, when the company submits an amendment to its ANDA to address the identified deficiencies, the application is again considered pending. Therefore, the ANDAs in the backlog are not all unreviewed, but may be applications that have had an initial review and are now awaiting a second or subsequent review of the company's attempts to satisfy approval requirements.

FDA has taken significant steps to improve our resources. Total spending on the Generic Drug Program is $64.6 million, which is more than a 66 percent increase from the comparable FY 2001 amount. FDA has increased its generic drugs full-time equivalent (FTE) positions from 134 in FY 2001 to 201 in FY 2006. Last year, FDA added 12 new FTE positions to OGD's staff. These individuals, now fully trained, have recently reached the point in their learning curve where they are now full contributors to the efforts of OGD. In addition, OGD has taken actions to streamline the ANDA review process. These actions include adding a

third chemistry review division and a fifth team in OGD's Division of Bioequivalence. Also, a number of new review practices have been implemented to improve interactions with generic drug companies. We have begun utilizing non-reviewer Project Management staff to take certain actions not requiring scientific expertise, thus alleviating the burden of these activities on the review staff. OGD has instituted other efficiencies to application review. These include:

- reviewing Drug Master Files (DMFs) prior to the time the related ANDAs are assigned, because the DMF evaluation is often the limiting factor in completing the ANDA review; (Experience with expedited review in the President's Emergency Plan for AIDS Relief program has shown that early DMF review generally shortens overall time to approval.)
- relying upon telephone discussions with ANDA sponsors when appropriate, as opposed to written correspondence, to resolve deficiencies more efficiently and expeditiously early in the review process;
- assigning applications to reviewers with relevant expertise or experience with a particular drug class to enable more efficient and timely reviews; and
- utilizing a new review format for the chemistry review. It is based on the structure of applications in the International Conference on Harmonization Common Technical Document. This format also is in keeping with CDER's quality-by-design initiatives and should eventually decrease review times and the need for submission of some supplements to approved ANDAs.

Because of these efforts, on the very day that the last patents or exclusivities expire on the innovator product, OGD has been able to approve at least one generic drug application in

most cases. And, if there are no products eligible for 180-day exclusivity, we have usually been able to approve two or more applications for the same products. In fact, very recently, FDA approved generic applications for pravastatin (Pravachol), sertraline (Zoloft), and simvastatin (Zocor) when the innovator protections expired. Many Americans use one of these drugs. The availability of generic versions of these three drugs should produce savings measured in the billions of dollars per year. We will work to continue our success so far in staying ahead of the curve on first-time generics and responding to pending applications.

Citizen Petitions

FDA regulations permit any interested person to file a citizen petition requesting FDA "to issue, amend, or revoke a regulation or order, or to take or refrain from taking any other form of administrative action" (Title 21, *Code of Federal Regulations* 10.25 and 10.30). Citizen petitions may be submitted at any time, requesting that FDA impose new criteria for approval of ANDAs. The petitions often make serious challenges to whether or not a generic product can be approved; that is, whether a specific application or a group of applications would meet the statutory requirements for approval.

It is incumbent upon FDA to consider and address the merits of petitions. The data and information submitted with these petitions require detailed analysis and precise scientific documentation, often involving multiple disciplines within CDER. Because the same issues sometimes are raised in a subsequent court challenge to an ANDA approval and because petitioners sometimes submit non-scientific petitions that raise purely legal questions related to ANDA approvals, a thorough legal review is also necessary. Although it is not required

that a citizen petition response be issued before approval of a related ANDA, it is important that FDA comprehensively assess the scientific issues prior to approval of the ANDA. It is very rare that petitions present new issues that CDER has not fully considered, but the Agency must nevertheless assure itself of that fact by reviewing the citizen petitions.

A high percentage of the petitions OGD reviews are denied. An analysis of petitions answered between calendar years 2001 and 2005, raising issues about the approvability of generic products (42 total responses), showed that FDA denied 33, denied three in part, and granted six. It should be noted that when petitions are granted, wholly or in part, it is often because FDA already has the proposed scientific or legal standard in place or is already planning to take the action that the petition requests. While the citizen petition process is a valuable mechanism for the Agency to receive information from the public, it is noteworthy that very few of these petitions on generic drug matters have presented data or analysis that significantly altered FDA's policies. Of the 42 citizen petition responses examined, only three petitions led to a change in Agency policy on the basis of data or information submitted in the petition.

CDER has made considerable efforts in the last year-and-a-half to improve the process for responding to citizen petitions. As part of this process, OGD constituted a group of highly qualified and skilled scientists dedicated to assessing the citizen petitions related to generic drugs and formulating FDA's responses to them. Other improvements include: increased prospective management of the petition response process; development of clear timelines for

completing actions; and improved communication among the CDER components involved in responding to citizen petitions.

Authorized Generics

The term "authorized generic" is generally used to describe an instance when an innovator company, in the face of pending generic competition, repackages its own product and markets it as a "generic." Prior FDA approval is not needed for the innovator company to do this, as review and approval occur under the auspices of the innovator's approved NDA. Generic drug companies, through citizen petitions and lawsuits, have sought FDA's intervention to halt the marketing of authorized generics. FDA determined, and the courts upheld, that the FD&C Act does not give FDA authority to intervene in the matter.

CONCLUSION

FDA appreciates the Committee's interest and concern about expediting the approval of generic drug products and the opportunity to discuss these important issues. I am constantly impressed by the dedication, skills and effectiveness of FDA staff responsible for reviewing generic drugs. In spite of a tremendous workload, be assured that there is a sense of purpose and knowledge, among my staff and this Administration that they are working towards an important public health mission. FDA will continue to work towards greater efficiency in ANDA review and attempt to deal with the issues discussed today and the many emerging challenges ahead. We are committed to continue to make additional generic products

available to the American public as soon as legally possible. I would be pleased to respond to questions.

Senator KOHL. Thank you very much, Mr. Buehler, and now we will turn to Mr. Leibowitz.

STATEMENT OF JON LEIBOWITZ, COMMISSIONER, FEDERAL TRADE COMMISSION, WASHINGTON, DC

Mr. LEIBOWITZ. Chairman Smith, Co-Chairman Kohl, protecting competition, as you know, in the pharmaceutical sector is a mainstay of our work at the FTC, and your hearing is both timely and important. Let me start, though, with the usual disclaimer. The written statement that we submitted today represents the views of the Commission. My oral testimony today reflects my own views and not necessarily the views of any other Commissioner or the Commission itself.

Mr. Chairman, the savings that generic drugs offer are particularly important for older Americans. Research indicates that 87 percent of persons aged 65 or older take at least one prescription drug on a regular basis. On average, seniors take four different prescription drugs daily. Persons over 65—and they only compose about 13 percent of the population—account for 42 percent of every dollar spent on prescription drugs.

There is a particular urgency to pharmaceutical competition issues right now. Recent decisions by some appellate courts are making it difficult to challenge agreements that delay generic competition. If these decisions are allowed to stand, prescription drug costs, already the fastest growing segment of our Nation's spending on health care, will rise even more dramatically.

These increased costs will burden not only individual consumers, especially older Americans, but also the Federal Government's new Medicare Part D drug program, which you mentioned, Senator Kohl, in your opening statement, and American businesses striving to compete in a global economy, for example, like General Motors, and I know you had their CEO testify here last week.

In my oral remarks this morning, I will focus primarily on what are called exclusion payments. By this I mean settlements of patent litigation in which the brand name drug firm pays a generic challenger to stay out of the market. Then I will briefly touch on two other issues: bottlenecks that keep subsequent generic filers off the market and so-called authorized generics.

Now, when Congress enacted the Hatch-Waxman statute in 1984, it encouraged speedy introduction of generics. That statutory framework, while ensuring that our pioneer drug firms remain the envy of the world—and they are—has also delivered enormous consumer savings. Indeed, as a general matter, when the first generic enters the market, it does so at a 20- to 30-percent discount off the brand prices, and prices drop even further, by as much as 80 percent, after other generic competitors go to market, and that is usually 6 months after the first generic entrant.

The consumer and government savings that result from generic entry will be lost, however, if companies settle through arrangements in which they share the monopoly profits that are preserved by delay. Sadly, the incentives to enter into these pernicious settlements are substantial because generic entry causes the branded drug firm to lose far more in revenues than the lower-priced generic can possibly earn. As a result, if both companies agree to

delay entry, both firms are better off financially. Of course, it is consumers who are left holding the bag, or more precisely footing the bill.

For the past decade, the FTC has made challenging patent settlements that delay generic entry a bipartisan priority. In the late 1990's, when we started seeing these disturbing settlement payments, we acted to stop them. The Commission obtained two major consents involving anti-competitive payments and we put pharmaceutical companies on notice that we would consider all available remedies, including disgorgement of profits, against similar conduct in the future.

As a result, our action stopped this conduct cold. It set forth rules that everyone in the pharmaceutical industry understood. If you settled a pharmaceutical patent case by paying off a generic, you would face antitrust scrutiny. As a result, to the best of our knowledge there were no such settlements between 2000 and 2004.

The Commission did rule in 2003 that in an earlier settlement in, I think, 1998, a payment from Schering-Plough, the brand, to Upsher-Smith, the generic, violated the antitrust laws. That case, by the way, involved a potassium supplement that was widely used and still is widely used by older Americans. The Eleventh Circuit reversed us in 2005, and the Second Circuit, in a two-to-one decision in the *In re Tamoxifen* case, issued a similar opinion late last year.

These decisions, which essentially hold that a patent-holder has a right to compensate a generic except where the brand's infringement suit is a sham, have dramatically altered the legal landscape, and we believe it has done so to the detriment of consumers.

Mr. Chairmen, this is not idle speculation. Thanks to the reporting requirement that Congress included in the 2003 Medicare Modernization Act—and you passed this law presumably because you were also troubled by these agreements—the FTC reviews each and every Hatch-Waxman settlement. Tellingly, here is what the data for the last few years tell us and what it reveals.

For fiscal year 2004 and the early part of 2005, none of the nearly 20 agreements reported contained a payment from the brand to the generic accompanied by a deferred generic entry. In other words, parties could and did settle patent litigation without money flowing to the generic.

In sharp contrast, the most recent data for the first half of fiscal year 2006—and that reflects agreements after the Schering and the Tamoxifen cases—is far more disturbing. Seven of the ten agreements between brands and generics during this period included a payment from a brand and an agreement to defer generic entry. In other words, just before Schering and Tamoxifen, there were almost no such payments. Just after these decisions, it appears to be the new way of doing business.

From our perspective, we will continue to be vigilant in looking for ways to challenge anti-competitive settlements, and I certainly hope the Supreme Court will eventually weigh in on this problem. A legislative approach, however, could provide swifter and a more comprehensive solution. For that reason, we strongly support the intent behind the Preserve Access to Affordable Generics Act, the bipartisan bill that you introduced, Senator Kohl, with Senator

Grassley, Senator Leahy and Senator Schumer. But drafting such a measure is challenging, so we are happy to work with you as the bill moves forward.

Let me very briefly raise two other issues. The first is yet another strategy that thwarts consumer access to generic drugs and which we believe undermines congressional intent, and we discuss this bottleneck issue in detail in our written submission. It involves legal complexities unique to Hatch-Waxman.

But boiled down into plain English, it is this: subsequent generics are supposed to have an alternative way to enter the market when the first generic delays its own entry. Instead, because of recent case law, they are stuck in a sort of pharmaceutical catch–22. The courts won't let them bring a patent challenge and the FDA won't let them market without winning one. It is a sort of drug purgatory and we believe one that results in considerable delays for consumers. We made a legislative recommendation to solve this problem in 2002 before I came to the Commission and it is in our written statement. We are happy to work with you on that.

The second matter is authorized generics, a product, as you know, that involves a chemically identical drug to the brand drug and the brand firm when the brand firm introduces its own generic. In recent years, brand firms have increasingly begun to market authorized generic drugs at precisely the same time that the first generic entrant begins its 180-day exclusivity period. In the short run, the entry of an authorized generic may benefit consumers by creating additional competition that lowers prices.

But critics assert that in the long term, consumers will be harmed because of the competition from authorized generics, and the significantly lower profits for the generic industry that result will basically decrease the incentives of generic firms to pursue entry especially for non-blockbuster drugs. At the Commission, we are now undertaking a study to examine the competitive impact of authorized generics.

Mr. Chairman, at a time when this Nation faces the challenge of ever-mounting health care costs, ensuring that seniors and other consumers have access to low-cost pharmaceuticals is a matter of critical concern. The FTC is committed to doing whatever we can to promote drug competition and we stand ready to assist your Committee.

Thank you.

[The prepared statement of Mr. Leibowitz follows:]

PREPARED STATEMENT OF THE FEDERAL TRADE COMMISSION

Before the

SPECIAL COMMITTEE ON AGING

of the

UNITED STATES SENATE

on

BARRIERS TO GENERIC ENTRY

July 20, 2006

Chairman Smith, Ranking Member Kohl, and Members of the Committee, I am Jon Leibowitz, Commissioner of the Federal Trade Commission ("FTC" or "Commission"). I am pleased to appear before you today to testify on behalf of the Commission regarding barriers to generic entry in the pharmaceutical industry.[1]

Advances in the pharmaceutical industry continue to bring enormous benefits to Americans. Because of pharmaceutical innovations, a growing number of medical conditions often can be treated more effectively with drugs and drug therapy than with alternative means (*e.g.*, surgery). The development of new drugs is risky and costly, however.

At the same time, the escalating cost of health care in the United States – and in particular, of prescription drugs – is an enormous, nationwide problem. As the Government Accountability Office reported last year: "Prescription drug spending as a share of national health expenditures increased from 5.8 percent in 1993 to 10.7 percent in 2003 and was the fastest growing segment of health care expenditures."[2] Older Americans, typically those in greatest need of health care in our population and often living on fixed incomes, bear a disproportionate share of these costs. Although people over 65 are only 13 percent of the population, they account for 42 percent of all drug expenditures.[3] Pharmaceutical expenditures are a concern not only to individual consumers, but also to government payers, private health plans, and employers. Generic drugs play an important role in containing rising prescription drug costs, by offering consumers therapeutically identical alternatives to brand-name drugs, at a significantly reduced cost.

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[1] This written statement represents the views of the Federal Trade Commission. My oral presentation and responses are my own and do not necessarily reflect the views of the Commission or of any Commissioner.

[2] Government Accountability Office, *PRESCRIPTION DRUGS: Price Trends for Frequently Used Brand and Generic Drugs from 2000 through 2004* at 1 (Aug. 2005).

[3] Families USA, *Cost Overdose: Growth in Drug Spending for the Elderly*, 1992-2010 at 2, 13 (July 2000).

To address the issue of escalating drug expenditures, and to ensure that the benefits of pharmaceutical innovation would continue, Congress passed the Hatch-Waxman Amendments[4] ("Hatch-Waxman" or "the Amendments") to the Food, Drug and Cosmetic Act ("FDC Act") in 1984.[5] Hatch-Waxman established a regulatory framework that sought to balance incentives for continued innovation by research-based pharmaceutical companies, on the one hand, and opportunities for market entry by generic drug manufacturers, on the other hand.[6] Without question, Hatch-Waxman has increased generic drug entry. The Congressional Budget Office estimated that, by purchasing generic equivalents of brand-name drugs, consumers saved $8-10 billion on retail purchases of prescription drugs in 1994 alone.[7] The federal and state governments also are significant purchasers of pharmaceuticals, and they likewise reap substantial savings from generic drugs.

Yet, in spite of this remarkable record of success, there have been, and continue to be, competitive problems in pharmaceutical markets. Although many drug manufacturers – including both brand-name and generic companies – have settled their patent suits in a manner that does not harm competition, others have entered anticompetitive settlements without providing a corresponding benefit to consumers. Responding to some of these abuses, in 2003 Congress included provisions in the Medicare Modernization Act ("MMA") that amended the

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[4] Drug Price Competition and Patent Term Restoration Act of 1984, Pub. L. No. 98-417, 98 Stat. 1585 (1984) (codified as amended 21 U.S.C. § 355 (1994)).

[5] 21 U.S.C. § 301 *et seq.*

[6] *See infra* notes 16-33 and accompanying text. The Amendments also were intended to encourage pharmaceutical innovation through patent term extensions.

[7] Congressional Budget Office, *How Increased Competition from Generic Drugs Has Affected Prices and Returns in the Pharmaceutical Industry* (July 1998), *available at* <http://www.cbo.gov/showdoc.cfm?index=655&sequence=0> (hereinafter "CBO Study").

Hatch-Waxman Act to require notice of settlement between brand and generic firms to the FTC and Department of Justice.

For its part, the Commission has aggressively protected competition in the pharmaceutical industry, including pursuing numerous antitrust enforcement actions affecting both brand-name and generic drug manufacturers.[8] The Commission also has filed amicus briefs on competition-related issues in a variety of pharmaceutical cases.[9] On a policy level, the Commission has promoted a greater understanding of the role of competition in the industry through multiple studies including our 2002 study entitled "Generic Drug Entry Prior to Patent Expiration" ("Generic Drug Study"), which recommended some of the changes made in the MMA.[10] Since the MMA filing requirement became effective in January 2004, Commission staff have issued annual reports on the types of patent settlements being entered.[11] Commission staff

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[8] *See, e.g.*, Federal Trade Commission, Petition for a Writ of Certiorari, *FTC v. Schering-Plough Corp.*, No. 05-273 (June 26, 2006) (denying cert. petition); *Schering-Plough Corp. v. F.T.C.*, 402 F.3d 1056 (11th Cir. 2005); *Schering-Plough Corp.*, No. 9297, 2003 WL 22989651 (F.T.C.) (Dec. 8, 2003) (Commission decision and final order); *Schering-Plough Corp., Upsher-Smith Labs., and American Home Products Corp.*, Dkt. No. 9297 (Apr. 5, 2002) (consent order as to American Home Products); *FTC v. Perrigo and Alpharma*, Civ. Action No. 1:04CV01397 (D.D.C. Aug. 12, 2004) (stipulated judgment); *Bristol-Myers Squibb Co.*, Dkt. No. C-4076 (Apr. 13, 2003) (consent order); *Biovail Corp. and Elan Corp. PLC*, Dkt. No. C-4057 (Aug. 20, 2002) (consent order); *Biovail Corp.*, Dkt. No. C-4060 (Oct. 4, 2002) (consent order); *Abbott Labs.*, Dkt. No. C-3945 (May 26, 2002) (consent order); *Geneva Pharms., Inc.*, Dkt. No. C-3946 (May 22, 2000); *Hoechst Marion Roussel, Inc.*, Dkt. No. 9293 (Apr. 4, 2001) (consent order); *FTC v. Mylan Labs., Inc. et al.*, 62 F. Supp. 2d 25 (D.D.C. 1999).

[9] *See, e.g.*, Brief for the Federal Trade Commission as Amicus Curiae Supporting *en banc* petition, *In re Tamoxifen Litigation*, (No. 03-7641) (2d Cir. Dec. 2, 2005); Brief for the Federal Trade Commission as Amicus Curiae Supporting *en banc* petition, *Teva Pharm. v. Pfizer Inc.*, (03CV-10167) (Fed. Cir. Feb. 5, 2005); Brief for the Federal Trade Commission as Amicus Curiae Supporting Appellants, *Teva Pharm. v. Pfizer Inc.*, (03CV-10167) (Fed. Cir. Feb. 5, 2005).

[10] Federal Trade Commission, *Generic Drug Entry Prior to Patent Expiration: An FTC Study* (July 2002), *available at* <http://www.ftc.gov/os/2002/07/genericdrugstudy.pdf> (hereinafter "Generic Drug Study").

[11] Bureau of Competition Report, Federal Trade Commission, *Agreements Filed with the Federal Trade Commission under the Medicare Prescription Drug, Improvement, and Modernization Act of 2003: Summary of Agreements Filed in FY 2005: A Report by the Bureau of Competition* (Apr. 2006), *available at* <http://www.ftc.gov/os/2006/04/fy2005drugsettlementsrpt.pdf>; Bureau of Competition Report, Federal Trade Commission, *Agreements Filed with the Federal Trade Commission under the Medicare Prescription Drug, Improvement, and Modernization Act of 2003; Summary of Agreements Filed in FY 2004: A Report by the Bureau*

also have conducted empirical analyses of competition in the pharmaceutical industry, including in-depth studies by the staff of the FTC's Bureau of Economics.[12] The Commission's efforts also have included filing comments with the United States Food and Drug Administration ("FDA") regarding the competitive aspects of Hatch-Waxman implementation,[13] as well as submitting testimony before Congress.[14] Furthermore, individual Commissioners have addressed the subject

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of Competition (Jan. 2005), *available at* <http://www.ftc.gov/os/2005/01/050107medicareactrpt.pdf>.

[12] Federal Trade Commission, Pharmacy Benefit Managers: Ownership of Mail-Order Pharmacies (August 2005), *available at* <http://www.ftc.gov/reports/pharmbenefit05/050906pharmbenefitrpt.pdf>; Federal Trade Commission, *To Promote Innovation: The Proper Balance of Competition and Patent Law and Policy* (Oct. 2003), *available at* <http://www.ftc.gov/os/2003/10/innovationrpt.pdf>; David Reiffen & Michael R. Ward, *Generic Drug Industry Dynamics*, Bureau of Economics Working Paper No. 248 (Feb. 2002) ("Reiffen and Ward"), *available at* <http://www.ftc.gov/be/econwork.htm>; Bureau of Economics Staff Report, Federal Trade Commission, *The Pharmaceutical Industry: A Discussion of Competitive and Antitrust Issues in an Environment of Change* (Mar. 1999), *available at* <http://www.ftc.gov/reports/pharmaceutical/drugrep.pdf>.

