

**Presentation to the
U.S. Senate Commerce Committee
April 23, 2002**

Drug Pricing & Consumer Costs

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**Testimony of Kathleen Jaeger
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Mr. Chairman. Members of the Committee. My name is Kathleen Jaeger, and I recently became President and CEO of the Generic Pharmaceutical Association. I am a pharmacist; an attorney, who specializes in FDA-regulatory law; and a long-time consumer and industry advocate. As a pharmacist and coming from a family-owned pharmacy background, I understand the need consumers have for choice, and the challenge of placing affordable medicine in their hands.

On behalf of GPHA and its members, I want to thank you for convening this hearing to discuss pharmaceutical cost and consumer access. The GPHA represents manufacturers and distributors of finished generic pharmaceutical products, manufacturers and distributors of bulk active pharmaceutical chemicals, and suppliers of other goods and services to the generic pharmaceutical industry. The GPHA membership supplies more than 90% of all generic prescriptions, representing over one billion written and filled prescriptions in the United States. We are a significant segment of America's pharmaceutical manufacturers. No other industry has made, nor continues to make, a greater contribution to affordable health care than the generic pharmaceutical industry.

The various interests represented at this hearing share a common concern: the need to make prescription medicines affordable to all Americans. Indeed, the lack of affordable medicines is one of the great social issues of our time. The generic pharmaceutical industry is uniquely positioned to address this common concern by virtue of its ability to deliver safe, effective prescriptions to the American public. Unfortunately, the generic industry's ability to deliver affordable medicines is being hampered by legal loopholes in the current law. I'm speaking, of course, of

the Drug Price Competition and Patent Term restoration Act of 1984, also known as Hatch-Waxman.

Since its enactment in 1984, Hatch-Waxman has served as the means by which prescription medicines are developed and delivered to the American public. During its legislative life, it has enabled American consumers, taxpayers, employers and insurers to save tens of billions of dollars each year. But as often happens with legislation, the environment in which Hatch-Waxman was crafted has significantly changed, and unintended loopholes are being manipulated in ways never envisioned by virtually all who were involved with the development and passage of the Act. The pharmaceutical industry that Hatch-Waxman was designed to address is a vastly different one today than it was in 1984. Because of this, Hatch-Waxman (one of the single most important consumer savings choice and legislation ever passed by Congress) needs to be modestly updated to assure the statute's stated intent of enhancing competition and preserving true innovation is preserved and enhanced.

The Generic Pharmaceutical Association believes that this Congress has a unique opportunity - given the American public's call for immediate and significant action on drug pricing -- -- to modernize and strengthen Hatch-Waxman, close loopholes that have reduced its effectiveness, and pass legislation that will achieve significant savings that can make medicines more affordable for all Americans and achieve offsets to finance a meaningful Medicare prescription drug benefit or other Congressional priorities.

To understand the need and value of updating Hatch-Waxman, one must take a close look at the pharmaceutical environment that exists today. According to the latest available data, total health care costs reached \$1.3 trillion in 2000. This represents a per capita health care expenditure of \$4,637. The total prescription drug expenditure in 2000 was \$121.8 billion, or approximately \$430 per person. Of that total, approximately \$11 billion, or \$38 per person, was spent on generic pharmaceuticals.

Last year, 45% of all prescriptions were filled with generic drugs. So while nearly one in every two prescriptions was filled with a generic drug, only approximately 8% of all dollars spent on drugs were spent on generic medicines. Brand name prescription drugs, conversely, represented 55% of all prescriptions but consumed approximately 92% of all drug therapy dollars spent. These numbers reveal a stark

reality: brand name prescription drugs exceed the cost of generics by almost ten fold.

Let's look at these same statistics from another perspective; namely, that of the patient or payer. The average price of a prescription dispensed with a generic drug in 2000 was \$19.33. The average price of a prescription dispensed with a brand name drug in 2000 was \$65.29. The difference was \$45.96 per prescription, or 238%.

Expressed another way, brand name prescription drugs represent about 22% more prescriptions than generic drugs yet consume almost 500% more retail sales dollars. No single generic drug achieved sales revenue of \$1.0 billion in 2000. This compares with 19 brand-name patent-protected drugs that had annual retail sales in excess of \$1.0 billion each.

Based on these data, it is impossible to dispute that generic pharmaceuticals provide consumers with substantial savings. It is equally impossible to dispute that the use of generic prescriptions, and the introduction of generic medicines will result in even greater savings to consumers, employers, insurers and our state and federal government.