[13] *Response to Citizen Petition by Ivax Pharmaceuticals, Inc.* (Apr. 5, 2005), *available at* <www.ftc.gov/os/2005/04/050407ltrivaxpharm.pdf> (recommending that FDA deny Ivax's request that the FDA prohibit delisting of patents from the Orange Book); *FDA: Applications for FDA Approval to Market a New Drug; Patent Listing Requirements and Application of 30-Month Stays on Approval of Abbreviated New Drug Applications Certifying That a Patent Claiming a Drug is Invalid or Will Not be Infringed*, Comment of the Federal Trade Commission (Dec. 23, 2002) ("30-Month Stay Comment"), *available at* <http://www.ftc.gov/be/v030002.pdf> (recommending modifications to FDA proposed rule on patent listing requirements and providing suggestions to the proposed patent declaration); *FDA: Citizen Petition*, Comment of the Staff of the Bureau of Competition and the Office of Policy Planning of the Federal Trade Commission Before the Food and Drug Administration (Mar. 2, 2000), *available at* <http://www.ftc.gov/be/v000005.pdf> (recommending modifications to the FDA's Proposed Rule on citizen petitions intended to discourage anticompetitive abuses of the FDA's regulatory processes); *FDA: 180-DayGeneric Drug Exclusivity for Abbreviated New Drug Applications*, Comment of the Staff of the Bureau of Competition and the Office of Policy Planning of the Federal Trade Commission Before the Food and Drug Administration (Nov. 4, 1999) ("Marketing Exclusivity Comment"), *available at* <http://www.ftc.gov/be/v990016.htm> (recommending that the FDA's Proposed Rule on 180-day marketing exclusivity be modified to limit exclusivity to the first ANDA filer and to require filing of patent litigation settlement agreements).

[14] Testimony of the Federal Trade Commission before the Committee on Judiciary, United States Senate, *Competition in the Pharmaceutical Industry* (June 17, 2003), *available at* <http://www.ftc.gov/os/testimony/108hearings.htm>; Testimony of the Federal Trade Commission before the Committee on Energy and Commerce, Subcommittee on Health, United States House of Representatives, *Study of Generic Drug Entry Prior to Patent Expiration* (Oct. 9, 2002), *available at* <http://www.ftc.gov/os/2002/10/genericstestimony021009.pdf>; Testimony of the Federal Trade Commission before the Committee on Commerce, Science, and Transportation, United States Senate, *Competition in the Pharmaceutical Industry* (Apr. 23, 2002), *available at* <http://www.ftc.gov/os/2002/04/pharmtestimony.htm>; Testimony of the Federal Trade Commission before the Committee on the Judiciary, United States Senate, *Competition in the Pharmaceutical Marketplace: Antitrust Implications of Patent Settlements* (May 24, 2001), *available at* <http://www.ftc.gov/os/2001/05/pharmtstmy.htm>.

of pharmaceutical competition before a variety of audiences, both to solicit input from affected parties and to promote discussion about practical solutions.[15]

This testimony will address the Commission's vigorous enforcement of the antitrust laws with respect to brand-name and generic drug competition, as well as current policy issues that implicate that competition and affect senior citizens' drug purchasing costs. The first two sections address how settlements of patent litigation, either alone or in combination with the 180-day exclusivity period, can delay generic entry. The testimony discusses (I) the types of patent settlements the Commission believes are anticompetitive, including possible legislative solutions to this problem, and (II) how brand companies have used 180-day exclusivity to block generic entry.

Next, the testimony reviews the antitrust implications of agreements entered outside the context of patent litigation. The testimony discusses (III) the Commission's ongoing litigation against Warner-Chilcott and Barr Laboratories, and (IV) the Commission's enforcement actions against agreements between generic companies that delay generic competition.

Finally (V), the testimony discusses the Commission's plan to study the impact of authorized generics on pharmaceutical markets.

I. Settlement of Patent Disputes in the Pharmaceutical Industry

Settlements of patent litigation are a significant threat to competition in the pharmaceutical industry when they include so-called "exclusion payments." These settlements,

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[15] *See, e.g.*, Deborah Platt Majoras, *A Government Perspective on IP and Antitrust Law* (June 21, 2006), *available at* <http://www.ftc.gov/speeches/majoras.htm>; Jon Leibowitz, *Exclusion Payments to Settle Pharmaceutical Patent Cases: They're B-a-a-a-ck! (The Role of the Commission, Congress, and the Courts)* (Apr. 24, 2006), *available at* <http://www.ftc.gov/speeches/leibowitz/060424PharmaSpeechACI.pdf>; Timothy J. Muris, *Competition and Intellectual Property Policy: The Way Ahead*, at 5-6 (Nov. 15, 2001), *available at* <http://www.ftc.gov/speeches/muris/intellectual.htm>.

which appear to be unique to the pharmaceutical industry, occur when a branded company shares a portion of its future profits with a potential generic entrant in exchange for the generic's agreement not to market its product. Although both the brand company and the generic company are better off financially, these settlements restrict competition at the expense of consumers, whose access to lower-priced generic drugs may be deferred for years.

A. The Benefits of Generic Competition

Generic competition in the pharmaceutical industry provides a significant benefit to consumers and, in particular, the elderly. Studies of the pharmaceutical industry indicate that the first generic competitor typically enters the market at 70 to 80 percent of the brand-name counterpart, and gains substantial share from the brand-name product in a short period of time.[16] Subsequent generic entrants may enter at even lower prices and cause the earlier entrants to reduce their prices. As a result of price competition, as well as the policies of public and private health plans and state laws that encourage the use of generic drugs, generic sellers typically capture anywhere from 44 to 80 percent of branded sales within the first full year after launch of a lower-priced generic product.[17]

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[16] *See* CBO Study, n. 6; *see generally* Reiffen & Ward, *Generic Drug Industry Dynamics*, 87 REVIEW OF ECON. & STAT. 37-79 (2005).

[17] CBO Study, xiii.

1. **Statutory Background**

Congress intended that the Hatch-Waxman Act would "make available more low cost generic drugs," while fully protecting legitimate patent claims.[18] The Act allows for accelerated FDA approval of a drug through an Abbreviated New Drug Application ("ANDA"), upon showing, among other things, that the new drug is "bioequivalent" to an approved drug.[19] It also encourages the development of generic drugs by declaring various research and development activities noninfringing.[20]

Pursuant to the FDC Act, a brand-name drug manufacturer seeking to market a new drug product must first obtain FDA approval by filing a New Drug Application ("NDA") that, among other things, demonstrates the drug product's safety and efficacy. At the time the NDA is filed, the NDA filer also must provide the FDA with certain categories of information regarding patents that cover the drug that is the subject of its NDA.[21] Upon receipt of the patent information, the FDA is required to list it in an agency publication entitled "Approved Drug Products with Therapeutic Equivalence," commonly known as the "Orange Book."[22]

Rather than requiring a generic manufacturer to repeat the costly and time-consuming NDA process, the Hatch-Waxman Amendments permit the company to file an Abbreviated New Drug Application ("ANDA"), which incorporates data that the "pioneer" manufacturer has

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[18] H.R. Rep. No. 857, 98th Cong., 2nd Sess., Pt. 1, at 14 (1984).

[19] 21 U.S.C. 355(j).

[20] 35 U.S.C. 271(e)(1); *see Merck KGaA* v. *Integra Lifesciences I, Ltd.*, No. 03-1237, 125 S. Ct. 2372 (June 13, 2005).

[21] 21 U.S.C. § 355(b)(1).

[22] *Id.* § 355(j)(7)(A).

already submitted to the FDA regarding the branded drug's safety and efficacy. The ANDA filer must demonstrate that the generic drug is "bioequivalent" to the relevant branded product.[23] The ANDA must contain, among other things, a certification regarding each patent listed in the Orange Book in conjunction with the relevant NDA.[24] One way to satisfy this requirement is to provide a "Paragraph IV" certification, asserting that the patent in question is invalid or not infringed.[25]

Filing a Paragraph IV certification potentially has significant regulatory implications, as it is a prerequisite to operation of the two most competitively sensitive provisions of the statute. The first of these is the automatic 30-month stay. An ANDA filer that makes a Paragraph IV certification must provide notice, including a detailed statement of the factual and legal bases for the ANDA filer's assertion that the patent is invalid or not infringed, to both the patent holder and the NDA filer.[26] Once the ANDA filer has provided such notice, a patent holder wishing to take advantage of the statutory stay provision must bring an infringement suit within 45 days.[27] If the patent holder does not bring suit within 45 days, the FDA may approve the ANDA immediately.[28] If the patent holder does bring suit, however, the filing of that suit triggers an

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[23] *Id.* § 355(j)(2)(A)(iv).

[24] *Id.* § 355(j)(2)(A)(vii).

[25] *Id.* ' 355(j)(2)(A)(vii)(IV).

[26] *Id.* § 355(j)(2)(B). Although the patent holder and the NDA filer will often be the same person, this is not always the case. The Hatch-Waxman Amendments require that all patents that claim the drug described in an NDA must be listed in the Orange Book. Occasionally, this requirement will cause an NDA filer to list a patent that it does not own.

[27] *Id.* § 355(j)(5)(B)(iii).

[28] *Id.*

automatic 30-month stay of FDA approval of the ANDA.[29] And, without FDA approval, a generic manufacturer cannot bring its product to market. The imposition of a stay can, consequently, forestall generic competition for a substantial period of time.

The second competitively sensitive consequence is the 180-day period of marketing exclusivity. To encourage generic drug manufacturers to challenge questionable patents by filing Paragraph IV certifications – a move that can potentially subject the company to costly and burdensome patent infringement litigation – the Hatch-Waxman Amendments provide that the first generic manufacturer (first-filer) to file an ANDA containing a Paragraph IV certification is awarded 180 days of marketing exclusivity, during which the FDA may not approve a potential competitor's ANDA.[30] The 180-day period is calculated from the date of the first commercial marketing of the generic drug product.[31] The potential impact of the 180-day exclusivity period is further magnified by the fact that, under the prevailing interpretation of the Hatch-Waxman Amendments, a second ANDA filer may not enter the market until the first filer's 180-day period of marketing exclusivity has expired, even if the first filer substantially delays commencement of the exclusivity period.[32] A first-filer can forfeit its exclusivity under certain conditions.[33]

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[29] *Id.*

[30] *Id.* § 355(j)(5)(B)(iv).

[31] *Id.*

[32] *See id.* § 355(j)(5)(B)(iv). As discussed in Section II, *infra*, the first ANDA filer's failure to commence its 180-day period of marketing exclusivity can create a bottleneck that prevents subsequent ANDAs from being approved and, consequently, prevents additional generic products from entering the market.

[33] *Id.* § 355(j)(5)(D); *see also infra* notes 62-64, and accompanying text.

2. Impact of Generic Competition

Experience has borne out the efficacy of the Hatch-Waxman process and the correctness of its premises – *i.e.*, that many patents will not stand in the way of generic entry if challenged, and that successful challenges can yield enormous benefits to consumers. The Commission studied all patent litigation initiated between 1992 and 2000 between brand-name drug manufacturers and Paragraph IV generic challengers, and found that the generics prevailed in cases involving 73 percent of the challenged drug products.[34] Many of these successes involved blockbuster drugs and allowed generic competition years before patent expiration (see chart).[35] Generic competition following successful patent challenges to Prozac, Zantac, Taxol, and Plantinol alone is estimated to have saved consumers more than $9 billion,[36] in addition to the savings to federal and state governments.

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[34] *Generic Drug Study*, at 19-20.

[35] SmithKline Beecham Corp. v. Apotex Corp., 247 F. Supp.2d 1011 (N.D. Ill. 2003), *aff'd on other grounds*, 403 F.3d 1331 (Fed. Cir. 2005) (patent claiming Paxil held invalid); *Astra Aktiebolag v. Andrx Pharms., Inc.*, 222 F. Supp.2d 423 (S.D.N.Y. 2002), *aff'd sub nom., In re Omeprazole Patent Litig.*, 84 Fed. App. 76 (Fed. Cir. 2003) (noninfringement of patents claiming Prilosec); *American Biosciences, Inc. v. Baker Norton Pharms. Inc.*, 2002 U.S. Dist. LEXIS 512 (C.D. Cal. Jan. 10, 2002) (patent claiming anticancer held invalid); *Eli Lilly & Co. v. Barr Labs., Inc.*, 251 F.3d 955 (Fed. Cir. 2001) (patent claiming antidepressant Prozac held invalid); *Glaxo, Inc. v. Novopharm, Ltd.*, 110 F.3d 1562 (Fed. Cir. 1997) (noninfringement of patents claiming Zantac).

[36] Generic Pharmaceuticals Marketplace Access and Consumer Issues: Hearing Before the Senate Commerce Comm., 107th Cong. (Apr. 23, 2002) (statement of Kathleen D. Jaeger, President & CEO, Generic Pharmaceutical Ass'n) at 12, *available at* <http://commerce.senate.gov/hearings/042302jaegar.pdf>.

Examples of Generic Entry Prior to Patent Expiration from Successful Patent Challenges

Drug	First Generic Entrant	Generic Entry Date	Brand Sales Prior to Generic Entry	Expiration Date of Last Patent
Zantac	Granutec	1997	$1.6 billion	2002
Taxol	Baker Norton	2000	$1.6 billion	2013
Prozac	Barr	2001	$2.5 billion	2004
Prilosec	Kudco	2002	$3.7 billion	2018
Paxil	Apotex	2003	$2.2 billion	2017

B. Exclusion Payments Harm Consumers

By increasing the likelihood of generic entry, however, the statute also increases the incentive for brand and generic manufacturers to conspire to share, rather than compete for, the expected profits generated by sales of both brand and generic drugs. In nearly any case in which generic entry is contemplated, the profit that the generic anticipates will be much less than the profit the brand-drug company makes from the same sales. Consequently, it typically will be more profitable for both parties if the brand-name manufacturer pays the generic manufacturer to settle the patent dispute and agree to defer entry. Although both the brand-name company and

the generic company are better off with the settlement, consumers lose the possibility of an earlier generic entry, either because the generic company would have prevailed in the lawsuit or the parties would have negotiated a settlement with an earlier entry date but no payment. Instead, consumers are left with the guarantee of delayed generic entry and paying higher prices.

Congress expressly recognized the risk that the Act might promote such market allocation agreements, and implicitly directed the enforcement agencies to prosecute such agreements by amending the Hatch-Waxman Act in 2003 to require brand-name companies and generic applicants to file patent settlement agreements with the Commission and the Department of Justice. As the Senate Report explained, those amendments sought in part to stamp out the "abuse" of Hatch-Waxman law resulting from "pacts between big pharmaceutical firms and makers of generic versions of brand name drugs, that are intended to keep lower cost drugs off the market."[37] In the words of Rep. Waxman, "[t]he law has been turned on its head. . . . We were trying to encourage more generics and through different business arrangements, the reverse has happened."[38]

The Commission has challenged patent settlements when it believes that brand-name and generic companies have eliminated the potential competition between them and shared the

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[37] S. Rep. No. 167, 107th Cong., 2nd Sess., at 4 (2002).

[38] Cheryl Gay Stolberg et al., *Keeping Down the Competition; How Companies Stall Generics and Keep Themselves Healthy*, N.Y. TIMES, July 23, 2000, at A11 (quoting Rep. Waxman). *See also* Statement of Sen. Orrin Hatch, Senate Floor Debates on S. 812 (2002), *available at* http://hatch.senate.gov/index.cfm?FuseAction=PressReleases.Detail&PressRelease_id ("As a coauthor of the Drug Price Competition and Patent Term Restoration Act, I can tell you that I find these type of reverse payment collusive arrangements appalling. I must concede, as a drafter of the law, that we came up short in our draftsmanship. We did not wish to encourage situations where payments were made to generic firms not to sell generic drugs and not to allow multi-source generic competition. . . . However the K-Dur case ultimately is decided, I commend [the FTC for] zealously reviewing these type of reverse payments cases to determine whether such agreements run afoul of the antitrust laws.").

resulting profits.[39] Although some have argued that all settlements include some form of consideration between the parties,[40] it is the type of consideration that matters. Other types of consideration, an early entry date or a royalty to the patent-holder or compromising on a damage claim, do not generally involve sharing the benefits that come from eliminating potential competition. Indeed, Section 1 of the Sherman Act's primary purpose is to prevent such sharing.

Initially, the Commission's enforcement efforts in this area appeared significantly to deter anticompetitive behavior. In the seven years between 1992 and 1999, there were fourteen final settlements between brand-name manufacturers and the generic first-filer.[41] Eight of those settlements between brand-name and generic first-filers included a payment from the brand-name to the generic company in exchange for the generic company's agreement not to market its product. In 1999, it was reported that the Federal Trade Commission was investigating agreements involving such payments. The Commission is not aware of any pharmaceutical settlement between a brand-name manufacturer and a generic filer that included both a payment

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[39] *Abbott Labs.*, Dkt. No. C-3945 (May 22, 2000) (consent order), complaint *available at* <http://www.ftc.gov/os/2000/05/c3945complaint.htm>; *Geneva Pharms., Inc.*, Dkt. No. C-3946 (May 22, 2000) (consent order), complaint *available at* <http://www.ftc.gov/os/2000/05/c3946complaint.htm>. The consent order in *Abbott Laboratories* is *available at* <http://www.ftc.gov/os/2000/03/abbot.do.htm>. The consent order in *Geneva Pharmaceuticals* is *available at* <http://www.ftc.gov/os/2000/03/genevad&o.htm>. The consent order in *Hoechst/Andrx* is *available at* <http://www.ftc.gov/os/2001/05/hoechstdo.htm>. *Hoechst Marion Roussel, Inc.*, Dkt. No. 9293 (May 8, 2001) (consent order), complaint *available at* http://www.ftc.gov/os/2000/03/hoechstandrxcomplaint.htm. *Bristol-Myers Squibb Co.*, Dkt. No. C-4076, *available at* <http://www.ftc.gov/os/caselist/c4076.htm>.

[40] *Schering*, 402 F.3d at 1074.

[41] Bureau of Competition Report, Federal Trade Commission, *Agreements Filed with the Federal Trade Commission under the Medicare Prescription Drug, Improvement, and Modernization Act of 2003: Summary of Agreements Filed in FY 2005: A Report by the Bureau of Competition* (Apr. 2006), *available at* <http://www.ftc.gov/os/2006/04/fy2005drugsettlementsrpt.pdf>.

to the generic company and an agreement by the generic company not to market its product between 2000 and the end of fiscal year 2004.[42]

During the same period, however, patent settlements did not disappear. To the contrary, in less than five years, there were at least as many settlements as there were in the seven years in which pharmaceutical companies were settling litigation with payments and restrictions on generic entry.[43] The parties simply found different ways to resolve their disputes. In other words, we were effectively enforcing the antitrust laws, and our enforcement efforts were an effective deterrent that benefitted consumers with lower priced drugs.

C. The Threat Exclusion Payment Settlements Currently Pose to Consumers

Two recent court decisions, however, have taken a lenient view of exclusion payment settlements, essentially holding that such settlements are legal unless the patent was obtained by fraud or that the infringement suit itself was a sham.[44] In the *Schering* case,[45] the Eleventh Circuit vacated a decision by the Commission finding two patent settlements to be anticompetitive. Schering-Plough Corporation ("Schering"), the manufacturer of a brand-name drug called "K-Dur 20," settled patent litigation with two manufacturers of generic counterparts, Upsher-Smith Laboratories, Inc. ("Upsher") and American Home Products Corporation ("AHP").

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[42] *Id.*

[43] We lack data for the approximately three year period between the end of the Generic Drug Study and the beginning of the MMA reporting period. It is quite likely that there are additional settlements that occurred during this period for which we do not have information.

[44] *Schering-Plough Corp. v. F.T.C.*, 403 F.3d 1056 (11th Cir. 2005); *In re Tamoxifen Citrate Antitrust Litig.*, 429 F.3d 370 (2d Cir. 2005).

[45] Federal Trade Commission, Petition for a Writ of Certiorari, *FTC v. Schering-Plough Corp.*, No. 05-273 (June 26, 2006) (denying cert. petition); *Schering-Plough Corp. v. F.T.C.*, 402 F.3d 1056 (11th Cir. 2005); *Schering-Plough Corp.*, No. 9297, 2003 WL 22989651 (F.T.C.) (Dec. 8, 2003) (Commission decision and final order); *Schering-Plough Corp., Upsher-Smith Labs., and American Home Products Corp.*, Dkt. No. 9297 (Apr. 2, 2002) (consent order as American Home Products).

The two generic manufacturers agreed to forbear marketing their generic drugs until specified dates in exchange for guaranteed cash payments totaling $60 million to Upsher and $15 million to AHP. A full trial was held before an administrative law judge, and the Commission reviewed the entire record *de novo*. The Commission concluded that in each settlement, Schering had paid its generic competitors to accept the settlement and that the settlements provided Schering with more protection from competition than a settlement without a payment or simply proceeding with litigation. As a result of these agreements, Schering continued to enjoy supracompetitive profits from K-Dur 20 for several more years, at the expense of consumers.

The court of appeals set aside the Commission's decision.[46] The court began with the startling premise that "neither the rule of reason nor the *per se* analysis is appropriate" in an antitrust case involving patents.[47] The court purported to assess whether the agreement exceeded the exclusionary potential of Schering's patent, but in doing so, the court relied on the incorrect supposition that the patent provided Schering with "the legal right to exclude Upsher and ESI from the market until they proved either that the . . . patent was invalid or that their products . . . did not infringe Schering's patent,"[48] and noted that there was no allegation that the patent claim was a "sham."[49] In particular, the court ruled that a payment by the patentee, accompanied by an agreement by the challenger to defer entry, could not support an inference that the challenger

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[46] *Schering*, 403 F.3d at 1058.

[47] *Id.* at 1065-66 (citing *Valley Drug Co.* v. *Geneva Pharms., Inc.*, 344 F.3d 1294 (11th Cir. 2003).

[48] *Id.* at 1066-67.

[49] *Id.* at 1068.

must have agreed to a later date in return for such payment, even if there was no other plausible explanation for the payment.[50]

The Commission sought Supreme Court review. Thirty-five states, AARP, and a patent policy think tank supported the Commission's petition. Last month, however, the Supreme Court denied certiorari review.

The Eleventh Circuit's decision already is having a negative legal and practical effect. Other courts have understood the ruling below to demand only an inquiry into the nominal reach of the patent, and not an assessment of the likelihood that the patent-holder could successfully effect exclusion through patent litigation.[51] Indeed, the Second Circuit, in ruling in similar cases, followed the Eleventh Circuit's holding and expressly embraced the "sham" standard.[52] Although there was a five-year hiatus in pay-offs to generics after the Commission commenced enforcement actions aimed at exclusion payment settlements, pharmaceutical companies have once again started entering into settlement agreements that include both compensation in various forms to generic challengers and restrictions on generic market entry.[53] There were three such agreements in fiscal 2005, two of which occurred after the Eleventh Circuit's decision in *Schering*. In the current fiscal year, we have seen significantly more settlements with payments and a restriction on entry– seven of ten agreements between brand-name and generic companies

[50] *Id.* at 1076.

[51] *See, e.g., In re Ciprofloxacin Hydrochloride Antitrust Litig.*, 363 F. Supp. 2d 514, 539 (E.D.N.Y. 2005), *appeal docketed*, No. 05-2851 (2d Cir. June 7, 2005) ("Cipro") (the ruling below "is more fairly read as requiring an evaluation of the scope of the patent's claims, and not a post hoc analysis of the patent's validity").

[52] *In re Tamoxifen Citrate Antitrust Litig.*, 429 F.3d 370 (2d Cir. 2005).

[53] Bureau of Competition Report, Federal Trade Commission, *Agreements Filed with the Federal Trade Commission under the Medicare Prescription Drug, Improvement, and Modernization Act of 2003: Summary of Agreements Filed in FY 2005: A Report by the Bureau of Competition* (Apr. 2006), *available at* <http://www.ftc.gov/os/2006/04/fy2005drugsettlementsrpt.pdf>.

included a payment from the brand-name to the generic company and an agreement to defer generic entry.[54]

The economic implications of the courts of appeals' rulings, which seem to invite collusive arrangements between brand-name drug companies and generic challengers, are staggering. American consumers and health plans spend over a hundred billion dollars on prescription drugs each year.[55] Of the twenty top-selling prescription drugs in the United States in 2004, eleven (with annual sales of nearly $25 billion) were the subject of litigation by generic firms seeking to enter the market under the terms of the Hatch-Waxman Act.[56] The prospect of consumer benefit from such challenges is enormous, to the extent that they lead to early, non-infringing generic entry. Under the courts of appeals' rulings, however, the parties in such cases will have the strong economic incentive discussed above to enter into settlements that share the benefits of continued monopoly prices and deprive consumers of the benefit of low-cost, non-infringing generic drugs.

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[54] *See* Leibowitz, *supra* note 15.

[55] In 2002 alone, for example, Americans spent over $160 billion for prescription drugs. *See* The Henry J. Kaiser Family Foundation, *Prescription Drug Trends*, at 1 (Oct. 2004). Retail prescription prices have increased an average of 7.4% annually from 1993-2003, almost triple the average inflation rate of 2.5% during that same period. *Id.; see also* Centers for Medicare & Medicaid Services, *Highlights – National Health Expenditures*, 2003, at 1 (Jan. 1, 2005) (prescription drug spending rose 14.9% in 2002 and 10.7% in 2003). They are projected to increase at an even higher average rate over the next decade (10.7% annually between 2004 and 2013). *Prescription Drug Trends* at 2. For the past two decades, spending for prescription drugs has been the fastest growing component of the national healthcare spending. *Id.* at 1.

[56] *See* Drug Topics, *Top 200 Brand-Name Drugs by Retail Dollars in 2004* (Feb. 21, 2005), <http://www.drugtopics.com> (listing top-selling drugs). SEC filings and public statements by the manufacturers of the twenty top-selling drugs indicate that the following eleven drugs are subject to litigation by generic rivals: Lipitor, Effexor-XR, Plavix, Celebrex, Neurontin, Protonix, Norvasc, Zyprexa, OxyContin, Fosamax, and Risperdal. See, e.g., Pfizer Inc., Form 10-Q (Aug. 8, 2005); Wyeth, Form 10-Q (Aug. 5, 2005); Purdue Pharma, L.P., Press Release (June 8, 2005).

One need look no further than the investment community for confirmation of the danger these rulings present. One analyst report describes the Eleventh Circuit's *Schering* decision as having "opened a Pandora's box of settlements" and observes that the decision provided "significant value" to both brand-name and generic companies.[57] Left out of the equation is the impact of the decision on consumers.

The issue of exclusion payments has been the subject of significant debate, but the Commission's position is clear. Where a patent holder makes a payment to a challenger to induce it to agree to a later entry than it would otherwise agree to, consumers are harmed *either* because a settlement with an earlier entry date might have been reached, *or* because continuation of the litigation without settlement would yield a greater prospect of competition.[58] Some who disagree with the Commission's position argue that we must presume the validity of the patent, and even infringement, and its exclusionary power for the full term unless patent litigation proves otherwise. They also argue that we must permit parties to settle patent litigation, which they may choose to do regardless of their positions on the merits, according to their own risk calculus at the time. These arguments, however, ignore both the law and the facts. There is no question that the result of patent litigation, and therefore the timing of generic entry, is uncertain. But the antitrust laws prohibit the paying of a potential competitor, as well as an existing competitor, to

[57] Stephanie Kirchgaessner and Patti Waldmeir, *Drug Patent Payoffs Bring a Scrutiny of Side-Effects*, Financial Times UK, Apr. 25, 2006, 2006 WLNR 6910048 (quoting S.G. Cowen & Co. analyst's report).

[58] For example, to return to the hypothetical patent claim with a 50% chance of success, if there are 10 years remaining in the patent term, continued litigation between the parties affords consumers an overall expected value of 5 years' competition, taking into account the likelihood of the two possible outcomes. If the parties instead reach a settlement in which the patent holder makes a payment to the challenger, and the challenger agrees to enter only one year prior to the expiration date, consumers are worse off, on average, than had the litigation gone forward. The court of appeals' approach, by contrast, would automatically endorse such a settlement because it is within the outer, nominal bounds of the patentee's claims.

stay out of the market, even if the entry is uncertain. We disagree with the argument that generic entry before the end of a patent term is too uncertain or unlikely to be of competitive concern, because Congress spoke on the issue and we know that would-be generic entrants have enjoyed a nearly 75 percent success rate in patent litigation initiated under Hatch-Waxman. As for the argument that challenging such payoffs will deter settlements, which generally are favored, legitimate patent settlements – using means other than exclusion payments – continued to occur without hindrance from the Commission decision.

Under the rulings in the Second Circuit's *Tamoxifen* decision and the Eleventh Circuit's *Schering* decision, exclusion payment settlements are legal unless the patent was obtained by fraud or the suit is a sham. Given that the brand-name and generic company are both better off avoiding the possibility of competition and sharing the resulting profits, there can be little doubt that, should those rulings become the controlling law, we will see more of these settlements and less generic competition. Already, we are seeing their return. The cost to consumers, insurers, employers, and the government will be tremendous. Although the Commission will continue to be vigilant in this area, litigating another case to conclusion will take years and provide little relief for those consumers harmed in the interim.

Prozac provides a telling example. In the course of the patent litigation, the generic company offered to drop its challenge if the brand-name company would pay it $200 million. The brand-name company refused because, in part, it believed such a settlement would violate the antitrust laws. The generic won the patent litigation, and consumers – and federal and state governments – saved over two billion dollars.[59] Under the legal standard articulated in the

[59] Stephanie Kirchgaessner & Patti Waldmeir, *Drug patent payoffs bring a scrutiny of side-effects*, FIN. TIMES UK, Apr. 25, 2006, 2006 WLNR 6910048.

Schering and *Tamoxifen* cases,[60] the settlement would have been legal, generic entry would not have occurred, and consumers would have had to pay higher prices until patent expiration.

D. Legislative Solutions to Anticompetitive Settlements

The Commission supports legislation addressing this problem. We recognize that crafting legislation that accomplishes those goals may be challenging, however. A law must be broad enough to prevent evasion or other anticompetitive practices that could render the legislation ineffective, but it should avoid unwarranted deterrence to settlement of suits. For these reasons, we strongly support the intent behind S. 3582, the "Preserve Access to Affordable Generics Act" – bipartisan legislation introduced by Senators Kohl, Leahy, Grassley, and Schumer. We would welcome the opportunity to work with Congress on any such legislative initiatives.

II. The 180-Day Exclusivity as a Bottleneck to Prevent Generic Entry

The impact of the courts of appeals' decisions sanctioning settlements incorporating exclusionary payments will be magnified by the effect of the Hatch-Waxman Act's 180-day exclusivity. Because of recent court decisions, settlements between a brand-name company and a first generic filer for a delayed entry date are more likely to create a bottleneck that prevent *any* generic competition through operation of the first generic filer's 180-day exclusivity.

When a first generic applicant enters into an agreement with a brand-name manufacturer to delay entering the market, either with or without an accompanying payment, the generic typically will not trigger the running of its 180-day exclusivity period until it enters the market on the agreed-upon date. For that reason, the first generic applicant's 180-day exclusivity period

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[60] *See supra* notes 44-50 and accompanying text.

will create a bottleneck that prevents any subsequent generic applicant from entering the market until the period runs.[61] Such a bottleneck would obviously benefit only the brand manufacturer and the first generic applicant, to the detriment of subsequent generic applicants and consumers. A subsequent generic can relieve the bottleneck only by triggering a forfeiture event that forces the first generic filer to either use or lose its exclusivity period within 75 days. One such forfeiture event[62] is a court decision[63] that the patent supporting the 180-day exclusivity period is invalid or not infringed.[64]

A problem arises if the brand-name company does not sue the subsequent ANDA filer, thereby eliminating the possibility that the generic company will obtain a favorable court decision and relieve the bottleneck. Having settled with the first challenger, perhaps for delayed entry, a brand-name company can preempt all subsequent generic challenges and the chance of any earlier generic entry by declining to sue subsequent ANDA filers. Indeed, a troubling trend by brand-name companies towards employing just such a strategy is increasingly evident.[65]

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[61] *See Generic Drug Study* at vii-xi, 57-58, 62-63.

[62] The other forfeiture events established by Title XI of the Medicare Prescription Drug, Improvement and Modernization Act of 2003 P.L. No. 108-173 (hereinafter "MMA") are a court-entered settlement that the patents are invalid or not infringed, or withdrawal of the patents from the Orange Book by the brand company. MMA § 1102(a)(1), amending 21 U.S.C. § 355(j)(5)(B)(iv).

[63] The decision must be "a final decision from which no appeal (other than a petition to the Supreme Court for a writ of *certiorari)* has been or can be taken that the patent is invalid or not infringed." MMA, § 1102(a)(1), amending 21 U.S.C. § 355(j)(5)(B)(iv).

[64] MMA § 1102(a)(1), amending 21 U.S.C. § 355(j)(5)(B)(iv). Prior to the MMA's amendment of the Hatch-Waxman Act, a court decision holding a challenged patent to be invalid or not infringed would trigger the running of the 180-day exclusivity period, rather than triggering a forfeiture event. In the MMA, however, Congress did not change the *type* of court decision (*e.g.*, one holding that the patent is invalid or not infringed) that would forfeit the exclusivity.

[65] *See, e.g., Teva Pharms. USA, Inc., v. FDA*, 2005 WL 2692489 (D.D.C. Oct. 21, 2005); *Apotex, Inc. v. Pfizer Inc.*, 385 F. Supp.2d 187 (S.D.N.Y. 2005), *aff'd*, 159 Fed.Appx. 1013, 2005 U.S. App. LEXIS 28102 (Fed. Cir. 2005); *Glaxo Group Ltd. v. Dr. Reddy's Labs, Ltd.*, 325 F. Supp.2d 502 (D.N.J. 2004); *Mutual Pharm. Co. v. Pfizer, Inc.*, 307 F. Supp.2d 88 (D.D.C. 2004).

Some generic companies facing this scenario have attempted to bring declaratory judgment actions of non-infringement and invalidity,[66] but that strategy has been unsuccessful thus far. A recent decision of the Federal Circuit, *Teva v. Pfizer*,[67] held that declaratory judgment is unavailable in this situation for lack of a Constitutionally-required case or controversy unless the brand-name company has raised a reasonable apprehension of suit in the subsequent ANDA filer. In that case, Pfizer, the brand-name manufacturer, had settled patent litigation with Ivax, the first generic applicant, with Ivax agreeing to delay entering the market for approximately two years. As a result, Ivax's 180-day exclusivity blocked Teva, the subsequent generic applicant, from entering. After Pfizer refused to bring suit against Teva or to provide it with a covenant not to sue, Teva filed an action seeking a declaration of non-infringement and invalidity. The district court dismissed the case without prejudice for lack of controversy and the Federal Circuit affirmed.[68]

Quite recently, the situation worsened. In March of this year, the D.C. Circuit revisited the issue and held that its prior decision did not bind FDA to treat dismissal of a declaratory judgment action as a court decision sufficient to trigger the exclusivity period.[69] Following that

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[66] The MMA amendments to the Hatch-Waxman Act state that the district courts, "shall, to the extent consistent with the Constitution, have subject matter jurisdiction" over such declaratory judgment actions. MMA § 1101(d). Those same amendments specify that a court decision of invalidity or non-infringement in a declaratory judgment action triggers a forfeiture event. MMA § 1102(a)(2).

[67] *Teva Pharms. USA, Inc. v. Pfizer Inc.*, 395 F.3d 1324 (Fed. Cir.), *cert. denied*, 126 S. Ct. 473 (2005).

[68] On appeal to the Federal Circuit, the Commission filed an amicus in support of Teva's position that there was a case or controversy. Brief for the Federal Trade Commission as Amicus Curiae Supporting *en banc* petition, *Teva Pharm. v. Pfizer Inc.*, (03CV-10167) (Fed. Cir. Feb. 5, 2005). The Commission argued that declaratory judgment actions by generic applicants play a vital role in the Hatch-Waxman regime by permitting them to eliminate the bottlenecks that delay them from entering the market. The Commission further argued that Teva's action satisfied the Supreme Court's test for identifying an actual controversy under Article III of the Constitution.

[69] *Teva Pharms. USA, Inc. v. FDA*, 441 F.3d 1 (D.C. Cir. 2006).

decision, FDA reversed its previous policy and no longer treats any dismissal of a declaratory judgment action, even those made with prejudice and having preclusive effect on the issues of infringement and validity, as a court decision for purposes of triggering the exclusivity period. Last month, the D.C. Circuit upheld that decision in *Apotex v. FDA*.[70]

There is a potential legislative remedy, however. At the time that the Commission released its Generic Drug Study in 2002, the D.C. Circuit had held that a dismissal of a declaratory judgment action for lack of a case or controversy was a court decision of non-infringement sufficient to trigger the 180-day exclusivity and clear the bottleneck.[71] Because of its concern with the bottleneck scenario described here, the Commission recommended that Congress codify this decision and clarify that dismissal of a declaratory judgment action brought by a generic applicant could trigger the 180-day exclusivity.[72] The 2003 amendments to the Hatch-Waxman Act did not incorporate this recommendation.

As a result of the Federal Circuit's decision in *Teva v. Pfizer* and the D.C. Circuit's decision in *Apotex v. FDA*, a subsequent generic filer that faces a bottleneck but has not been sued has no mechanism to relieve that bottleneck. It cannot pursue a declaratory judgment action, and dismissal of that attempt will not trigger the 180-day exclusivity or a forfeiture event. Even if the subsequent filer has a strong case for noninfringement, the bottleneck postpones consumer access to any lower-priced generic version of the drug. Indeed, in those circumstances, it is contrary to the Hatch-Waxman Act's purposes of encouraging meritorious patent challenges

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[70] *Apotex, Inc. v. FDA*, 449 F.3d 1249 (D.C. Cir. 2006).

[71] *Teva Pharms. USA, Inc. v. FDA*, 182 F.3d 1003 (D.C. Cir. 1999).

[72] *Generic Drug Study* at x-xi.

and promoting generic entry to delay market entry by later applicants when the brand-name manufacturer and first generic applicant are involved in protracted litigation, or have settled their litigation without resolving the issues of validity or infringement.

For these reasons, the Commission reiterates the recommendation of the Generic Drug Study: Congress should clarify that dismissal of an action brought by a generic applicant seeking a declaratory judgment constitutes a forfeiture event for the 180-day exclusivity period.

III. Warner-Chilcott Barr: Challenging a Naked Agreement not to Compete

Agreements between brand-name and generic companies entered outside of patent litigation can also harm consumers. Last year the Commission filed an action against Warner Chilcott and Barr Laboratories, two sellers of prescription drugs.[73] The Commission alleges that two companies entered an agreement not to compete that was not part of a patent settlement.[74] Warner Chilcott sells Ovcon 35 ("Ovcon"), an oral contraceptive used to prevent pregnancy. Barr is the only company approved by the FDA to sell a generic version of the drug in competition with Warner Chilcott's brand Ovcon. Prior to the challenged agreement, Barr planned to compete with Warner Chilcott by selling Barr's lower-priced generic Ovcon once Barr received FDA approval. Both Warner Chilcott and Barr predicted that entry of Barr's lower-priced generic into the market would reduce Warner Chilcott's higher-priced brand Ovcon's sales, by capturing approximately 50 percent of Ovcon's business in the first year alone.

The complaint alleges that to forestall this competitive threat and to protect its Ovcon sales, Warner Chilcott entered into an agreement with Barr preventing entry of Barr's generic

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[73] *F.T.C. v. Warner Chilcott et. al.*, Civ. Action No. 1:05-CV-2179 (D.D.C. Nov. 7, 2005).

[74] The Complaint is *available at* <http://www.ftc.gov/os/caselist/0410034/051107comp0410034%20.pdf>

Ovcon into the United States for five years. In exchange for Barr's agreement to keep its generic Ovcon off the market, Warner Chilcott paid Barr $20 million. Instead of entering and competing, Barr would agree to be available as a second supplier of Ovcon to Warner Chilcott if Warner Chilcott so requested. The complaint charges that the effect of this anticompetitive agreement between Warner Chilcott and Barr has been to deprive purchasers of the choice of a lower-cost generic alternative to Warner Chilcott's higher-priced brand Ovcon.

The case is pending in the U.S. District Court for the District of Columbia. The Commission is seeking appropriate injunctive relief. Thirty-four states and the District of Columbia also filed a case against Warner Chilcott and Barr Laboratories in the same court. In addition, plaintiffs representing both direct purchasers and indirect purchasers have filed suit, seeking treble damages. Discovery in the government enforcement actions closes at the end of this year. The court has not set a trial date.

IV. Agreements between Generic Manufacturers

Although agreements between generic entrants have attracted significantly less attention than those between brand-name and generic companies, they too can raise competitive concerns and may draw antitrust scrutiny, and the Commission challenges agreements between generic entrants when they are anticompetitive. As in the case of agreements between brand-name companies and generic applicants, the economic incentives to collude can be strong. Studies indicate that the first generic typically enters the market at 70 to 80 percent of the price of the corresponding brand[75] and rapidly secures as much as a two-thirds market share. The second generic typically enters at an even lower price and, like the first, rapidly secures market share.

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[75] *Supra* page 6.

Collusion between the generic firms can thus be a means of preventing price erosion in the short term, though it may become substantially less feasible if subsequent ANDAs are approved and additional competitors enter the market.

In August 2004, the Commission entered a stipulated judgment with two generic drug manufacturers to resolve charges that they entered into a horizontal market allocation.[76] According to the Commission's complaint, Perrigo and Alpharma were the only two approved manufacturers of a generic over-the-counter product that is bioequivalent to Children's Motrin (store-brand Children's Motrin), a drug product to relieve pain and inflammation in children.[77] The Commission's complaint alleges that, prior to entering the challenged agreement, Perrigo and Alpharma aggressively competed to secure customers for their respective product launches in June 1998.

In April 1998, because of a change in the interpretation of the FDA's regulations, Alpharma became entitled to the 180-day exclusivity. Alpharma's exclusivity rights blocked the FDA from granting final approval to Perrigo's ANDA. The complaint alleges that Perrigo approached Alpharma about entering an agreement that would allow Perrigo to compete during the 180-day exclusivity period.

On June 16, 1998, Alpharma and Perrigo signed an agreement that eliminated the companies' vigorous competition to secure customers of store-brand children's liquid ibuprofen. Under the agreement, Alpharma relinquished its exclusivity but promised not to compete with its

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[76] *FTC v. Perrigo and Alpharma*, Civ. Action No. 1:04CV01397 (D.D.C. Aug. 12, 2004); *see also*, *Biovail Corp.* and *Elan Corp.* PLC, Dkt. No. C-4057 (Aug. 15, 2002), consent order *available at* <http://www.ftc.gov/os/2002/08/biovaldo.pdf>.

[77] The Commission's complaint against Alpharma and Perrigo is *available at* <http://www.ftc.gov/os/caselist/0210197/040812comp0210197.pdf>.

generic Children's Motrin product for seven years. Perrigo obtained the exclusive right to do so during that period. In exchange for Alpharma's promises not to compete, Perrigo agreed to pay Alpharma a lump sum fee and royalty on Perrigo's net sales of store-brand Children's Motrin.

The Commission sought and obtained a permanent injunction in federal court. Under the stipulated orders, the defendants (1) agreed to pay over six million dollars to customers that were allegedly overcharged, (2) agreed not to enter similar agreements in the future, and (3) agreed to provide notice of other generic-generic agreements that either defendant enters.[78]

V. Authorized Generics

A new strategy in the pharmaceutical industry is the brand-name company's marketing of a so-called "authorized generic" during the 180-day exclusivity period. An authorized generic is chemically identical to a particular brand-name drug, which the brand-name manufacturer authorizes to be marketed as a generic version under the approval that the FDA granted for the brand-name drug. The brand-name manufacturer either sells the authorized generic itself through a subsidiary or licenses a generic firm to sell the authorized generic. The label typically differs for the brand-name drug and its authorized generic equivalent, but the drug product is exactly the same.

Issues have been raised regarding the impact of authorized generics and the 180-day exclusivity period. As discussed above, the first generic applicant to file an application with a

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[78] The stipulated order against Alpharma is *available at* <http://www.ftc.gov/os/caselist/0210197/040812alpharma.pdf>. The stipulated order against Perrigo is *available at* <http://www.ftc.gov/os/caselist/0210197/040812perrigo.pdf>.

The Commission also is active in merger enforcement involving the pharmaceutical industry. In a consent order finalized in March 2006, the Commission ordered Teva Pharmaceutical Industries and IVAX Corporation to divest 15 generic pharmaceutical products before allowing Teva's $7.4 billion acquisition of IVAX to proceed. *Teva Pharm. Indus. Ltd., and IVAX Corp.*, File No. 051 0214, Dkt. No. C-4155 (Mar. 7, 2006), *available at* http://www.ftc.gov/os/caselist/0510214/0510214do060307.pdf.