Despite the indisputable savings to be gleaned from generics, brand name medicines continue to control the market. As a result, the nation's prescription drug bill continues to show double-digit annual increases. And consumers, employers, insurers and government agencies are feeling the effects.

Although a majority of Americans have some form of insurance that helps defray the direct costs of prescription medicines, for an increasing number of consumers, the burden of rising prescription costs lands directly on their pocketbooks. The uninsured population, which currently exceeds 40 million people and could reach 30% of the labor force by 2009 (up from 23% in 1999), is hit the hardest.

It is well documented that the high cost of prescription medicines has a direct effect on patient usage. Look at the statistics. A recent survey of 1,010 adults by Harris Interactive revealed some very disturbing drug trends. Of surveyed patients, 22% did not purchase at least one prescription issued by their doctor in the previous year because of cost. Additionally, 14% of patients reported taking a drug in smaller doses than prescribed and 16% reported taking their prescribed medication less frequently than prescribed to save money. Such statistics can

hardly be said to be consistent with our society's goal of adequate health care. Clearly, cost is central to the issue of compliance.

Major employers, such as GM, are feeling the profound effect of escalating pharmaceutical costs, and are actively encouraging generic drug utilization. Physicians are increasingly aware of the impact that rising drug prices are having on their patients. The AMA has a policy statement that "supports programs whose purpose is to contain the rising cost of prescription drugs." The policy specifically encourages physicians to be aware of prescription drug prices and the availability of generic versions of brand name drugs. Health plans such as Blue Cross/Blue Shield, CIGNA, Well Point, Aetna, and others are engaging in more and more programs to foster generic drug utilization.

It is time for this Congress to join these companies and organizations in the fight against escalating prescription costs by restoring the original balance of Hatch-Waxman. Modernization of Hatch-Waxman is not simply the desire of the GPHA. Indeed, a coalition of leading governors, businesses, and labor leaders has asked the Congress to revisit Hatch-Waxman. The coalition, Business for Affordable Medicine, believes that loopholes in the current legislative scheme are undermining the intent of the law, and are being exploited to extend patents through convoluted legal machinations at considerable expense to employers and consumers/taxpayers.

Modernizing Hatch-Waxman could address the central issues of cost and patient access to prescription medicines. Modernization also would encourage the brand industry to refocus its resources on true product innovation, rather than devoting those resources to legal maneuverings designed solely to extend monopoly protection on existing products.

To understand our ideas for modernizing and strengthening Hatch-Waxman, let's look at the issue central to the current legislative proposal, the Schumer/McCain (Brown/Emerson) bill: the automatic thirty month stay of ANDA approvals.

Let me start by emphatically stating that the generic pharmaceutical industry supports patent rights, intellectual property protection, and the right of any pharmaceutical company – brand or generic -- to recoup its investment and make a reasonable profit for its shareholders. In fact, all publicly owned pharmaceutical companies, without exception, have responsibilities to seek to produce a reasonable return on the shareholders' investment. However, the key word is

“reasonable.” We should not be drawn into the false argument that it is necessary for the pharmaceutical industry to consistently and significantly top every other industry in the nation in every measure of profits, in order to be able to afford necessary and desirable investment to discover and develop new pharmaceuticals. To the contrary, unreasonable market exclusivity stifles competition, thereby removing the incentive for true innovation. Extending monopoly protection beyond its intended bounds only removes the incentive to develop new products. We recognize the dangers of monopolies in virtually every other area of our economy. It is time to recognize untoward effects that brand name “life cycle management: market exclusivity” practices are having on this nation’s health care system.

When Hatch-Waxman was created, it recognized the delicate balance between intellectual property protection and competition; between brand and generic business interests; and between consumer savings and return on brand investment. The intent of Hatch-Waxman was to protect the legitimate patent interests of the brand pharmaceutical company, but allow for generic competition within a finite period, thereby providing consumers with cost-efficient alternatives, driving drug developers back to the labs to create the next new wonder drug.