Paragraph IV certification (claiming that patent protecting the brand drug is either invalid or not infringed) receives 180 days of market exclusivity, which means the FDA cannot approve any additional ANDA filers until 180 days after the first-filer begins marketing its product. The 180-day marketing exclusivity period does not preclude competition from NDA-approved authorized generics, however.[79]

In recent years and with increasing frequency, brand-name drug manufacturers have begun to market authorized generic drugs at precisely the same time that a paragraph IV generic is beginning its period of 180-day marketing exclusivity. The likely effects of this practice on generic competition have been subject to some debate. In the short run, the entry of an authorized generic drug may benefit consumers by creating additional competition that lowers generic prices further than if only the paragraph IV generic were marketed. Many generic manufacturers assert, however, that in the long run consumers will be harmed because an expectation of competition from authorized generics will significantly decrease the incentives of generic manufacturers to pursue entry prior to patent expiration, especially for "non-blockbuster" drugs. For a generic manufacturer, the additional competition from an authorized generic may result in significantly less profit during the period of 180-day exclusivity than if the generic manufacturer had no authorized-generic competition during that time. Another concern is that, in the context of settlement, the brand-name manufacturer will promise to forego introducing an authorized generic in exchange for the first-filer agreeing to push back its entry date.

There is no publicly available, comprehensive economic study that assesses the likely short- and long-run effects of entry by authorized generics on generic competition. Thus, the

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[79] *Teva Pharm. Indus. v. FDA*, 410 F.3d 51 (D.C. Cir. 2005).

Commission has proposed to undertake such a study to examine both the likely short-term competitive effects of authorized generic drug entry and, to the extent possible, the likely long-term impact of entry by authorized generic drugs on competition by generic manufacturers. The Commission stated its intention to rely on data and information from the FDA, brand manufacturers, independent generic manufacturers, and authorized generic companies. In March of this year, the Commission issued a notice in the Federal Register describing the study and the types of information it would be seeking. The Commission received public comments through the end of June and is now reviewing those comments. After the Commission finishes reviewing those comments and makes any changes to the study, it will publish a second notice and seek OMB's approval for the subpoenas.

Conclusion

Thank you for this opportunity to share the Commission's views on the barriers to generic entry. The Commission looks forward to working closely with the Committee, as it has in the past, to ensure that competition in this critical sector of the economy remains vigorous.

Senator KOHL. Thank you, Commissioner Leibowitz. Commissioner Leibowitz, after the FTC lost the Schering case, as you pointed out, I introduced legislation to prevent brand name drug companies from paying off generics to stay off the market. I understand that the FTC has not taken a formal position on our bill as of yet.

Can you tell us why the FTC has not endorsed this legislation?

Mr. LEIBOWITZ. Well, we strongly support the intent of your legislation, but the FTC is the epitome of a consensus-driven agency. We haven't reviewed the legislation in detail. By the way, I believe it will go to Senator Smith's subcommittee, which is the FTC subcommittee on the Commerce Committee. But we are very supportive of what you are trying to do and we are very supportive of a legislative solution.

Senator KOHL. Is the FTC pursuing other cases to challenge different payoffs in an effort to get a better result in court? Is the FTC holding public hearings on this issue?

Mr. LEIBOWITZ. We are looking to find cases so that we can create, for example, a split in the circuits that would militate toward the Supreme Court taking a case. I can't discuss any of our individual investigations publicly, but we are looking to find a case. As for a public hearing, we have not initiated one. I would be glad to take that back to the Commission and talk to them about it.

Senator KOHL. You referred to authorized generics. As you pointed out, the FTC is currently studying the effects of authorized generics. The question is does the FTC have the authority to address this anti-competitive practice, or do you believe that we also need to find a legislative fix for this issue. What is your opinion on that, Commissioner Leibowitz?

Mr. LEIBOWITZ. Well, I don't know that authorized generics rises to the level of an antitrust violation, which is really what is within our purview at the FTC. We certainly think that it is an important public policy issue and we are committed to doing a very thorough study and looking at both the potential short-term benefits and the potential long-term problems that it may cause.

Senator KOHL. Mr. Buehler, over the last 5 years, as you have been discussing this morning, the number of generic drug applications have increased 150 percent, while your budget to work with this increase has not increased nearly to that percentage. Of the close to 800 applications that you have already received this year, as you pointed out, you have only approved a little more than half. So what is your plan to eliminate this backlog? How long do you expect it to take before we can eliminate this backlog?

Mr. BUEHLER. To be able to eliminate the backlog, we would have to increase the monthly average of approvals from our present 40 applications to somewhere between 65 and 70. To be able to do that, we have submitted a plan that we believe, with additional resources, FTEs, of about 70 to 100 over 3 years—this would entail $16 to $19 million annually. We would be able to create new review teams, continue to enhance the efficiency of our review process, and be able to first attain parity with the number of applications that we are receiving, and we are about a minus 300 right now. Once we attain parity, we will be able to address the backlog, and hope-

fully within 3 to 4 years be able to begin to whittle down this number.

Senator KOHL. With respect to the amount of time that it takes to review these petitions, since the start of your process over a year-and-a-half ago, what is the average time right now?

Mr. BUEHLER. For the petitions, sir?

Senator KOHL. Yes.

Mr. BUEHLER. Citizen petitions usually take about 6 months to review. We have a statutory 6-month timeframe to review citizen petitions. They are taking about that time, although we do get scientifically challenging ones that can run quite a bit longer than that.

Senator KOHL. Senator Smith.

The CHAIRMAN. Gary, is the backlog, in your view, then just a manpower issue?

Mr. BUEHLER. For the most part, yes. These applications are all types, and we have done a number of analyses on the types of applications in our backlog and we have analyzed them by patent certification and we have found that there are about an equal number of paragraph I and paragraph II certification applications, which are applications that either have no patents or the patents have expired. These tend to be older drugs and drugs that probably already have generic competition.

The CHAIRMAN. So there is nothing in your processes that you think could be streamlined without compromising safety?

Mr. BUEHLER. We have looked at our process very carefully and I have said to my division directors that we have got to identify things that we do that we don't have to do that don't impact the safety and efficacy of the products. But at the same time, we have to be very aware of what we do do that does impact safety and efficacy.

My mandate, my mission in life is to make sure that every generic drug that goes out on the market is safe, effective and bioequivalent and the American public can take these products with confidence. So we can reduce our process and the fat in our process, but only to a certain point. These are all full-standing applications with full data packages that have to be reviewed.

The CHAIRMAN. I don't in any way want you to take from my question that we want to compromise safety or efficacy of these drugs. We are counting on you for that, but obviously if there is something that can be streamlined systemically, great, do it, but don't compromise those two things.

As to the manpower issue, have you sought the authorization from the appropriate committee and are you getting the appropriations to add the staff?

Mr. BUEHLER. We have provided our plan to Senator Kohl. He had requested a plan from us a few months ago and we have provided it to Senator Kohl.

Mr. LEIBOWITZ. If I could just add one thing, Chairman Smith.

The CHAIRMAN. Yes.

Mr. LEIBOWITZ. We work very closely with the FDA and in response to a request from them several years ago, we did raise the potential for abuse of citizen petitions. Very often, they are filed at the eleventh hour. As Mr. Buehler's testimony points out, they usu-

ally raise redundant issues that have been resolved by the FDA. I was really heartened to see that in his testimony it looks like FDA is looking at ways to sort of tweak their rule so that maybe you would have to raise a citizens' petition earlier. That might solve part of the problem.

The CHAIRMAN. OK, so you are not barring the citizen, but you are just saying it can't be unduly dilatory in this process.

Mr. LEIBOWITZ. Yes, that is right.

The CHAIRMAN. Well, I hope you will succeed. You have got the ear of the right person in the Appropriations Committee. I guess it is the Health, Education and Welfare Committee that gives you the authorization for more, and if I can help, let me know.

Mr. BUEHLER. Thank you, Mr. Chairman.

The CHAIRMAN. I assume that with patents expiring, this issue is going to grow. It is not going to go down, and I think that is what your chart is saying.

Mr. BUEHLER. It doesn't look like our submissions are declining, no.

The CHAIRMAN. Jon, I am troubled by the holding. I am not an antitrust lawyer, but I do know something about antitrust law and I can't imagine a lower court finding that this was not uncompetitive action. What was their rationale and what was their holding?

Mr. LEIBOWITZ. Well, I think rather than looking at it from an antitrust perspective, which is the way we look at these cases—and I think the way Senator Hatch, one of the drafters of Hatch-Waxman, does—I think they looked at it more as patent case, and also wanted to ensure the benefit of settlements.

Having said that, what we found from 2000 to 2004 when we pretty much stopped this practice cold was that there were plenty of settlements; there were just no settlements with money. So, of course, reasonable people can disagree. The Eleventh Circuit disagreed with us, but we think our position is the right one.

The CHAIRMAN. On what basis did they disagree? I am not expecting you to agree with them, but I mean what was their rationale?

Mr. LEIBOWITZ. Well, their rationale essentially was that settlements are very important and as long as the settlement didn't go beyond—in the Eleventh Circuit—as long as the settlement didn't go beyond the scope of the patent, then this was an agreement that really shouldn't be analyzed under a rule of reason or a per se analysis or any antitrust approach.

The CHAIRMAN. So antitrust wasn't even considered?

Mr. LEIBOWITZ. I guess I would say that it was looked at, but it wasn't considered; at least it wasn't considered sufficiently.

The CHAIRMAN. Obviously, that would fall under the Justice Department to bring that action, I suppose, under antitrust.

Mr. LEIBOWITZ. We bring antitrust cases. We share that jurisdiction——

The CHAIRMAN. With them?

Mr. LEIBOWITZ. With the Justice Department. That is right.

The CHAIRMAN. The Supreme Court denied certiorari?

Mr. LEIBOWITZ. The Supreme Court denied cert. You know, the Supreme Court gets a lot of applications for cert. Some people believed that there wasn't a sufficient split in the circuits to make it

a case that they wanted to take or they ought to take. Hopefully, some other cases will come with better case law—if we bring further cases perhaps someday they will take it, perhaps someday soon.

The CHAIRMAN. But as you saw it from the FTC, you clearly could demonstrate monetary impact to the marketplace.

Mr. LEIBOWITZ. Yes, we thought we did. We thought we did it compellingly. The Eleventh Circuit disagreed with us.

The CHAIRMAN. But they didn't consider the antitrust implications?

Mr. LEIBOWITZ. From our perspective, at least, not sufficiently.

The CHAIRMAN. That is amazing to me. You know, I am not an antitrust lawyer, but it seems like an antitrust violation, per se.

Mr. LEIBOWITZ. It certainly seemed to us like an antitrust violation. I wasn't on the Commission when we wrote our own opinion, but it was very compelling when I read it and I wasn't as persuaded by the Eleventh Circuit. But that is the nature of judicial review here.

The only other point I want to mention is during the debate on the 2003 Medicare Amendments where Congress gave us the authority and really required us to review all of these settlements, Senator Hatch himself, one of the coauthors of Hatch-Waxman, said these types of reverse payments are "appalling". I think what Congress intended to do by requiring us to review all of these settlements was to see which ones were anti-competitive.

The CHAIRMAN. So the legislation you have given to Senator Kohl's care provides the legal clarifications necessary under patent law to remedy this?

Mr. LEIBOWITZ. It basically would prohibit under the FTC Act these types of agreements where there was compensation, cash compensation particularly, given to the generic from the brand for the generic to stay out of the market. We don't think that was the intent of Hatch-Waxman. We don't think the Eleventh Circuit got it right. Reasonable people can disagree, but that is our hope.

The CHAIRMAN. Well, we will surely take it up in the Commerce Committee post haste.

Mr. LEIBOWITZ. Thank you so much. We appreciate that.

The CHAIRMAN. To your reference on the catch–22 issue, talk to me about the legal clarifications there that you need.

Mr. LEIBOWITZ. Well, under Hatch-Waxman, as I understand it, usually the first filer gets 180 days of exclusivity. That is the approach that Congress took when it designed Hatch-Waxman. But if the first filer for some reason—sometimes it might be because of a payment, sometimes because their challenge is weak—agrees to not enter for several years, there is supposed to be a way for subsequent patent challengers to trigger the 180 days by winning a declaratory judgment.

Because of decisions in the D.C. Circuit and the Federal Circuit, they haven't been able to do that. So we have a proposal, again written by the staff in 2002, that is in my testimony that would solve that problem, and we believe do it in a constitutional way. There are different ways you can do it.

The CHAIRMAN. Where is that legislation now?

Mr. LEIBOWITZ. That legislation is in my testimony, but has not been introduced.

The CHAIRMAN. So we need it introduced.

Mr. LEIBOWITZ. Certainly, if you decide that introducing that legislation is a good idea, we would be supportive of it.

The CHAIRMAN. Thank you, Mr. Chairman.

Senator KOHL. Thank you very much, Chairman Smith.

We are joined today by our colleague, Senator Clinton, from New York. We will turn to you for your thoughts, comments and questions.

Senator CLINTON. Thank you very much, and once again thanks to Senator Smith and Senator Kohl for doing these very informative hearings. I would ask unanimous consent to submit my statement to the record.

The CHAIRMAN. Without objection.

[The prepared statement of Senator Clinton follows:]

PREPARED STATEMENT OF SENATOR HILLARY RODHAM CLINTON

Prescription drugs are vital to preventing and treating illness and helping to avoid more costly medical problems. Spending in the U.S. for prescription drugs was almost $189 billion in 2004, over 4 and half times the amount spent in 1990. And although prescription drug spending has been a relatively small proportion of national health care spending compared to hospital or physician services, it is one of the fastest growing components, increasing over the past decade at double-digit rates compared to single-digit increases for hospital or physician services.

As the population ages and our healthcare system faces increasing pressures, finding real and legitimate cost savings must be a top priority. And prescription drugs are clearly a place we should be looking. The 2003 Medicare prescription drug law explicitly prohibited the government from using the collective purchasing power of more than 40 million seniors to negotiate lower drug prices, in stark contrast to the authority to reduce prescription drug costs that other federal agencies and programs have including the VA and DoD. In addition, many of my colleagues and I continue to call for passage of legislation to allow for the safe reimportation of prescription drugs. But I think the real potential—and I thank and commend the Chair and Ranking Member for having the foresight to hold this hearing—is in generic drugs.

According to a 1998 CBO analysis, generics save consumers between $8 and $10 billion each year. And generic drugs are now used to fill more than half—approximately 55 percent—of all prescriptions each year, but account for only about 13 percent of spending on prescription drugs.

It is estimated that every 1 percent increase in generic utilization results in a 1–2 percent total cost savings. But since generic substitution rates are in the range of 90 percent, the greatest potential for cost savings rests with bringing new generics to the market. And the recent study that PCMA did, and that they talk about in their testimony today, really highlights the future potential of cost savings as brand drugs come off patent and generics are able to enter the market. The PCMA analysis found the potential for $49 billion in savings across the healthcare system from 14 drugs that are going off patent in the next five years. Medicare's share of that total is approximately $23 billion.

One important component that I am particularly interested in for ensuring that generic drugs are able to come to market is the establishment of a clear pathway for generic biologics. Since the passage of Hatch-Waxman in 1984, scientific advances have made the biotechnology industry an integral part of the pharmaceutical industry and we must update this law to reflect the critical role biologics now play in treatment.

And biologics are a major driver of increasing prescription drug costs. Six biotech pharmaceuticals—Procrit, Epogen, Neuposen, Intron-A, Humulin and Rituxan generated sales of more than $1 billion in 2003 and the top three biotech pharmaceuticals: Neupogen, Epogen and Intron A cost patients $23,098, $10,348 and $5,850 respectively, each year. As evidenced by these examples, generic competition for biopharmaceuticals has the potential to offer consumers dramatic and substantial savings.

As the number of biologics grows, and the lifecycle of these products matures, the patents on these products expire. In 2004 there were more than a dozen biopharmaceuticals for which U.S. patents have expired, or will expire by 2006. Providing a clear pathway for bringing generic biologics to market provides a significant opportunity to save healthcare dollars and I look forward to exploring this in more detail this morning and as we move forward.

Thank you, Mr. Chairman.

Senator CLINTON. Mr. Buehler, I recognize that the FDA has been very public about its belief that it does not have the legislative authority to develop a pathway that would allow the vast majority of generic biologics to enter the market. However, the FDA began working on drug-specific guidance documents 7 years ago during the Clinton administration to provide information to companies about two biologics—insulin and growth hormone—drugs that you have asserted authority over.

While these guidance documents are not an explicit pathway, they would certainly facilitate bringing a biogeneric for each of these drugs to the market. But just last month, after 7 years, the FDA announced that it is reversing course and will instead begin all over again and develop industry-wide guidance on this issue.

Now, I am particularly concerned about this because since the passage of Hatch-Waxman in 1984, a lot of scientific advances have been made and the biotechnology industry is now an integral part of our pharmaceutical industry. I think we have to update the law to reflect the critical role that biologics are now playing in treatment of disease. Biologics are a major driver of increasing prescription drug costs. Six biotech pharmaceuticals are generating more than $1 billion in sales and the top three biotech pharmaceuticals—Neupogen, Epogen and Intron-A—cost patients $23,000, $10,000 and $5,000, respectively, each year.

So as the number of biologics grows and the life cycle of these products mature, the patents on these products expire. In 2004, there were more than a dozen pharmaceuticals for which U.S. patents have expired or will expire by the end of 2006. So providing a clear pathway for bringing generic biologics to market provides a significant opportunity to save health care dollars.

So now even where the FDA has accepted authority to facilitate bringing a generic to the market and where you have spent 7 years, you have missed the opportunity to save millions of dollars for consumers and taxpayers. In fact, just for insulin and growth hormone alone, the Medicaid program spent $752 million last year. If a biogeneric had been on the market in 2005, the Medicaid program could have saved over $100 million on these two drugs alone. Of course, the savings in Medicare and the health care system overall would be even greater.

So with that preface, Mr. Buehler, why after 7 years did the FDA decide to change course, No. 1? No. 2, what happened to the insulin and growth hormone specific documents you were working on?

Mr. BUEHLER. Well, first, let me preface, Senator Clinton, that through the extensive discussions we have been having at the agency over generic biologics, the initial feeling is that my office would not be involved in the review and approval of these products because of the complexity of the molecules and the feeling that there would be the need for some additional clinical work that

would accompany the application that could not be submitted in an ANDA and could not be reviewed in the Office of Generic Drugs.

So the direction that the discussions are going are that these particular applications would be what we call 505(b)(2) applications, which are a hybrid application that is reviewed in the Office of New Drugs and gives the applicant the capability to do a number of various studies that are requested by FDA.

These are complex molecules. There is a lot of concern at the agency that when biogenerics are available, they are clearly—as the concern is for small molecules, they are clearly bioequivalent products that can be used interchangeably in the marketplace. So we are taking our time in making sure that the requirements for these products are clearly delineated and scientifically based.

The reason I believe—and again I am not privy to a lot of these discussions because my office is not going to be involved in the review and approval of these products, but I believe the thought was that we wanted to put out a global document that would cover the class of biogenerics or follow-on protein products from the very simplest to the more complex, and that we can provide a road map for the industry that would outline the requirements for FDA approval.

Senator CLINTON. Well, Mr. Buehler, just so I understand, was your office involved in the 7 years of study with respect to insulin and growth hormone?

Mr. BUEHLER. We were involved in the discussions, and clearly our scientists were involved in the discussions with the scientists from the Office of New Drugs. But at a certain point, the Office of New Drugs and the clinicians in the Office of New Drugs felt that these particular applications should be put in as a (b)(2) application so that it would allow us to request more information, if needed, for these particular products.

Senator CLINTON. So is it your understanding that the Office of New Drugs will handle both the original biologics and the generic version of the biologics?

Mr. BUEHLER. At this point, I believe that is the direction we are going, yes.

Senator CLINTON. Now, would you or anyone else who is here with you from the FDA know who has possession of the guidance documents that were generated with respect to insulin or growth hormone?

Mr. BUEHLER. I do not know.

Senator CLINTON. Is there anyone else from FDA who knows who has possession?

Mr. BUEHLER. We can get back to you with that.

Senator CLINTON. I think it would be very useful because this is an area which is crying out for some legislative direction. It doesn't really have a specific pathway yet, and because the FDA has taken the position that it doesn't have authority, I think that we need to look to see how we are going to handle both the biologics and then, of course, the generic biologics. I think it would be useful to have those guidance documents because 7 years of effort went into those.

So, Mr. Chairman, I might ask that we try to obtain those guidance documents to see if it can inform our concerns about the generic issue, in general, but specifically in this new field of biologics,

because I am concerned that we don't yet have a framework for this and I think we need to work on that. So I look forward to getting more information from the FDA about this process and then trying to figure out what we might do to work with the FDA to create a better understanding of how this is going to be handled because I think Mr. Buehler very correctly said this is incredibly complicated and so we need some guidance.

I understand from the reports I got that there was some very good questioning by the Chairman and the Ranking Member about whether the FDA has the resources to do what we are asking them to do, and I don't think it does. This new field which is about to explode on biologics will add even more burden, but there is no better place to put it if it is well-resourced. So I think that has to be taken into account as well.

Thank you.

Senator KOHL. Thank you very much, Senator Clinton.

We would like to thank the first panel. You have been really good, very informative, and at this point we will go on to the next panel.

Mr. LEIBOWITZ. Thank you.

Mr. BUEHLER. Thank you.

Senator KOHL. The first witness on our second panel is Heather Bresch, who is the senior vice president of Corporate Strategic Development at Mylan Laboratories. Mylan Laboratories is a leading U.S.-based generic pharmaceutical company and one of the world's leading providers of prescription medications. Ms. Bresch has 15 years of experience in the generic pharmaceutical industry, including multiple senior positions with Mylan Laboratories and the Generic Pharmaceutical Association. She is here to provide us with firsthand examples of the challenges generic pharmaceutical companies face in getting their medicines on the market. We welcome you.

The second witness will be Mark Merritt. Mr. Merritt serves as president of the Pharmaceutical Care Management Association, the national association representing America's pharmacy benefit managers which administers prescription drug plans for more than 200 million Americans. Mr. Merritt will demonstrate the cost savings associated with increased utilization of generic drugs, as well as recent analysis showing the potential savings seniors and Medicare could realize over the next 5 years.

We thank you both for coming, and so we will start with you, Ms. Bresch.

STATEMENT OF HEATHER BRESCH, SENIOR VICE PRESIDENT OF CORPORATE STRATEGIC DEVELOPMENT, OFFICE OF THE CHIEF EXECUTIVE OFFICER, MYLAN LABORATORIES, INC., CANONSBURG, PA

Ms. BRESCH. Thank you, Chairman Smith and Co-Chairman Kohl and members of the Committee on Aging. I am Heather Bresch, with Mylan Laboratories, one of the world's leading providers of prescription drugs.

Fifty-five percent of all drugs dispensed today in the United States are filled by generic drugs. However, this 55-percent generic utilization only consumes 15 percent of America's drug spend. The average cost of a brand drug is about $95, while the average cost of a generic drug is less than $30.

My written testimony today addresses a number of issues. However, I wanted to devote my limited time with you today to talk about two of the more debilitating obstacles facing our industry: the misuse of authorized generics and the abuse of citizen petitions by brand companies.

To save consumers billions of dollars, the Hatch-Waxman Act of 1984 created a balance encouraging innovation and promoting access to affordable medicines. The only incentive provided to generic companies to challenge questionable brand patents was the 180-day exclusivity period.

Members of this Committee, the release of authorized generics during this exclusivity period is the single greatest threat to the viability of the generic industry going forward. Supporters of authorized generics claim that consumers benefit from this practice through lower prices, as cited by a recent study by PhRMA. A soon to be released independent study proves that nothing could be further from the truth.

PhRMA's study looked at wholesale prices, not retail- level prices. The independent study replicates PhRMA's products and calculations, but uses the retail price. It is also important to note that this study shows that 90 percent of our population is insured by a third-party payer or the government. So while they realize savings with a generic product coming to market because it establishes a generic co-pay, the presence of an authorized generic provides no additional savings to this group.

The remaining 10 percent of our population who pays cash saw virtually no additional savings from the presence of an authorized generic during the 180 days. Brand companies would never lower their price or launch an authorized generic without the presence of a true generic coming to the market.

For brand companies, authorized generics are a long-term strategy designed to debilitate our industry because they understand this revenue very importantly generates and enables us to further challenge questionable patents in their pipeline. There is no short-term benefit and there is long-term detriment to the generic industry because of this practice.

In fact, to use the exact words of J.P. Garner, CEO of Glaxo, quote, "The idea was somebody has a 6-month exclusivity, but we are king-maker. We can make a generic company compete during a very profitable time. We are not a generic company and we do not wish to become one. If we acquired the most successful generic

company in the world, it would barely move our needle on profit." Authorized generics are on the marketplace solely to cripple the industry. Eli Lilly CEO Sidney Laurel said back in December 2003, "For this to really work, you would have to have the whole industry do this systematically each time a patent expires so that you would truly eliminate the incentive and the calculation that generic companies would make." Well, to my knowledge, since December of 2003, each and every generic launch has been met in the marketplace with an authorized generic.

Brand companies also leverage authorized generics during settlement negotiations. We are aware, Senator Kohl, of your bill which seeks to prohibit any and all consideration but early entry of brand generic patent settlements. But we think this approach goes too far. The truth be told, unless and until the authorized generic problem is resolved, the patent settlement issue cannot rationally be discussed. Even if the generic company has invalidated a patent or believes that it will, the fact that a brand company can release an authorized generic during the 180-day period dramatically reduces the generic returns and leaves the generic with little choice and no bargaining power.

During the time period that Commissioner Leibowitz discussed that they reviewed patent settlements, the phenomenon of authorized generics has escalated dramatically. So we do not think it is coincidental the types of patent settlements that you are reviewing and their coordination with the practice of authorized generics.

The second tactic I want to discuss is the abuse of the citizen petition process to improperly delay competition. Frequently, a brand company will file a petition on the eve of FDA approval of a generic product to delay its approval. The brand strategy is that it will take months or longer for the FDA to answer the petition, during which time final approval of the generic drug will not be granted, and during which time brands can receive millions of dollars of day of revenue by delaying competition.

A review of citizen petitions filed with the FDA over the last 3 years reveals a very clear picture. During the last 3 years, brand companies have filed 45 petitions requesting the delay of FDA approval of a generic drug. Of these 45 petitions, the average time at the agency is 13 months. The FDA has ruled on 21, denying 20 of them, but not before causing delay anywhere from a few months to over a year.

To bring this critical issue sharply into focus, consider Mylan's successful challenge to J and J's brand name incontinence drug Ditropan XL. On August 29, 2005, with a decision expected at any moment, J and J filed an eleventh-hour citizen petition requesting that the FDA rethink its standards for approving a generic version of this drug. On September 26, 2005, not even a month later, a Federal district court found that J and J's patent was invalid and not infringed. However, today, 11 months later, the patent stands invalid, but consumers wait to enjoy the lower cost of a generic alternative because Mylan cannot receive final approval due to the citizen petition, even though we received tentative approval months and months ago.

In conclusion, we believe that Congress cannot stand still with such threats facing our health care system and the viability of the

generic drug industry. We applaud this Committee for conducting these hearings and urge Congress to take action now in two specific areas. We urge you to support legislation introduced yesterday by Senator Rockefeller and cosponsored by Senator Schumer and Senator Leahy.

Let me be clear about a very important point. The generic industry is not opposed to honest competition. Following the 180 days of exclusivity, we recognize the right of any company with an FDA-approved product, including the brand itself, to compete in the generic marketplace. But competition timed to hurt the long-term viability of our industry will lead to an escalation of the health care crisis, not its resolution.

Second, in 1999 the FDA proposed a rule that would have separated the review of citizen petitions from the approval of the generic product, and the FTC weighed in on the rule and even enhanced it. With little explanation, the FDA withdrew this proposed rule in 2003. We urge Congress to call on the FDA to reissue its proposed rule of 1999. If the FDA fails to take such action, we urge Congress to act immediately to support the bipartisan bill, Stabenow-Lott, which implements effectively the same rule.

I want to thank the Committee again for its time and interest in making sure seniors and all Americans have access to affordable, safe generic pharmaceuticals. I am happy to answer any questions you may have.

[The prepared statement of Ms. Bresch follows:]

Testimony of

Heather Bresch

Senior Vice President of Corporate Strategic Development
Office of the CEO
Mylan Laboratories Inc.

The Generic Drug Maze:
Speeding Access to Affordable, Life Saving Drugs.

United States Senate
Special Committee on Aging

Washington, D.C.
July 20, 2006

Thank you Chairman Smith, Ranking Member Kohl and Members of the Special Committee on Aging. I am Heather Bresch, Senior Vice President of Corporate Strategic Development in the Office of the CEO of Mylan Laboratories. Mylan has been in existence for 45 years. We are the largest U.S.-based generic pharmaceutical manufacturer, supplying more than 150 FDA-approved prescription generic drugs, and we are one of the world's leading suppliers of prescription medicines having manufactured more than 12 billion tablets and capsules during the most recent fiscal year. Mylan is also the largest supplier, brand or generic, of prescription transdermal patches, with more than 88 million units dispensed in 2005. Mylan has consistently been recognized by the FDA and by the pharmacy community for the excellent quality of its products.

While I am speaking on behalf of Mylan today, I also served as Chairman of the Generic Pharmaceutical Association for two terms and currently serve as Vice Chair. GPhA represents more than 100 generic manufacturers and distributors of finished generic products, as well as manufacturers and distributors of bulk active pharmaceutical chemicals.

Generic products are now used to fill more than one-and-a-half billion prescriptions in the U.S. every year, which accounts for about 54 percent of all prescriptions dispensed across the country. Considering that the average cost of a brand prescription is about $95.00, while the average cost of a prescription filled with a generic is less than $29.00, use of generic drugs generates billions of dollars in savings for consumers as well as businesses, and state and federal government agencies. The Congressional Budget Office estimated, for example, that by purchasing generic drugs when available as substitutes for brand-name drugs, consumers save between $8 billion and $10 billion a year on prescription purchases made at retail pharmacies.

Mr. Chairman, our country is facing a crisis in rising healthcare costs and the generic pharmaceutical industry represents one of the few proven solutions to contain those costs.

So I am pleased to be here today to discuss ways to improve access to generic drugs and to share our views on the harm done to consumers and government when new generic drugs are delayed. I will specifically address four tactics purposefully used to slow down or block the entry of generic pharmaceuticals into the marketplace. These tactics cost American consumers, businesses, insurers and our government millions of dollars every day.

By way of background *Hatch-Waxman* - officially "The Drug Price Competition and Patent Term Restoration Act of 1984" - reflected an attempt by Congress to strike a balance between two policy objectives: to incentivize name-brand pharmaceutical firms to make the investments necessary to research and develop new drug products; and also to enable competitors to bring lower-cost, bioequivalent and therapeutically equivalent generic versions of those drugs to market. *Hatch-Waxman*, is designed to both reward innovation and encourage access to affordable medicines. When the balance is disturbed the system is jeopardized and it is consumers, the government and taxpayers who suffer the economic consequences.

In terms of the branded pharmaceutical side of the scale, this legislation protects intellectual property in a variety of ways. *Hatch-Waxman* provides the means for innovators to restore up to 5 years of patent life to compensate for time the product underwent regulatory review at the FDA. In subsequent legislation branded pharmaceutical companies were offered 5 years of data exclusivity for new chemical entities, a supplement of 3 years of data exclusivity for clinical trials, 6 months marketing exclusivity for pediatric studies, and an automatic 30-month stay of generic approvals in order to resolve patent disputes.

With respect to the generic pharmaceutical side of the scale, Hatch-Waxman streamlined the generic drug approval processes and provided 180 days of market exclusivity to financially incentivize generic manufacturers to challenge the validity of questionable patents held by brand manufacturers. The marketing exclusivity period allowed the generic companies to gain the significant financial resources necessary to reinvest and

continue to develop additional generic products.

Notable examples of the system working the way it was intended occurred when Mylan challenged patents on the name brand drugs Buspar® and Procardia XL® and brought generic versions of those drugs years before patent expiration. Another well known patent challenge by a different generic company invalidated a key patent on Prozac®. Hundreds of millions of dollars in savings were realized by consumers and the government as a result of these successes.

The system worked well until the early 2000s, when branded pharmaceutical companies began to exploit certain legislative loopholes. While Congress put an end to some of these practices in 2003 with the passage of Hatch-Waxman reform in the *Medicare Modernization Act* (MMA), unfortunately, brand companies were already using new tactics to extend their monopolies.

These tactics include first, authorized generics, which are simply branded products relabeled as generics and then systematically dumped into the generic marketplace during the 180-day exclusivity period. A second tactic is the use of frivolous citizen petitions raising unfounded safety-issues. These petitions are strategically filed with the FDA to delay generic entry. Third, legal maneuvering around Congress' attempt to allow for a declaratory judgment trigger can create a bottle-neck of generic drug approvals. And fourth, exploitation of pediatric exclusivity rules to gain extended monopoly for drugs that should not be used in the pediatric population.

AUTHORIZED GENERICS

Mr. Chairman, in our industry there is no issue more hotly debated than that of authorized generics. This brand tactic is the "authorizing" of a third party to sell the brand product dressed as a generic as soon as the first true generic begins to enjoy its 180 days of statutory exclusivity. This practice can all but eliminate the financial benefit of the market exclusivity for the first generic filer.

Let me be very clear: the generic industry is not opposed to authorize generics *per se*. Our issue lies only in the marketing of authorized generics during the 180-days of exclusivity as provided under *Hatch-Waxman*. Following the 180-days of exclusivity granted to the first generic filer, we recognize the right of any company with an FDA-approved product, including the brand company, to compete in the generic marketplace. The issue is *when* the authorized generic is brought to market. As this committee is aware, it is the timing of the introduction of the authorized generic that has caught the attention of the FTC and is being examined in their pending study.

The words of several brand pharmaceutical CEOs best demonstrate their motives.

> In December 2003 in a Pink Sheet Article Eli Lilly CEO Sidney Laurel was quoted saying that systematically launching authorized generics each time a patent expires would mean the brand industry could *"truly eliminate the incentive in the calculation that generic companies would make."*
>
> In June 2006 in a Wall Street Journal article Pfizer's Hank McConnell was asked whether Pfizer subsidiary Greenstone aimed mainly to give generic-drug maker fits or to preserve some sales for Pfizer, he quipped, "Both are good things."
>
> In April 2003 press release, GlaxoSmithKline announced an authorized generic agreement for Paxil®, the blockbuster antidepressant. The agreement prevented the authorized generic from becoming available until "another generic version fully substitutable for Paxil becomes available." In other words the authorized generic was prohibited from launching until the generic filer with 180 days of exclusivity was launched.
>
> In February 2004 earnings conference call GlaxoSmithKline CEO J.P. Garner said *"The idea was somebody has a six month exclusivity, but we*

are a king maker; we can make a generic company compete during [the 180-day exclusivity]."

"King maker" doesn't sound like the competitive balance intended by congress when enacting *Hatch-Waxman.*

Supporters of authorized generics say they reduce prices in the short term, arguing that consumers benefit and that authorized generics are somehow consumer-friendly. They cite a recent report by the Pharmaceutical Research and Manufacturers of America ("PhRMA") saying that there is a 15 percent reduction in price as a result of authorized generics during the 180-day exclusivity period. Nothing could be further from the truth. This study only looked at prices at the *wholesale level* - not the retail level - where in fact consumers do not realize those savings.

Prescription drugs move through a multi-step pharmaceutical "supply chain" when making their way from manufacturer to wholesaler, to patient (end user or consumer) and prices paid for drugs vary for each entity within the supply chain. For example, large wholesalers, national pharmacy chains and major health insurers - those entities in the middle on the chart -- can negotiate steep price discounts from drugs manufacturers, especially when the market becomes commoditized with multiple generic players. Individual consumers, on the other hand, typically pay retail prices for drugs without negotiating with pharmacists.

Therefore, to measure any discount off the brand drug price - the savings that generics offer - data from the price point between wholesaler/chain and consumer must be used. Using price data obtained at the point between manufacturer and wholesaler does not reflect any potential discounts available to consumers.

I would be remiss if I did not address the connection between authorized generics and patent settlements between brand and generic companies. There has been increasing attention on the issue of patent settlements, by Congress, the FTC, the press and the public. We are aware, Senator Kohl, of your bill which seeks to prohibit generic drug

companies from receiving anything of value from patent settlements. As settlements come under scrutiny, we must remember that patent settlements, in and of themselves, are not bad. In fact, a settlement involving breast cancer treatment Tamoxifen allowed a generic version to enter the market nine years prior to the date when the patent in question expired. The reality is that in almost every other type of case, settling litigation is *encouraged* as an efficient means of resolving dispute and economizing valuable court resources. The option of settling is particularly important to generic companies attempting to challenge brand patents. These challenges are extremely costly - and the outcomes of even the best cases are uncertain. Generic companies need the ability to settle cases in a way that preserves their ability to fight another day.

But more to the point, brand companies have a stronger bargaining position thanks to authorized generics. Brand companies use authorized generics as a "trump card" in settlement negotiations. Even if the generic company believes it can invalidate the brand's patents, the brand company threatens to release an authorized generic during the 180-day exclusivity period, at prices that gut generic returns. This leaves the generic with little choice and no bargaining power.

The FTC has recognized the crucial role authorized generics play in settlement negotiations. FTC Commissioner Jon Leibowitz noted in a recent speech at the Second Annual In-House Counsel's Forum on Pharmaceutical Antitrust in Philadelphia, that "the profits to be made in the 180-day exclusivity period are reduced substantially [by authorized generics], perhaps even cut in half. So the generic firm's calculus in the fight-versus-settle equation may now be more heavily weighted towards settling. Rather than gamble on winning in court, a generic may decide that a fixed entry date and guaranteed revenue stream is a better value than rolling the dice." Mr. Chairman any consideration of patent settlements reform must take authorized generics into account.

CITIZEN PETITIONS

Mr. Chairman, the second tactic being used by brand companies to delay access to

generic drugs is the abuse of the citizen petition process.

The brand industry is misusing the citizen petition process to improperly delay generic competition. As intended, the citizen petition mechanism provides a formal opportunity to request the FDA to take or not take a particular administrative action about very specific issues, such as scientific concerns about a particular product's safety or bioequivalence. However, when the process is abused, a citizen petition can become a tool for the brand industry to delay timely entry of safe and effective generic drugs.

Frequently, a brand company will file a frivolous petition on the eve of FDA approval of a generic equivalent. This despite the fact that the FDA may have already granted a tentative approval, meaning that FDA already determined the generic product is safe and effective. The brand strategy is that it will take several months for the FDA to decide the petition, during which time approval of the generic drug is held in limbo. The brand is not required to submit petitions with merit. What the brand company can do is block competition for several months beyond the life of the 20-year patent, thereby extending its monopoly on the market.

The submission of these "eleventh-hour" petitions has caught the attention of the FTC and of the FDA as far back as 1999. That year, the FDA issued a proposed rule to address the problem that would have decoupled the approval process from the process for addressing citizen petitions. The proposed rule, unfortunately, was withdrawn in 2003.

Examples of egregious abuses of the citizen petition process are many. In the case of the drug Arava®, Aventis filed a citizen petition requesting that the FDA deny approval for generic leflunomide unless the generic could demonstrate that 5x20 mg tablets were bioequivalent to 1x100mg tablet. The FDA ultimately denied the petition, noting in its reasons that the "petition was submitted approximately one year after [expiration of brand exclusivity]. [...] This would be at the end of the normal ANDA review cycle for an ANDA submitted on or near the date ANDAs were first eligible for submission, suggesting that the petition intends (at least in part) to delay generic competition." The

petition was successful in this regard - it resulted in approximately 6-months delay to generic entry and economic harm to consumers and the government.

In an ongoing example, Wyeth filed a petition to delay approval of generic Effexor XR® two weeks before the patent expired. For each day that the brand succeeds in delaying generic entry, it benefits from approximately $7 million in sales. The delay to generic entry is over three months, and counting.

Yet another example may currently be seen at Mylan Laboratories. Our company is currently experiencing a delayed generic approval solely because of an eleventh hour citizen petition filed by the branded drug company. In September of 2005, we successfully defended a patent infringement suit and invalidated a patent covering the name brand drug Ditropan XL®. Mylan's generic version of the drug had already been tentatively approved by the FDA, meaning the lawsuit was the only thing standing in the way of our ability to launch our product. On the eve of a decision from the district court invalidating the patent, Ortho McNeil Pharmaceuticals filed a citizen petition requesting that FDA re-think its standards for approving generic versions of this drug. The petition raised no new information that had not been long known to Ortho-McNeil and certainly appears to have been timed to delay final approval of our generic drug. Ten months later, the patent stands invalid but we are still unable to obtain final approval from the FDA to launch our product because of the citizen petition.

Frivolous citizen petitions give brand companies an undeserved patent extension, at no cost and with no consequences. These extensions provide anywhere from a few months to over a year of additional monopoly. In contrast, a generic applicant must invest considerable resources on bioequivalence studies, incur significant development costs to design around patent, and legal costs to challenge brand patents in the hopes of benefiting from what was supposed to be 180 days of exclusivity.

A review of the citizen petitions filed with the FDA since MMA reveals a clear picture. Since MMA brand companies have filed 45 petitions requesting delay in FDA approval

of a competing generic drug. Of these 45 petitions, the FDA has ruled on 21, denying 20 of them - or 95% - but not before causing delay anywhere from a few months to over a year. Of these, ten were identified as "eleventh hour petitions" (defined as petitions filed 6 months prior or 4 months after the earliest estimated generic entry date). Since MMA, *no eleventh hour petitions have been approved by the FDA.*

We are pleased that the Senate and House Appropriations Committees insisted that the FDA inform Congress of actions being taken to improve the citizen petition process. In April of this year, the FDA delivered its report stating that, going forward, objectionable citizen petitions would be sent to the FTC for review. We do not believe forwarding citizen petitions to the FTC improves the process. In fact, it merely adds more time to the already delayed generic entry. Therefore, we urge Congress to support legislation like the bipartisan Stabenow-Lott bill to bring a meaningful resolution to this problem.

DECLARATORY JUDGEMENTS

Third, I want to discuss the declaratory judgment provision in the current regulatory scheme.

At the urging of the generic industry, Congress included language in MMA to the effect that if a brand company refused to sue a generic applicant, the generic could seek a judgment declaring the patent in question to be invalid, unenforceable or not infringed. This is important because there are times when a brand company will decide, for strategic reasons, to sue on some but not all of its patents.

This leaves the generic with two options, even if the generic prevails on the particular patents at issue in the suit: stay off the market, or enter the market "at risk" of treble damages for infringing the remaining patents. This could be a 'bet your company' decision for a generic manufacturer. The problem is that the US Court of Appeals for the Federal Circuit, which has jurisdiction over all patent cases, has held that the courts do not have jurisdiction to hear these declaratory judgment suits.

Declaratory judgment can be fixed. In order for a court to accept jurisdiction to grant a declaratory judgment, it must determine that the generic has a "reasonable apprehension of suit". So far, the courts have refused to hold this. Congress can legislate that a reasonable apprehension does exist, even if the brand fails to sue. This would effectively give courts jurisdiction to determine the patent questions and allow generic companies to clear patent issues much earlier without having to launch their product at risk.

PEDIATRIC EXCLUSIVITY

The fourth tactic is securing unwarranted extensions of monopolies through misuse of pediatric exclusivity rules. Under current interpretations of the regulations, almost all drugs are eligible for an additional period of exclusivity in which generics cannot be approved if pediatric studies are completed. This gaming was illustrated recently when Bristol Myers Squibb got six months of additional patent protection in exchange for conducting pediatric studies on Pravigard PAC® (pravastatin and aspirin), even though the FDA requires that the product be labeled with a caution against use in children less than 18 years of age. Affordable generic versions of this product will be blocked from the market for an additional half year because the brand company conducted studies in children using a drug that FDA said shouldn't be given to children in the first place.

In summary, Mr. Chairman, we believe that Congress cannot remain passive in the face of such threats to the US healthcare system.

Authorized generics launched into the 180 day exclusivity period can only be eliminated through legislation. As for citizen petitions, the FDA has full authority to reinstate its own rule from 1999 and separate generic approvals from the citizen petitions process.

The time is now for Congress to take action to ensure timely access to affordable drugs. This is all the more important as we stand to move into the world of biotechnology drugs. Generic biologics, such as insulin, are a reality and a pathway to their approval is critical

for our healthcare system to survive. The branded versions of these biologic drugs can cost tens and even hundreds of thousands of dollars a year to treat a single patient, and there is currently no regulatory pathway for approving generic versions of these drugs. Patients and insurers cannot afford to pay for the branded versions of these medications, often used to treat cancer and other serious illnesses, so it is crucial that the current loopholes in *Hatch-Waxman* be closed and the balance reconfigured before their consequences inhibit generic biologics as well.

I want to thank the committee again for its time and interest in making sure seniors and all Americans have access to affordable, safe generic pharmaceuticals. I am happy to answer any questions you might have.

Senator KOHL. We thank you very much.
Mr. Merritt.

STATEMENT OF MARK MERRITT, PRESIDENT AND CHIEF EXECUTIVE OFFICER, PHARMACEUTICAL CARE MANAGEMENT ASSOCIATION, WASHINGTON, DC

Mr. MERRITT. Thank you, Senator Kohl, Senator Smith, Senator Clinton, other members of the Committee. I am Mark Merritt, president of PCMA, the Pharmaceutical Care Management Association, which represents pharmacy benefit managers, or PBMs. PBMs administer drug benefits for more than 200 million Americans with coverage provided through private and public purchasers. We appreciate the invitation to be here today.

PBMs work on behalf of employers, unions, government agencies and others to help offer their people drug benefits that are as generous and affordable as possible. We don't set the price, prescribe or produce these drugs. Our job is to use our enormous purchasing power on behalf of our thousands of clients to generate competitive pricing from drug manufacturers and drugstores so that payers and consumers get the best deal possible. As a result of these efforts, PBMs typically reduce costs for purchasers and consumers by an average of 25 percent.

Regarding generics, PBMs do as much or more than anyone in America to increase generic utilization where appropriate, and we do this in a number of ways. First, we design formularies that offer consumers significant incentives to choose generic drugs when appropriate. We offer lower co-pays, step therapy programs and options like mail service pharmacy which tend to have a higher generic substitution rate than those achieved by retail pharmacies.

Second, we educate consumers, physicians and pharmacists about the availability of generics themselves. It is not always apparent to them, and we do as much as we can through calls and letters, and so forth, to make sure everybody knows of the affordable alternatives available to them.

Third, we have played a major leadership role in the e-prescribing front, which empowers physicians and patients to better understand their options and to make more affordable choices while they are still in the doctor's office.

PBMs routinely get generic substitution rates above 90 percent, and this hearing is very timely. PCMA looked at the impact of generics coming to market and found an unprecedented number of brands coming off patent in the next few years. As a result, we believe the potential savings across the entire health system will be $49 billion over 5 years, from 2006 to 2010, if these generic market entries happen when they are supposed to.

The challenge for all of us is to not only increase the utilization of the current generics available, but to expand the number of generics that come to market. PCMA offers the following recommendations on how to bring this about.

First, Congress should enact S. 2300, the Lower Price Drugs Act, cosponsored by you, Senator Kohl. Second, the funding of the Office of Generic Drugs needs to be increased so that generic applications can be moved through faster.

Third, PCMA believes Congress should establish a clear legal pathway to approve biogenerics sooner rather than later. Last year alone, the cost of biologics soared 17.5 percent, compared with traditional drugs which increased by 10 percent, and biologic costs are expected to represent $90 billion of drug spend in 2009. Obviously, there are no generic alternatives to make prices more competitive in this area.

Traditional drugs are created from chemicals, whereas biologics are derived from living organisms and are regulated differently by the Federal Government. While some argue that the science of creating generic biologics is not fully developed, progress is being made on a daily basis and the European Union has already approved legislation that creates a regulatory pathway for the approval of biogenerics. For these reasons, PCMA recommends that Congress create a clear legal pathway for generic biologics which would allow for some needed competition to bring down prices.

Fourth, and finally, PCMA believes Congress should adopt a national, uniform e-prescribing standard to make it easier for physicians in both the commercial market and with Medicare patients to adopt this revolutionary technology. E-prescribing empowers the physician and patient by showing them the choices of drugs in a plan formulary, including low-cost generic options and mail service pharmacy options, and again all while everybody is still in the doctor's office, the doctor and patient working together on this.

One e-prescribing demonstration project increased generic utilization by more than 7 percent in 1 year alone. Similarly, a recent study showed that widespread adoption of e-prescribing could save $29 billion annually, part of this because of increased generic utilization.

The key is having one simple, uniform e-prescribing standard for physicians to actually encourage them to use this technology. A doctor in Washington, DC is much more likely to embrace and actually use e-prescribing if they are not required to comply with four different standards to accommodate their patients in DC, Maryland, Virginia, and now the Medicare program.

PCMA is pleased to have the opportunity to testify here today and we look forward to working with the Committee as it considers these issues further. I would be happy to answer any questions the Committee may have.

[The prepared statement of Mr. Merritt follows:]

PCMA
PHARMACEUTICAL CARE
MANAGEMENT ASSOCIATION

Testimony of Mark Merritt

President & Chief Executive Officer

Pharmaceutical Care Management Association

Before the

UNITED STATES SENATE
SPECIAL COMMITTEE ON AGING

The Generic Drug Maze: Speeding Access to Affordable, Life Saving Drugs

July 20, 2006

Good Morning Chairman Smith, Ranking Member Kohl, and all the Members of the Senate Aging Committee.

I am Mark Merritt, President of the Pharmaceutical Care Management Association (PCMA). PCMA is the national association representing America's pharmacy benefit managers (PBMs), which administer prescription drug plans for more than 200 million Americans with health coverage provided through Fortune 500 employers, health insurers, labor unions, and Medicare.

I am pleased to be here today to discuss barriers to generic-drug entry into the marketplace. It is estimated that approximately $12 billion in brand-name drugs are anticipated to lose patent protection in 2006; another $11 billion in 2007; and $10 billion in 2008; increasing global sales of generic drugs from $29 billion in 2003 to $49 billion in 2007.[1] [2] Given the unprecedented levels of brands coming off patent, PCMA believes that this is a timely and important hearing and we applaud the Committee for its leadership.

PBMs' PROVEN TRACK RECORD

First, let me provide you some background on PBMs. PBMs have a long and distinguished record of administering drug benefits in the commercial marketplace – including designing and implementing cost-effective generic drug-utilization programs. As a result, PBMs have generated savings averaging 25 percent compared to unmanaged drug expenditures, although the savings PBMs achieve with generics are generally much deeper.

PBMs have a strong track record for delivering quality prescription-drug benefits with generous savings for consumers and purchasers. PBMs generate increased efficiencies by pooling the purchasing ability of millions of consumers to foster price competition between drug manufacturers and retail pharmacies where none previously existed. PBMs generate savings and improve quality by using cost containment, clinical, and utilization-management tools designed

[1] Drug Topics, Generics Supplement, April 2006
[2] "Use of Generic Therapeutic Substitution Can Save Billions in Drug Costs", Drug Benefit Trends, March 2006.

to balance consumers' and purchasers' needs for affordability, choice, and access. Such tools include:

- pharmacy and therapeutic (P&T) committee formulary development and review;
- pharmacy network management;
- negotiation and administration of product discounts, including manufacturer rebates;
- mail-service pharmacy;
- drug utilization review (DUR);
- generic substitution;
- clinical prior-authorization and step therapy;
- consumer and physician education;
- disease management; and
- prescription compliance programs.

Throughout the health care system, and now including the Medicare program, pharmacy benefit management tools are recognized as essential to improving outcomes and ensuring value-based purchasing. Prior to the advent of these tools, there was no system-wide approach that fully addressed the real dangers associated with misuse, overuse, or underuse of prescription drugs and escalating prescription drug costs.

PBMs' tools have delivered results. A recent study published in *Health Affairs* by CMS actuaries revealed that prescription drug spending in 2004 slowed to its lowest growth rate in the past 10 years, rising 8.2 percent. Since 1999 alone, the rate of growth in prescription drug spending has dropped by more than 50 percent. Overall, health spending grew in 2004 at a 7.9 percent clip, down from 8.2 percent in 2003.[3] The study's authors cited the rapid growth in the use of lower-priced generic drugs and mail-service pharmacies as two of the four key reasons.

[3]Smith, Cowan, Heffler, et al, CMS National Health Accounts Team, "National Health Spending in 2004: Recent Slow-Down Led By Prescription Drug Spending", *Health Affairs*, 25, no. 1 (2006: 186 – 196).

GENERICS REDUCE COSTS FOR CONSUMERS & PAYERS

It is estimated that every 1 percent increase in generic utilization results in 1-2 percent total cost savings. The brand and generic cost differential is on average between $60-80 per prescription.[4] For example, the average brand-name prescription in 2004 was $96.01, compared to the average generic prescription price of $28.74.

PCMA recently examined the top 100 drugs used by seniors to arrive at a conservative estimate of potential cost-savings to Medicare and the entire health care system. We found that at least 14 brand-name drugs commonly used by seniors to treat conditions such as high cholesterol, depression, heart disease, and hypertension are anticipated to go off patent or lose exclusivity during the next five years. Since generic drugs cost an average 30 to 80 percent less than brand-name drugs, the savings are huge.[5] PCMA calculated that from 2006 to 2010 the savings across the entire health system would be $49 billion as a result of these drugs going generic. Seniors and the Medicare Part D program could potentially save, at a minimum, more than $23 billion dollars over the next five years.[6]

	2006	2007	2008	2009	2010	2006-2010
Potential Savings from drugs going generic in 2006	$3,203,013,699	$5,832,000,000	$5,304,000,000	$4,824,000,000	$4,824,000,000	$24,087,013,699
Potential Savings from drugs going generic in 2007	$0	$1,453,946,301	$4,422,600,000	$4,422,600,000	$4,422,600,000	$14,721,746,301
Potential Savings from drugs going generic in 2008	$0	$0	$1,472,202,740	$2,106,000,000	$2,106,000,000	$5,684,202,740
Potential Savings from drugs going generic in 2009	$0	$0	$0	$301,808,219	$2,160,000,000	$2,461,808,219
Total Potential Savings	$3,203,013,699	$7,285,946,301	$11,726,802,740	$12,662,408,219	$14,520,600,000	$49,398,770,959

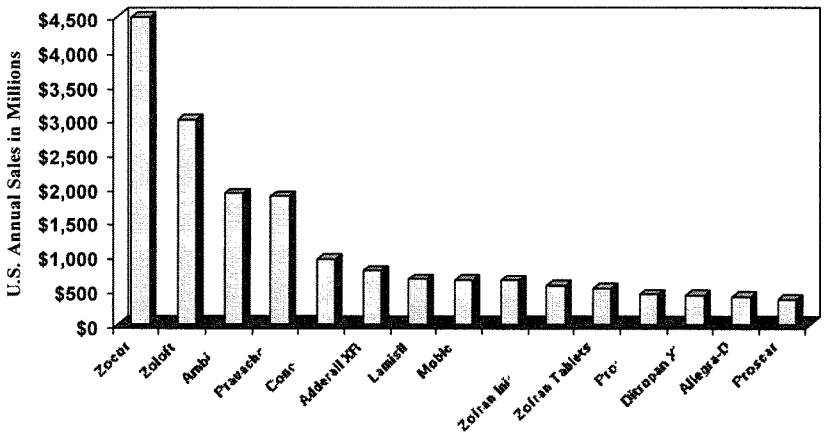
Source: PCMA analysis, April 2006

[4] Generic Pharmaceutical Industry Association, http://www.gphaonline.org. Accessed May, 2006
[5] Generic Pharmaceutical Industry Association, "About Generics," Accessed April 6, 2006, available at http://www.gphaonline.org/Content/NavigationMenu/AboutGenerics/Statistics/Statistics.htm
[6] Pharmaceutical Care Management Association Analysis, April, 2006

PBMs' ROLE IN PROMOTING THE USE OF GENERIC DRUGS

PBMs have played a critical role in encouraging the use of generic drugs as part of the comprehensive drug-benefit services provided to plan participants and our clients. One PBM estimated that it saved its clients $322 million in 2005 through its generic-related initiatives. In 2006, there is an almost unprecedented amount of branded drug spend that is expected to lose patent protection. In particular, patent expirations on Zocor and Pravachol will offer payers and patients their first significant opportunity to realize big savings in one of the largest drug classes, anti-cholesterol medications. PBMs work with clients to develop plans to maximize the uptake of these new generic entrants, as well as the other numerous drugs expected to go generic this year.

Brands with Expected Generic Launches in 2006-2007



PBM generic drug programs have greatly impacted generic substitution rates (GSR). For example, in 2005 one PCMA member company had an overall GSR of 93.5 percent, with their mail-service pharmacy achieving a high GSR faster than retail pharmacies. Within 1 month of a new generic drug becoming available, a mail-service pharmacy can have success in substituting the new generic for the brand more than 90 percent of the time. In contrast, it may take a retail pharmacy three or more months to achieve the same substitution rate.

PBM programs increase generic utilization through consumer and physician education programs, plan design, e-prescribing, and the use of mail-service pharmacies.

- **Plan design:** PBMs implement a variety drug-plan design options that encourage the use of generic drugs. These options include reduced copayments for generic drugs; step therapy programs that encourage doctors to prescribe the brand medication only after the patient has tried the generic first; and, in some cases, physician authorization for the brand product when a generic product is available.

- **Education/Incentives/Interventions/Communications:** Through proactive, concurrent and retrospective programs, PBMs empower and educate physicians, pharmacists, and patients about the safety and effectiveness of generic drugs.

    - **Physicians:** Physician outreach includes sampling programs, education through retrospective DUR (drug utilization review) letters, and physician profiling and report cards. The final decision to dispense a brand or generic drug rests with the prescribing physician.

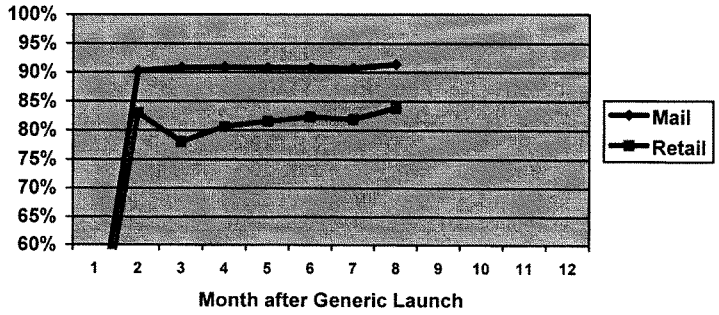
    - **Patients:** Education tools include general and direct mailings explaining the value and affordability of generic drugs. Patient-specific mailings are sent when a patient is identified as using a brand when a generic equivalent is available.

- **Pharmacists:** In addition, PBMs educate pharmacists through on-line communications at the point-of-sale that alert the pharmacist to a generic drug's availability. PBMs also provide incentives such as higher dispensing fees to encourage the dispensing of generic drugs and provide extensive analytic and reporting tools to aid pharmacies in improving generic substitution rates.

- **E-Prescribing:** One of the most vital programs to assist in the dispensing of generic drugs by physicians is electronic prescribing (e-prescribing). E-prescribing gives physicians the ability to view the range of prescription options at the point-of-prescribing, along with the patient's medication history and specific drug-formulary information. In addition, as it often easier to prescribe, pronounce and spell the brand name drug, e-prescribing is even more valuable as a tool to encourage generic substitution at the point-of-prescribing. E-prescribing allows for a better dialogue between the physician and the patient and avoids calls to the physician's office to ask for a generic-drug substitution after the prescription has already been written.

- **Mail-Service Pharmacy:** An FTC study last year noted that PBM mail-service pharmacies are efficient in encouraging the use of generics. [7] As I mentioned previously, PBMs can reach a higher GSR much faster through mail service pharmacies than at the retail pharmacy counter.

Generic Substitution Rates for Generics launched in 2005



[7] "Pharmacy Benefit Managers: Ownership of Mail Order Pharmacies", Federal Trade Commission, August 2005.

OPPORTUNITIES FOR CONGRESS AND THE ADMINISTRATION

While I'm not a patent lawyer, I do believe that PBMs are in a good position to speak to the economic impact that delayed entry for generics has on payers. Generic drugs now account for about 12 percent of the nation's $250 billion annual in drug spend and more than 53 percent of prescriptions filled. IMS Health, a company that tracks the industry, predicts that the market share of generics will exceed 65 percent within four years as several blockbuster drugs go off patent.

Because current generic substitution rates are generally over 90 percent, the greatest opportunity today to increase the savings realized from generic drugs lies in increasing the availability of generic drugs generally.

There are many factors that create barriers to the availability of generic drug alternatives. Some of these barriers can be addressed by Congress and the Administration. PCMA urges action to eliminate unnecessary barriers that keep generic alternatives from entering the marketplace. Following are four areas where PCMA believes Congress and the Administration should take action to significantly increase generic drug utilization:

1. **Support S. 2300 to close legal loopholes;**
2. **Create a legal pathway for generic biologics;**
3. **Increase funding for the Office of Generic Drugs; and**
4. **Create a national, uniform standard for e-prescribing.**

1. CLOSING LOOPHOLES

With the passage of the Drug Price Competition and Patent Term Restoration Act of 1984, commonly referred to as the Hatch-Waxman Act, Congress established an abbreviated new drug application (ANDA) process for faster generic-drug entry onto the market. Over time, brand-name manufacturers have found loopholes in the Act that allow them to extend their patents beyond the initial period, thereby frustrating the purpose Hatch-Waxman and delaying the introduction of generic drugs to market. MMA took some corrective actions by eliminating

abuses of the 30-month stay and delaying the start date for the 180-day exclusivity period for generic manufacturers. However, there is still work to be done in order to ensure that the Hatch-Waxman Act removes *all* barriers that exist to increased competition and generic drug availability.

Specifically, PCMA would like to commend the goals of S.2300, The Lower PRICED Drugs Act, designed to close some of those loopholes. S.2300 was introduced by Senator Stabenow and is cosponsored by Senators Lott and the Ranking Member of this Committee, Senator Kohl. The bill has support from a wide range of interest groups including PCMA, the National Association of Chain Drug Stores, General Motors Corporation, Caterpillar, Inc., DaimlerChrysler, Ford Motor Company, AARP, Families USA, and the AFL-CIO, among others. We believe that it provides an excellent starting point for discussion of these important issues.

Specifically, S. 2300 seeks to do three very important things:

1. Reform the Citizen Petition process;
2. Reduce the delay in generic entry when patents are challenged in court; and,
3. Provide an avenue for additional generic antibiotics through its reforms.

Citizen Petitions. The Citizen Petition process was intended to allow citizens to raise questions for FDA's consideration relating to drug products. While PCMA believes that the process of identifying health and safety concerns is an extremely important one, we believe the process must be reformed. One investment firm recently stated, "...One of the easiest devices a branded company uses to delay generic competition is the Citizen Petition (CP). Anyone can file a CP, and this act alone typically triggers the suspension of any final FDA approval of a generic drug."

In fact, the OIG issued a report identifying FDA problems associated with CPs and the FDA subsequently issued draft regulations to address the concerns raised in the OIG report. The FDA later withdrew its draft regulations.

There is some evidence that the brand drug industry has been using the CP process to delay entry of generic drugs to the marketplace. The Lott-Stabenow bill would seek to curb this activity by:

- Requiring the generic approval process to move forward while a petition is considered;
- Requiring that final action on a petition be taken within 6 months of the petition being received;
- Requiring that petitions be signed and include a verification that the petitioner has taken reasonable steps to ensure all relevant information is included in the petition; and
- Ensuring that generic applicants don't lose their 180-day exclusivity solely because a citizen petition has been filed.

Patent Challenge Clarification. Before a generic drug can come to market, the generic applicant must get FDA approval and state whether it will challenge any of the relevant patents held by the brand manufacturer. This challenge often spurs a lawsuit by the brand that triggers a 30-month delay before the FDA can approve the generic drug. Although the law states that the courts may shorten the 30-month "stay" period, the stay is very rarely shortened, even in cases of egregious brand company delay tactics. While the MMA closed some loopholes regarding the 30-month stay, some brand-name manufacturers continue to deliberately delay the generic approval process. The delay tactics can and do prevent generic availability. S. 2300 would clarify that the courts should consider whether brand manufacturers are unnecessarily delaying the generic approval process.

Generic Antibiotics. Certain antibiotics licensed prior to November 12, 1997 are not listed in the FDA's official compilation of drug patents commonly called the "Orange Book." Because they are not listed, the generic alternatives are precluded from coming to market even though they may be safe and effective and, as a result, Americans are denied the generic versions of this essential category of drugs. S. 2300 would allow the generic versions for which patents are not listed in the Orange Book to enter the market.

2. GENERIC BIOLOGICS

Biologics are drugs to treat complex, chronic conditions and are extremely costly and remain costly over a long period of time because there is currently no competition in the market. The huge growth in biologics, or specialty drugs, is expected to reach $90 billion by 2009. This explosive growth is challenging because there is currently no legal pathway for generic biologic competition. Last year alone the cost of biologics soared 17.5 percent compared with traditional drugs which increased 10 percent. [8]

Challenges in Creating a Regulatory Pathway for Biogenerics

Biologics differ from traditional drugs in that they are typically large molecule products derived from living organisms rather than chemicals which are used to create tradition drugs. Their development and manufacturing are typically very complicated which is why most biologics have both content and process patents. The traditional drug approval process is typically regulated by the Food, Drug and Cosmetic Act (FDCA). Most biologics, on the other hand, are regulated under the authority of the Public Health Service Act (PHSA).[9] FDA regulates drugs and biologics under these different authorities. There is disagreement about how much authority FDA has to approve biogenerics. Legislation is needed to establish a clear pathway for biogenerics to enter the market and increase competition.

While some argue that the science of creating biogenerics is not fully developed, progress is being made daily to better understand how to analyze and evaluate the clinical evidence that will prove bioequivalence. Few dispute that there is a need for Congress to act to create a clear legal pathway for the widespread development of biogenerics.

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[8] Express Scripts, "Drug Trend Report 2005", June 2006.

[9] From FDA: The FD&C Act defines drugs by their intended use, as "(A) articles intended for use in the diagnosis, cure, mitigation, treatment, or prevention of disease and (B) articles (other than food) intended to affect the structure or any function of the body of man or other animals" (FD&C Act, sec. 201(g)(1)). A biological product is defined, in relevant part, under the PHS Act, as "a virus, therapeutic serum, toxin, antitoxin, vaccine, blood, or blood component or derivative, allergenic product, or analogous product . . . applicable to the prevention, treatment or cure of a disease or condition of human beings." (PHS Act, sec 351(i)).

Action in Europe

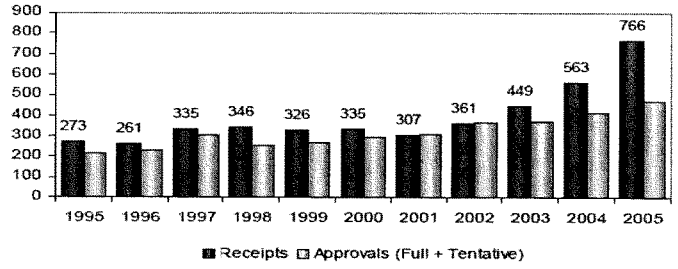
The European Union has approved legislation which creates a regulatory pathway for the approval of biogenerics. Europe's FDA-equivalent regulatory body has adopted regulatory guidance for considering biogenerics on a product by product basis. To date, they have approved generic versions of Omnitrope and Valtropin under this guidance. Further action is anticipated on products like Epogen in the near future.

PCMA believes that Congress should not wait until the cost of biologic drugs hits critical mass and the health care system is in crisis. PBMs must be allowed to exhaust every avenue to promote competition and define value for products through competition in the market. PCMA encourages Congressional action to establish a legal pathway for competition.

3. OFFICE OF GENERIC DRUGS (OGD) AT THE FDA

Published reports have highlighted that the generic drug backlog at the FDA is at an all-time high of more than 800 applications. While the OGD approved 361 generic drug applications in 2005, it actually received 766 generic applications in 2005. As a result, experts say, fewer generic drugs will be available to consumers in the years ahead than the industry is ready and able to provide. The FDA backlog is expected to balloon in the next few years given the volume of generics coming to market.[10]

Pace of Approvals Not Meeting Pace of Submissions



Source: FDA, Banc of America Securities

[10] Kaufman, Marc. "Generic Drugs Hit Backlog At FDA." *Washington Post*, February 4, 2006

With a large backlog of generic drug applications pending and more coming into the FDA every month, it is vital that the necessary resources are provided to the OGD now to insure review of these applications occurs within the statutory limit of 6 months. Currently, FDA estimates the average review time is 15 months and projected to increase to 17.5 months in the year. It takes OGD up to two years to fully train qualified examiners. PCMA supports increased funding this year to resolve the backlog that will only worsen over the coming years and applauds the work of Senator Kohl in helping to secure such funding. In addition, it is important that the FDA not be allowed to divert those funds to other programs or offices.

4. E-PRESCRIBING

PBMs promote electronic prescribing (e-prescribing) which has had a positive impact on patient care and the use of generic-drug alternatives. Physicians are often not fully aware of brand-to-generic substitution opportunities. In addition, it's often easier to prescribe, pronounce and spell a brand name drug name (e.g., Dyazide) than a generic one (hydrochlorothiazide/triamterene). Therefore, e-prescribing technology is particularly important as it allows physicians to view the range of generic alternatives available, along with the patient's medication history, and the patient's specific drug formulary information in order to make a more personalized, informed decision with the patient right there.

In one demonstration program started in February 2005 and using e-prescribing technology, three large employers teamed up to improve quality and determine the effects on prescription drug costs. They found that e-prescribing technology increased the generic use rate by 7.3 percent resulting in $3.1 million in savings for one year.[11] According to information on one of the employer's website, they found significant benefits for patients, physicians, pharmacists, and employers. For patients, there was greater safety, cost savings, convenience, and time saved.

[11] "HAP, Henry Ford Health System e-Prescribing Technology Hits 500,000 'Scripts", Henry Ford Health Systems, http://www.henryfordhealth.org/body.cfm?id=46335&action=detail&ref=560. Accessed July 2006.

The benefits for physicians also included safety and time savings, but found a more efficient workflow process, as well. For pharmacists, there was less wait time and the elimination of illegible hand-written prescriptions that can result in mistakes. Finally, the American College of Physicians stated that with 3 billion in prescriptions each year, universal adoption of e-prescribing could save $27 billion annually through the reduction in medical errors, hospitalizations, and formulary compliance.

Regrettably, the regulations implementing the new MMA only established a uniform e-prescribing standard only under Medicare. The myriad of state e-prescribing laws and now the 51st Medicare standard for e-prescribing has done little to encourage physicians to adopt the new technology. PCMA believes that the adoption of a national, uniform standard for e-prescribing laws would greatly encourage compliance by physicians and others and would lead to greater generic drug utilization. PCMA recommends regulatory or statutory clarity to create a national, uniform standard for e-prescribing across both government-funded and commercial books of business.

CONCLUSION

PCMA is pleased to have had the opportunity to testify here today and we look forward to working with the Committee as it considers these issues further. I would be happy to answer any questions Members may have.

Senator KOHL. Thank you very much, Mr. Merritt.

Ms. Bresch, in your company's experience, what is the biggest roadblock that you face when trying to get one of your drugs to market?

Ms. BRESCH. Well, I think, Senator, I highlighted in my testimony the authorized generics and the citizen petition process. Certainly, in my written testimony I talk about several other obstacles such as declaratory judgments, as Commissioner Leibowitz discussed.

I believe that as we look at generic biologics, which is a vital role of the next frontier, I think, for the pharmaceutical industry, brands and generics alike, if we do not fix the obstacles we face today, I can only imagine what it would do to health care costs if a generic company would need to take on the additional cost in litigation and whatever that pathway may be, the costs that it would take to bring a generic biologic to market if we faced an authorized generic at the same time competing with us in the marketplace.

So while we know that generic biologics are going to be a vital component, we need a pathway sooner than later. If we don't fix some of these issues today, we believe that it is only going to lead to more billions of dollars in costs for the government and consumers. So that is why to fix authorized generics, declaratory judgments—we believe that you are going to restore a competitive marketplace in allowing a level playing field to be put back in place and give the generic company the leverage and bargaining power it had before these practices were implemented.

Senator KOHL. Mr. Merritt, do you have a comment on that?

Mr. MERRITT. Well, I just think that we need to clarify whatever confusion there is on how we can get generics to market faster. In other words, if it is a funding problem with OGD, then let's solve that. On the generic biologic front, I am not a patent lawyer and I am not a scientist, but I know from a public policy point of view and from the point of view of all the people who pay for health care in this country who hire us to help them get more affordable care, the fact that there is no generic pathway right now is a big problem. Competition is the key to getting these prices lower. Without it, we are not going to get the savings that we need.

Senator KOHL. What do you say to the comment that these roadblocks for the most part, if not entirely, are just there to prevent generic companies from getting products to market that are otherwise entirely safe, and the roadblocks are put there—and in many cases they are legal—just to maximize profits for the brand name manufacturer at the expense of customers all across the country? Is there any useful purpose that these roadblocks are serving, Ms. Bresch?

Ms. BRESCH. Certainly, not in my opinion. I believe that the FDA is well equipped to handle the scientific issues, the approval process for a generic drug. I think we heard Mr. Buehler talk about while there may be some backlog, certainly they are addressing the prominent issues that we face to make sure they put out their safe and effective medicines when approved.

I believe that as you look historically at the delay tactics that brand companies have used, I can't say they have served any purpose in our health care system. Generic drugs continue to save ev-

eryone billions and billions of dollars. I think that while they are maximizing their franchise for their shareholders, there is certainly nothing being done to the benefit of the consumer or the health care system.

Senator KOHL. Mr. Merritt, do you agree with that?

Mr. MERRITT. Well, I would prefer not to ascribe motives as to why it is not happening, but it needs to happen. Every time we talk to somebody, we get a different answer as to why it is not happening and it is always a rational, complex answer. But I mean if we can send a man to the moon, we can get a regulatory pathway for generic biologics. It is going to happen; it has to happen. There are too many people who need these drugs. They are great products.

But to not have competition, to not find a scientific way that is both legal and is clinically sound—that, to me, doesn't make sense. I am sure there is a way to do it. I don't have the expertise on how to do it, but I think Congress needs to get involved to make sure there is consensus around how to do it and make it happen.

Senator KOHL. Thank you very much.

Mr. Chairman.

The CHAIRMAN. Heather, you indicated that it was the FDA that had a regulation out in 2002 and pulled it?

Ms. BRESCH. They issued guidelines in 1999 that would have decoupled the citizen petition process from the ANDA approval process. So while we certainly are all for citizen petitions being filed and raising any issues that an interested party or a citizen wants to raise, we don't believe that blocking the ANDA approval was in the best interest because as our data shows, the majority of them are eleventh hour that don't raise any new issues.

So what the rule did was put in place the mechanisms to still have the process, not delay——

The CHAIRMAN. You have to timely file?

Ms. BRESCH. Timely filed, and allow the process to go on as it should. The FTC weighed in on that rule and said they thought that that was a great step to ensure that there wasn't a delay of the generic entry.

The CHAIRMAN. Do you have to raise new issues under the proposed rule?

Ms. BRESCH. No, it didn't limit the issues you could raise. What it did limit is the direct attack on a specific company's product. So, for instance, if you wanted to raise an issue on the process of the generic drugs or a specific test or process that the FDA was doing, you could raise that. You couldn't make it product-specific, because a lot of times these petitions try to bring in some specific process on a specific product that they have known about for months and years specifically because we are usually in litigation for months and years prior. So they are familiar with all the information. So it doesn't limit what you can raise. It certainly just limits the fact that you can't use it to specifically tie it to a generic drug approval.

The CHAIRMAN. In your view, why was it pulled?

Ms. BRESCH. As I stated, it was with very little explanation in 2003 that it was pulled. So it came under the Clinton administration and was pulled out under the Bush administration. The only thing on the record was that back in 2003, they felt that there

wasn't a backlog of citizen petitions. But I think recent testimony from Mr. Bradshaw, FDA counsel, and others within the FDA has now very much admitted on the record that they are seeing a dramatic increase and a backlog in citizen petitions.

So we have been in to HHS and the FDA asking them to please reissue these guidelines, especially with the FTC comments that they made to them. It would certainly dramatically alter the way citizen petitions are used.

The CHAIRMAN. Are they going to reissue it?

Ms. BRESCH. We have no commitment that they are going to reissue it. So as I mentioned, Senators Stabenow and Lott have introduced a bill that pretty much does the exact same thing that the rule did in 1999. So our feeling is it certainly could be done administratively. They do not need legislation, as they once did in 1999. They did need legislation then; we don't need it now. But if they won't act and reissue the guidelines, certainly the legislation would correct the problem.

The CHAIRMAN. It needs to be fixed. We want consumers to have opportunities to petition, but, you know, if it amounts to no more than just an abuse of process, that abuse ought to stop.

Ms. BRESCH. We have had many personal experiences with citizen petitions, but right now with Ditropan XL, it has been 11 months. We have had tentative approval, which means our application meets all scientific and regulatory issues. We have invalidated the patent. The Federal district court found it to be invalid, and yet we can't receive final approval because the FDA hasn't signed off on the petition J and J filed.

The CHAIRMAN. Thank you.

Senator KOHL. Thank you very much.

Senator Clinton.

Senator CLINTON. I want to compliment these two witnesses. They are extremely informative and very clear in the information they are providing, and I appreciate both of you for being here.

Mr. Merritt, I am really interested in your comments about e-prescribing because I think e-prescribing has been a great advance. When I went down to Houston after Katrina and visited a lot of the evacuees, one of the big problems they had was dealing with chronically ill people, frail elderly people who had been evacuated. They were evacuated often either without their medicine or without adequate supply. They didn't have any way of getting back to their physicians. Doctors' offices and hospital records were destroyed. Pharmacies were flooded.

In talking with the physicians who were attempting to make sense out of all of this, the only good news was that for those patients who had shopped at a pharmacy that used e-prescribing, they could get into those national systems and that was the only way they could reconstruct what the dosage and the particular prescription was for an individual. So e-prescribing, in general, has been a great gift.

Now, e-prescribing also increases generic utilization and it is another example of why we need to adopt a national framework for the electronic exchange of information in our health care system. As you know, we have been trying here in the Congress. I worked with Senators Frist, Enzi and Kennedy, and last year the Senate

unanimously passed a bill to set up a framework for electronic medical records which, of course, would include e-prescribing. We are trying to get it through the House, so if anybody has any influence over on the other side, I hope that you will help us with that.

I think that the experience with e-prescribing provides us with a lesson about broader health information technology implementation. As your testimony notes, the Medicare law that was enacted included a provision that called for a uniform standard for e-prescribing, but it was implemented only to apply to the Medicare population. So your example was a good one. You might have a pharmacy trying to figure out how to deal with four different standards right here in the District—Virginia, the District, Maryland and Medicare.

We ended up, then, with 50 State e-prescribing laws, and a 51st, namely the Medicare standard. That is too complicated, that is too expensive. We are once again shooting ourselves in both feet. We are making everything so expensive because we can't get rational about what we need to be doing to minimize the expense and maximize quality and safety.

It is one of my biggest concerns about the broader implementation of health IT. If we don't pass a national legislative framework, that is what is going to happen across the board. GW Hospital will have a different system than Georgetown, which will have a different system than Johns Hopkins. You know, once again we are going to be in the Tower of Babel and we are going to be spending billions of dollars for no purpose. It is not going to cure anybody. It is not going to put a doctor or a nurse at anybody's bedside. It drives me crazy.

I mean, we need a set of national standards and the only place to get that is from the national government that creates the architecture, systems that can talk to each other, systems that can cross-cut on quality and maximize savings.

So I would appreciate perhaps, because as you can tell, I am passionate about this and I don't understand why we just don't do it, if you could expand perhaps on your testimony any lessons in implementation, any of the additional barriers or problems that you have seen with this increasing differentiation in e-prescribing that is going on.

Mr. MERRITT. Sure. Well, first of all doctors, if you talk to them, obviously—and, of course, you have talked to thousands of them—they don't want one more thing to have to do or one new gadget to have to figure out. So the key is how do we get them integrated into the system, and so adoption has got to be as simple as possible.

One standard that not only one doctor can look at and find out that it is easy for her to do, but can also talk to the AMA, to other physicians organizations, and so forth, to get easy clarity, guidance, any education that needs to happen—that is the best pathway to getting this done. So the biggest problem that we have seen is just the fact that it is new, the fact that people have no idea of the enormous benefits that it will have.

Everybody talks about the very important IOM study, and they are releasing more information and probably already have by now on medical errors that will be prevented by e-prescribing. But there

is another huge cost saver that e-prescribing offers, in that it brings doctors into the benefits and cost equation. Doctors currently have no idea of what formulary information people have. So they will go in and say, "Well, you have a cholesterol problem. I have got some free Lipitor. Why don't you take that?" That is their way of helping them address the cost issue.

But if they knew that this person had on their formulary a generic with a five-dollar co-pay or perhaps waived co-pay—or if they had generic samples available, that would even be better—but if they knew that and had it on a little PDA, a little hand-held computer, and could show the person, hey, there are a couple of different options here and they are all basically the same, but this one is cheaper, do you want it, bang, it gets rid of all the noise around this issue.

Direct to consumer advertising pushes people in all kinds of ways. Physician detailing by PhRMA companies pushes them all kinds of ways. To have that little hand-held device with that information cuts through all of that in a moment and will save literally billions of dollars.

Senator CLINTON. May I ask just one more question?

Senator KOHL. Sure.

Senator CLINTON. I wanted to ask Ms. Bresch, who raised another issue of great concern to me, the pediatric exclusivity issue—and I think it is very important that we do provide a path for testing drugs to make sure that they are safe on our children and we know what dosage is permissible. We have made some progress on that with the Pediatric Research Equity Act and the Best Pharmaceuticals for Children Act.

Now, the Best Pharmaceuticals for Children Act provides pediatric exclusivity incentives to manufacturers that conduct pediatric studies, and I think that that has helped to improve confidence in the safety of drugs for children. The FDA allows companies to request waivers from requirements to conduct pediatric studies for drugs that are not likely to be used in the overall pediatric population, such as drugs for ovarian cancer, for example.

Now, in your testimony you noted that some companies that should be seeking waivers are instead conducting pediatric studies to receive the 6 months of exclusivity made available under the Best Pharmaceuticals Act, and that is another abuse of the system because they have no intention of making this drug available for the pediatric population. But they go ahead and claim they are and take advantage of it and get the 6 months of additional exclusivity.

Do you have any suggestions about what actions the FDA could take to ensure that drugs that are obviously not geared to the pediatric population do not qualify for the exclusivity incentives?

Ms. BRESCH. I believe that the intention of the law and what it was seeking to do was a great act by Congress to make sure, as you said, that the drugs are safe on children and we know dosages, and so forth. I think as with anything, there are some loopholes and abuses that have taken place with this practice.

I think the way the law was intentionally set out, the FDA would have to look at data, would look at a product and be interested in more information in the pediatric population. They would then have to request a PhRMA company to do the studies, and that

would then earn them the 6 months of additional exclusivity in the marketplace.

I can tell you today as one of the largest generic manufacturers, every product in our pipeline, every product that we look at, every timing that we look at, we automatically add 6 months of exclusivity to every single product we look at. So somewhere from the intention and the spirit of the law to its actions today, I think something has been lost in the translation because it is not limited to any specific universe of drugs or things that need to be looked at.

So I think one thing that we would urge is to go back and look at the original framework, at how the request would be made to PhRMA to look at these studies. Just recently, within the last couple of weeks, a product that is a combination of a product with aspirin—we all know that aspirin is not recommended for children in the pediatric population. Yet, because of what you just explained, Senator Clinton, they received 6 months' exclusivity to show that this product should not be used in children. So we completely concur that, again, there is an abuse of this practice that needs to be looked at before I think the bill is reexamined next year as it sunsets.

Senator CLINTON. Thank you.

Senator KOHL. Thank you very much, Senator Clinton.

In closing this hearing, I just want to make, I think, a fairly obvious comment. There are few areas that provide more opportunity for us to serve consumers all across this country than tackling this whole issue of prescription drugs and bringing them to the American people at the lowest possible cost.

We are fighting legitimate legal obstacles with respect to the pharmaceutical companies and their desire to do well by their stockholders. But that is not our job here. Our job is to do well by the American people, and there are a lot of barriers out there that we have to knock down and I think we have touched on many of them this morning. It is an urgent issue and I personally feel determined, and I know my colleagues feel the same way, to make measurable progress in a short amount of time.

Your testimony this morning adds urgency and a lot of illumination to the problem, so we very much appreciate your being here. Unless there are any more comments—Senator Smith, would you like to add anything?

The CHAIRMAN. No. Well said.

Senator KOHL. Senator Clinton.

Senator CLINTON. No, thank you.

Senator KOHL. Thank you very much for being here.

Ms. BRESCH. Thank you.

Mr. MERRITT. Thank you very much.

Senator KOHL. We are adjourned.

[Whereupon, at 11:28 a.m., the Committee was adjourned.]

APPENDIX

July 27, 2006

Senator Gordon H. Smith
404 Russell Building
United States Senate
Washington, DC 20510

Senator Herb Kohl
330 Hart Senate Office Building
United States Senate
Washington, D.C. 20510

Dear Senators Smith and Kohl:

On behalf of the Generic Pharmaceutical Association (GPhA) and its members, I write to express the Association's views on issues raised during the July 20, 2006 hearings before the Special Committee on Aging, of the United States Senate. That hearing, entitled "The Generic Drug Maze: Speeding Access to Affordable, Life Saving Drugs," touched on issues vital to the continued success of the generic pharmaceutical industry – an industry that saves consumers and taxpayers literally billions of dollars each year in prescription drugs costs. Indeed, no other industry has made, or continues to make, a greater contribution to affordable health care than the generic pharmaceutical industry. GPhA requests that these comments be made part of the written record for that hearing.

DISCUSSION

To begin, GPhA would like to thank Senator Kohl for his leadership in supporting additional funding for generic drug products. The $10 million dollar increase to FDA's Office of Generic Drugs, found in the Senate's Appropriation Bill, further evidences his strong commitment to providing access to affordable pharmaceuticals. These additional funds are the first step in reducing the record number of generic applications now pending before the Agency. According to IMS Health, prescription drugs worth $121.5 billion will come off patent between 2006 and 2011. Consequently, it is more important than ever that FDA approve generic applications in a timely manner.

In this statement, GPhA would like to urge Congress to take additional efforts that, without question, would increase the public's access to affordable medicines. Specifically, GPhA asks this Committee, and Congress as a whole, to address some of the most significant obstacles to effective generic market entry, including those discussed below.

First, far and away the biggest obstacle to generic market entry is the lack of an approval pathway for generic biologics, sometimes referred to as biogenerics. According to IMS Health, biologic drug product sales jumped 17.2% in 2005, to $32.8 billion. An approval pathway would allow generic companies to develop and market less-expensive versions of these drugs. In turn, patients and taxpayers would save billions of dollars on biologic products alone. FDA's refusal to act makes Congress the only means for obtaining the necessary regulatory

mechanism. GPhA once again urges Congress to act in this area, as patients simply cannot afford to wait any longer.

Second, attacks on the 180-day exclusivity provision of the Hatch-Waxman Amendments to the Federal Food, Drug, and Cosmetic Act threaten the continued viability of the modern generic pharmaceutical industry. Here, GPhA discusses two specific threats to the continued viability of the 180-day provision: so-called "authorized generics," attacks on the ability of generic companies to settle patent challenges. As discussed in more detail below, each of these things by itself severely undermines the only incentive that Congress created for companies to challenge the drug patents that block generic market entry. Together, however, these forces combine to create a significant disincentive to the development of new generic drug products, generally, and future challenges to brand patents, specifically. Unless Congress acts to re-establish the balance first enacted with Hatch-Waxman, the generic industry, and the consumers who rely on that industry, will suffer.

Finally, GPhA briefly outlines some additional issues relevant to effective generic market entry, including systematic abuse of the FDA citizen petition process by brand companies.

I. Congress Must Act With Respect To Generic Biologics.

Biologic drug products currently represent a major part of health care expenditures in the United States each year. While the regulatory and patent system should incentivize and reward true innovation in the biologics arena, the market exclusivity on such compounds should not last forever. Today, it does. For example, Genzyme's drug Cerezyme® currently costs between $200,000 and $600,000 per year, per patient.[1] So, 14 years *after* the product first came to market and four years *after* the end of its regulatory exclusivity period,[2] Genzyme enjoys a gross profit margin of more than 90% on this drug.[3] The reason is simple – no generic competition. This is an untenable situation for the patients and taxpayers that have to shoulder these significant costs. Allowing generic competition would ensure increased access, lower prices, and lead to greater innovation. FDA has the authority, technology, and specialized expertise to adopt a pathway for the approval of generic biologics. FDA, however, has failed to do so.

Over the past thirty years, significant advancements have been made in the fields of genetic engineering, molecular biology, recombinant protein technology, and protein purification. The now-existing technology allows biologics to be characterized and compared analytically. Thus, the current state of the art with respect to biologic products allows for an abbreviated approval process for biogenerics. Nevertheless, FDA has displayed a disappointing, but consistent, pattern of delay and inaction. For example, in 1999, FDA indicated it may be prepared to approve growth hormones using efficacy data based on surrogate end-points, such as changes in hormone levels. In March 2001, the Agency announced that it was working on two generic biologics guidances for human growth hormone (HGH) and insulin. Drafting on the

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[1] "*As Biotech Drug Prices Surge, U.S. Is Hunting for a Solution*," WALL ST. J. (12/28/05).
[2] *Id.*
[3] "*A Biotech Drug Extends Life, But at What Price?*," WALL ST. J. (11/16/05).

HGH guidance, according to at least one FDA staffer, was done by April 2002. Yet, the Agency issued nothing. In 2004, the Agency again made statements regarding the imminent publication of guidance on HGH and insulin. And, again, the Agency issued nothing. It is now 2006 and the generic industry still has no guidance from FDA. Indeed, it appears that now the Agency no longer intends to ever provide guidance on HGH or insulin. Specifically, in March of this year, FDA responded to a letter sent to the Agency by Senator Hatch and Congressman Waxman. In its response, FDA stated that the Agency will not release guidance documents for biogeneric insulin and HGH. Rather, FDA decided that "it would be more appropriate to publish guidances that are more broadly applicable to (follow-on protein products) in general." FDA, however, gave no indication as to when it would publish such guidances. FDA's failure to provide a pathway for generic versions of products such as these is inexcusable, and the public has been forced to pay the price.

Because FDA has refused to act, it is incumbent on Congress to step in and enact legislation that creates a biogeneric approval pathway that FDA must follow. GPhA again urges Congress to enact legislation that provides an efficiant and effective abbreviated approval pathway for generic biologics and prevents brand companies from gaming the system to delay the approval of such products. This is the only way that the public will gain access to more affordable biologic medicines.

II. The 180-Day Generic Exclusivity Provision Is Essential To Increasing Generic Competition, And Attacks On That Provision Threaten The Generic Industry.

Attacks on the 180-day generic exclusivity provision threaten the continued viability of the modern generic pharmaceutical industry. It is this incentive, and this incentive alone, that spurs many generic companies to seek approval to market drug products prior to patent expiration. Without it, there will be far fewer patent challenges and thus far fewer affordable drugs hitting the market prior to patent expiration. Additionally, without a viable generic incentive, brand companies will revert to evergreening patents to extend product monopolies for years to the detriment of taxpayers and consumers. GPhA urges Congress to take action to shore up the exclusivity incentive.

A. The 180-Day Generic Exclusivity Period Is Essential If Generic Drugs Are To Be Marketed In A Timely Manner.

Congress passed the historic Hatch-Waxman Amendments in order to "make available more low cost generic drugs" to the public.[4] The 180-day exclusivity period is critical to carrying out Congress' goal of "get[ting] generic drugs into the hands of patients at reasonable prices–fast."[5]

Congress recognized that generic drug companies assume considerable risks and costs challenging the patents that protect brand-name drug products from competition. It does, in fact, cost millions of dollars to develop an ANDA drug. Patent disputes take years and millions, if not tens of millions, of dollars to litigate and, in the end, there is no guarantee of success. But,

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[4] *Apotex, Inc. v. Shalala*, 53 F. Supp. 2d 454, 461 (D.D.C. 1999) (quotations and citation omitted).
[5] *In re Barr Labs.*, 930 F.2d 72, 76 (D.C. Cir. 1991).

as Congress also recognized, such challenges are absolutely essential if the public is to have access to affordable generic drugs before the expiration of all brand patents.

To encourage companies to mount these necessary patent challenges, Congress created a *quid pro quo* for generic companies – *i.e.*, expend the resources to mount the first patent challenge in exchange for "the right to sell [the] drug without competition for 180 days."[6] The revenues from the exclusivity period allow the generic company to recoup its investment and, significantly, to develop additional products and undertake future patent challenges. Because generic companies sell their products at a small fraction of the brand price, the sales generated during the exclusivity period are vitally important to many companies' product pipelines.

The fact is, the public needs the patent challenge process to work today more than ever before. Back in 1984, brand companies typically obtained one or two patents per drug product. Today, brand companies obtain dozens of patents relating to a single drug product. And brand companies submit these patents to FDA, which in turn act as approval barriers of generic products under the Hatch-Waxman Amendments. So, while most of these patents add little by way of innovation, if left unchallenged they nevertheless would extend the brand company's monopoly for years. Indeed, at present, it is not uncommon for brands to have a portfolio of patents that extend protection on a drug product out two, three, or even four decades. If generic companies do not mount increasingly costly challenges to these patents, the public will be forced to pay monopoly prices until the last of these patents expires.

B. Attacks On The Generic Exclusivity Incentive Threaten The Modern Generic Drug Industry.

Hatch-Waxman will not work to increase generic competition unless companies remove the patents that often protect brand drugs from competition and launch a generic product prior to patent expiration. But without the exclusivity incentive, companies simply will not take on the risk and expense inherent in challenging brand drug patents. This is precisely why Congress created the incentive in the first place. GPhA thus urges Congress to work to eliminate those forces that destroy the exclusivity period.

1. The Brand Industry's Use Of Authorized Generics Prevents Hatch-Waxman From Working As Congress Intended, Which Harms Consumers And Taxpayers.

Brand companies know that generic exclusivity leads to increased and earlier generic market entry. This is why they have employed numerous tactics over the years to devalue that incentive. Perhaps no tactic has caused more damage than the brand practice of launching a so-called "authorized generic" during the exclusivity period. As discussed briefly below, this practice severely curtails the benefit that generic companies receive from a successful patent challenge. Consequently, just as the brands intended, the practice has had a chilling effect on the generic industry.

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[6] *Purepac Pharm. Co. v. Thompson*, 354 F.3d 877, 878 (D.C. Cir. 2004).

For nearly 20 years, when a generic company challenged a brand company's patents, it marketed its generic product free from other generic competition for 180 days – just as Congress intended when enacting Hatch-Waxman in 1984. But in 2003, the brands began their now widespread practice of launching an "authorized generic," as FDA calls them, during the exclusivity period. An authorized generic merely is the brand's own product repackaged and sold through traditional generic drug distribution channels. (Brand's market their authorized generic either through a subsidiary or third-party.) Because the brand is selling part of its inventory as a generic, it competes with the true ANDA generic during the exclusivity period.

As the brands themselves must concede, they do not make a significant amount of money from their authorized generic sales. But, of course, authorized generics are not about the brands making more money. They are about punishing the true generic by gutting the value of the generic exclusivity incentive. In this important respect, authorized generics have worked perfectly. To GPhA's knowledge, the brands have launched an authorized generic during every 180-day generic exclusivity period since September 2003. Such products have improperly deprived generic companies of literally hundreds of millions of dollars in sales. Indeed, the first generic to challenge the Paxil® patents lost revenues of nearly $400 million on this product alone when the brand launched an authorized generic during the true generic's exclusivity period. Instances like this have repeated themselves over and over again with each new generic launch and, in the process, have discouraged generic companies from investing in future patent challenges.

Some brands have tried to justify this tactic by arguing that authorized generics are pro-consumer because their existence lowers the price of all generics. Not so. The harm that authorized generics do to competition far outweighs any short-term benefit that might be seen. By discouraging future patent challenges, authorized generics inevitably lead to less competition and unnecessarily long brand monopolies. This is, of course, why GPhA has strongly encouraged Congress to take action against authorized generics.

Significantly, GPhA is not the only party to point out the anti-competitive nature of authorized generics. For example, responding to FTC's invitation for comments on its proposed authorized generics study, several groups submitted comments detailing the damage that authorized generics do to competition. These groups recognize that authorized generics are harmful to consumers because they do not – nor are they intended to – promote competition. In its comments, for instance, AARP explained that the "practice of authorized generics is just one growing trend in the industry's arsenal of anticompetitive practices."[7] Similarly, Consumers Union, the non-profit publisher of *Consumer Reports*, also explained that authorized generics are nothing more than "a device to moderate or slow true competition."[8] Mylan Laboratories also recently testified before this Committee on the dangers that authorized generics present to the generic pharmaceutical industry. These are, of course, but a few of the groups and individuals who oppose the continued introduction of authorized generics into the market because of the negative impact that such products will have on generic competition in the long run.

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[7] AARP's 6/5/06 Comments to FTC Study at 2; *see also* Prescription Access Litigation Project's 6/5/06 Comments to FTC Study at 4.

[8] Consumers Union's 6/4/06 Comments to FTC Study at 1.

GPhA hopes that Congress finally will take notice of the dangers that authorized generics pose to competition and the public's access to lower-priced generic drugs. If Congress fails to take the appropriate action now, the public ultimately will pay the price as fewer generic drugs enter the market in the years to come.

2. A Generic Company's Ability To Resolve Its Patent Litigation Should Not Be Limited.

GPhA and its members are, and have always been, deeply committed to providing the public with affordable generic drug products, and to do so as expeditiously as possible under the circumstances. The Association has long championed legislative measures that would expedite generic market entry. Similarly, GPhA has steadfastly fought against measures that would impede the progress made by the 1984 Hatch-Waxman Amendments and the 2003 MMA. Current legislative efforts to stifle a generic company's ability to resolve patent disputes is one such measure. The simple fact is that, in some instances, litigation settlements turn out to be the means by which consumers are guaranteed access to generic drugs before patent expiration. Indeed, patent litigation settlements are the sole means by which the public can be guaranteed generic access prior to patent expiration. Legislation that limits a generic company's ability to settle patent disputes would lead to fewer patent challenges and, in many cases, delayed market entry.

Patent litigation is an all or nothing proposition. The patent is infringed or not. The patent is valid or not. Consequently, taking a patent challenge all the way to decision necessarily means that the generic company risks being kept off the market entirely until patent expiration. The public obviously does not benefit from such a result. Litigation settlements that guarantee generic market entry prior to patent expiration, therefore, are inherently pro-consumer. "Also, settlements can include other provisions not directly related to the patent in suit that help to ensure meaningful generic entry." The public, without question, benefits from the pre-patent expiration marketing of more affordable drug products.

Moreover, settlements allow the generic company to direct its limited resources away from litigation and towards the development of additional product candidates. Patent litigation requires generic companies to dedicate a tremendous amount of resources, not just financial, but human resources as well. Settlements allow the generic company to refocus its resources into selecting and developing new products – products that the company otherwise would not have been able to pursue. For many generic companies, the new products being developed will include new products that require a patent challenge. In this way, settlements potentially increase not only the number of new products that generic companies can develop, but also the number of patent challenges that they can afford to undertake. Patent challenges, in turn, benefit the public.

Those who criticize settlements, including the FTC, not only ignore their pro-consumer results, but also the high risk that comes with patent litigation. Patents receive a statutory presumption of validity, which imposes a higher burden of proof on a generic that must invalidate a patent in order to launch its product. In non-infringement cases, the outcome frequently hinges on the court's determination of what the claims of the patent mean. Even if the

generic company wins below in light of the district court's claim construction, the Federal Circuit reviews claim construction without giving any deference to the decision below. In doing so, the Federal Circuit reverses, in whole or in part, almost 40% of all claim constructions.[9] A significant percentage – 53% – of *all* district court decisions in patent cases are reversed, in whole or in part, on appeal to the Federal Circuit.[10] Thus, a generic company successful below still risks losing its litigation. Generic companies have, in fact, had favorable district court non-infringement decisions reversed by the Federal Circuit once that court gave a different construction of the patent claims.

Those who criticize settlements also seem to assume, albeit erroneously, that absent a settlement, the generic company would have immediately gone to market. For example, in its July 20 written testimony before this Committee, the FTC stated that many generic settlements may defer generic competition for years. Such contentions assume that the generic company at issue would launch at the earliest legal opportunity. But such assumptions fail to appreciate the fact that the first ANDA applicant rarely can afford to launch in the face of infringement damages. In the brand/generic context, an at-risk launch could result in potentially catastrophic damages for the generic company – damages that far outweigh the ANDA applicant's sales. Specifically, if ultimately found to infringe the brand company's patent, the brand could seek its "lost profits" as damages. But because a generic company sells its product at a fraction of the branded price, the brand company's lost profits will far exceed the money that the generic company makes. Paying lost profits on a branded product with a high volume of sales could threaten the generic company's continued existence. Perhaps nothing illustrates this danger better than the fact that since enactment of Hatch-Waxman Amendments more than twenty years ago, just a handful generic companies have ever launched absent at least a favorable district court decision. And, of course, an at-risk launch does not guarantee that the public will have access to a lower-priced generic product. Brand companies have sought and obtained preliminary injunctive relief that has prevented the generic company from continuing to market its lower-priced product.

Additionally, FTC's testimony criticizes so-called "reverse payments," branding them *per se* anti-competitive. GPhA respectfully submits that it would be grave mistake to automatically label certain aspects of pharmaceutical settlements as anti-competitive *per se*, without carefully reviewing all of the relevant details of each individual case. There is, for example, nothing inherently anti-competitive about settlement payments from the brand company to the generic company. Indeed, Solicitor General submitted a brief to the United States Supreme Court in which it observed that the competing considerations involved "suggest that the mere presence of a reverse payment in the Hatch-Waxman context is *not sufficient* to establish that the settlement is unlawful," adding that the Hatch-Waxman statutory scheme may "create unique justifications" for payments flowing from the brand to the generic.[11]

Finally, the FTC's testimony suggests that there has been an up-tick in the number of settlements since the U.S. Court of Appeals for the Eleventh Circuit issued its decision in *FTC*

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[9] *See Cybor Corp. v. FAS Tech., Inc.*, 138 F.3d 1448, 1476 (Fed. Cir. 1998) (Rader, J. dissenting).
[10] *See id.* at 1476 (Rader, J. dissenting).
[11] Brief for the United States as *Amicus Curiae*, *Federal Trade Commission v. Schering-Plough Corp.*, No. 05-273, at 11, 10 (filed May 2006) (arguing that FTC's petition for a writ of certiorari should be denied) (emphasis added).

v. Schering and suggests that this decision is responsible for that increase. Even assuming that FTC is correct, and that there has been an up-tick in settlements recently, attributing that increase to a single court decision would a serious mistake. Doing so also would demonstrate a dangerous failure to appreciate the complexity of the forces at work in the pharmaceutical industry. For example, the generic industry, in many critical respects, is under attack. Brand companies employ a vast array of tactics to delay generic competition and make patent challenges less appealing. As discussed above, for instance, brand companies now launch authorized generics that rob the generic of its hard-earned and much-needed generic exclusivity. Brands began widespread use of this tactic in 2003. Once generics realized that this tactic would be employed during all 180-day exclusivity periods, they realized that brands were forcing them to consider patent settlements far more than they otherwise would have had to do. As discussed below, brand companies also abuse the FDA's citizen petition process to significantly delay generic market entry. FDA has not only failed to stop these abuses, but has itself hurt the generic industry by adopting policies that devalue the 180-day generic exclusivity period and thus further discourage the patent challenges that must happen if lower-priced products are to hit the market prior to patent expiration.

GPhA strongly encourages Congress to carefully consider any legislation that would limit a generic company's ability to settle. Such legislation would serve only to further tip the balance in favor of brand companies, to the detriment of the public.

III. Additional Concerns For Effective And Prompt Generic Market Entry.

A. Brand Abuse Of The FDA Citizen Petition Process Delays Generic Approvals.

Brand companies manipulate FDA's citizen petition process to improperly maintain their monopolies. These petitions, sometimes referred to as blocking petitions, ask FDA to withhold ANDA approval unless applicants carry out time-consuming and scientifically unnecessary tests and studies. Because FDA virtually always delays ANDA approval until it deals with even the most frivolous petitions, ANDA approvals are significantly delayed, as it takes the Agency months and even years to complete its evaluation. In the meantime, the public is forced to pay millions of dollars for brand name products because FDA has not approved a generic alternative. And make no mistake, the brand petitions are without merit, although the delay they cause is very real. For example, of the 35 or so generic blocking petitions that brand representatives filed in 2004 and 2005, FDA had only ruled on about half as of July 24, 2006. Yet, because no one has held brand companies accountable for this anti-competitive behavior, they have everything to gain and nothing to lose by continuing to file these blocking petitions. Indeed, as Mylan aptly explained in its recent written testimony, "[f]rivolous citizen petitions given brand companies an undeserved patent extension, at no cost and with no consequences."

In a report to House and Senate appropriations committees, FDA recently indicated that it will refer suspect citizen petitions to the Federal Trade Commission. This could be a step towards stopping the abuse of citizen petitions, but further action must be taken. In an effort to curb the brand companies abuse of the citizen petition process, Senators Debbie Stabenow and Trent Lott introduced S.2300, the "Lower Priced Drugs Act." GPhA, like PCMA

in its written testimony to this Committee, encourages Congress to give careful consideration to S.2300, as it contain provisions could help prevent the filing of anti-competitive citizen petitions that serve only to protect the brand companies' interests and block the public's access to affordable generic alternatives.

B. Free Trade Agreements Must Protect Generic's Right To Compete.

The United States' Free Trade Agreements ("FTAs") must protect generic competition. Currently, the United States Trade Representative ("USTR") is including intellectual property (IP) and pharmaceutical provisions in FTAs that fail to promote access to affordable generics. Moreover, these provisions provide more IP and market protections to the brand companies than those afforded to their products under U.S. law. Such provisions serve to: (1) block generic drug exports to foreign territories; (2) significantly delay the availability of affordable drugs in those territories; and (3) create an avenue to delay domestic generic competition.

Recent FTAs have increased the protection of innovation in the pharmaceutical industry, while at the same time excluding provisions that ensure the availability of affordable medication to consumers both abroad and in the United States. Many FTAs, for example, have provisions that require patent "linkage" provisions. In other words, these provisions mandate that the United States' trading partner establish a generic approval system that is similar to the one in the United States – one that provides brand companies with the means to block foreign government generic approvals by using patents which may or may not specifically claim the brand product.. But these same provisions do not provide a means for generic companies to challenge these brand patents and, as a result, needlessly block generic competition. Thus, there is no incentive for the early resolution of patent disputes, nor is there a limit on the types of drug patents that can be listed for a drug product. Such measures grant brand companies *de facto* patent extensions, encourage lower quality patents, and unnecessarily delay the availability of affordable generic drugs. They not only are inconsistent with U.S. law, but they also thwart generic competition both domestically and abroad, and places the foreign country, at a minimum, in a pre-MMA position where the brand industry controls the generic approval system to the detriment of patients Accordingly, the USTR should be required to modify provisions in current and future FTAs (and negotiating templates) so that they provide balance between pharmaceutical innovation and ensuring that foreign and domestic consumers have timely access to affordable drugs.

C. Declaratory Judgment Actions.

While Congress designed Hatch-Waxman to expedite generic market entry, brand companies nevertheless found ways to manipulate the statutory system – ways to delay generic competition. One such abuse saw brand companies refusing to litigate patent disputes with generic companies concurrently with FDA's review of the generic application.

For years, generic companies tried to bring declaratory judgment ("DJ") suits against brand companies that refused to timely litigate patent disputes against all applicants for a particular drug. Those efforts failed, as the courts nearly always dismissed such cases for lack of

subject matter jurisdiction. In 2003, Congress stepped in to fix the problem. MMA contained provisions designed to allow generic drug companies to obtain patent certainty in those instances in which the brand company does not initiate suit after learning of the generic's paragraph IV ANDA filing. But as Congress must know, the U.S. Court of Appeals for the Federal Circuit disregarded the plain language of the statute and Congress' intent, holding that the MMA's DJ provisions did not change the law.

As a result of the Federal Circuit's ruling, brand companies once again will be able to manipulate the system and, in the process, delay access to affordable prescription medicines. This result is particularly untenable now, as America begins paying for the prescription drug benefit that Congress also enacted as part of the MMA.

At present, one generic drug company is seeking to have the Federal Circuit's decision reversed. Apotex Inc. has filed a petition for writ of certiorari in the U.S. Supreme Court. *See Apotex Inc. and Apotex Corp. v. Pfizer Inc.* (Case No. 05-1006). The Court recently asked the Solicitor General to submit an amicus brief setting for the views of the United States on Apotex's challenge. GPhA strongly encourages Congress to weigh in on this important issue so that the MMA's DJ provisions can function as Congress intended.

D. Congress Should Investigate The Lack Of Management Oversight At OGD.

Given the immense importance of generic drugs to the U.S. healthcare system, the prominence of Office of Generic Drugs (OGD) within the Center for Drug Evaluation and Research (CDER) organizational structure should be substantially increased. Over the past 15 years, numerous organizational changes have taken place within FDA to respond to changing priorities and new responsibilities. But despite the importance of generic drugs to the American public, OGD nevertheless has remained distant to the highest level of authority in CDER. Change is sorely needed.

Generic drugs account for over 56% of the prescriptions dispensed in the U.S. Yet, OGD resides within the Office of Pharmaceutical Science, which is responsible for a diverse set of programs, including some new drug review activities and research professionals. OGD must continually compete against these programs for administrative and budgetary resources. Equally as untenable, OGD is not a priority program within the current structure. Therefore, the emphasis on the critical OGD program is diminished, rather than enhanced, in the current FDA structure.

Restructuring FDA to establish a direct reporting line between OGD and the Director of CDER would ensure the most efficient and effective direction of the generic drug program. By making OGD a priority program for the Director of CDER, OGD management would have immediate access to top level decision makers when CDER is considering budgetary and human resource allocation. Further, by direct report responsibilities, the Director of CDER could provide the high level leadership necessary to address critical issues impacting the availability of generic drugs, including citizen petition challenges, resolution of scientific decisions that may otherwise lag, promoting development of the scientific requirements for an abbreviated pathway for biogenerics. Still further, reorganization would establish accountability

for the performance of this critical program. Under the current structure, several CDER units outside of OGD influence OGD's ability to carry out its important functions. As a result, accountability of its performance is diffuse. Through reorganization and direct attention by top CDER officials, there will be clear and direct lines of responsibility and accountability. The ability to implement and direct critical initiatives by top level CDER officials should assure scientific clarity, timely decisions and robust communications that will go a long way towards establishing the generic drug program as one of FDA's, and the nation', top priorities.

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GPhA strongly urges Congress to give careful consideration to the issues discussed above, as the satisfactory resolution of these issues is vital to increasing the public's access to affordable generic medicines.

Very truly yours,

Kathleen Jaeger,
President and CEO, GPhA

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