The drafters of Hatch-Waxman also recognized that not all patents are created equal. Patents are sometimes found to be invalid, or not infringed upon by competing products. For this reason, Hatch-Waxman established a mechanism by which generic manufacturers can challenge patents which may improperly block competition. Under the Hatch-Waxman system, brand companies "list" the patents with FDA that claim their drug. When a generic manufacturer files an application with FDA, it must tell the agency whether it is challenging any of the patents listed by the brand. If so, the brand company is given 45 days to sue the generic for patent infringement. Once a suit is filed, FDA is barred from approving the generic drug for 30 months, or until the litigation is resolved. The merits of the patent infringement suit have no effect upon the affect of the stay. A completely meritless suit enjoys the same 30-month stay as a meritorious one.

Most of the abuses that I will discuss today stem directly, or indirectly, from the "30-month stay." Over the past several years, the brand industry has discovered the enormous financial windfall that flows from the 30-month stay. Of all the industries in the U.S., only the brand pharmaceutical industry is given a special, unqualified ability to fend off competition. From a brand company's perspective, the 30-month stay, and its consequent windfall is almost too good to be true. As

noted, the merits of the patent infringement claim are totally irrelevant - the 30 month injunction is free - all that is required is a lawsuit. Furthermore, if a brand company strategically manages the timing of its patent applications, it can stack multiple 30-month stays on top of each other and keep competition out of market indefinitely, regardless of the merits of the patent case.

The potential for a free 30-month stay, creates an irresistible incentive for brand companies to list more and more patents with FDA. Many times these patents do not even claim the approved drug or its uses. The patents are listed solely for the purpose of getting a free 30-month stay and extending the brand company's monopoly.

It is hard to imagine that the founders and negotiators of Hatch-Waxman would have fully anticipated the creative ways in which the patent challenge process could be manipulated to prevent competition. Patent protection was intended to give the brand pharmaceutical industry 20 years of exclusivity. At the end of that date-certain period, the patent should expire and competition should be allowed to begin. Today, there is no such thing as date certain patent expiration, and no limit to what can be patented to prevent generic competition. Patents are stacked one upon the other, timed purposely to create a minefield of patent uncertainty. In fact, since the enactment of Hatch-Waxman in 1984, the average number of patents filed per blockbuster has increased five-fold – from 2 to an astounding 10 patents per drug.

Because my time is limited, I will provide but a few examples. The anticonvulsant drug, Neurontin®, represents one good example. By listing patents with FDA that do not claim the marketed form of the drug or an approved medical use, the brand manufacturer of this \$1.1 billion per year drug has been able to delay generic competition for 18 months past the expiration of the drug's basic patent. The potential lost savings to Americans by this delay has already amounted to approximately \$825 million. With each new day, the public loses an additional \$ 1.5 million. Furthermore, by strategically timing the submission of an additional patent to FDA, the brand company effectively converted the automatic 30-month stay of generic approvals into 54 months of additional market exclusivity.

Another example of similar abuse occurred with the antidepressant drug, Wellbutrin®. Affordable generic versions of the \$113 million per year drug were effectively stalled for 5 years by the brand company's listing of 6 unapproved medical uses of Wellbutrin®. As a result, consumers lost potential savings of

approximately \$275 million. These patents, as well as the Neurontin® patents mentioned above, were unrelated to the FDA-approved form and use of the brand-name drug. Rather, they were listed simply to preserve exclusivity, and to reap the windfall of hundreds of millions of dollars.

These are just a two of the many examples that demonstrate that in the brand industry's eyes, anything can, and will be, considered suitable for patent protection and monopoly extension.

We seek to modernize Hatch-Waxman, to restore the original balance between protecting innovation and promoting competition, which will provide affordable medicines to Americans. We support the decision by this committee to hear this issue, and to explore ways to increase consumer prescription drug savings. We support the efforts of Senators McCain and Schumer, and others, for proposing ideas that would close the loopholes in the Hatch-Waxman Act and accelerate generic competition, brand innovation, and consumer savings.

Repeated abuses of the provisions of Hatch-Waxman have prevented, and will continue to prevent or delay, drug competition, crippling private and public insurance budgets and needlessly burdening consumers. Specific abuses and problems include:

- Patent Orange Book Listings. For virtually every blockbuster drug, brand name companies continuously and strategically add new "Orange Book" patent listings. Each new patent listing triggers a new 30-month stay, preventing generic drugs from receiving FDA approval and from going to market. As I mentioned earlier, if the brand name chooses to file a lawsuit, a 30-month stay is automatic, regardless of the merits of the new patent, and results in an automatic delay in generic approvals until the stay expires or a court resolves the dispute. By staggering their Orange Book listings, the brand name companies indefinitely extend their market exclusivity. In the past 18 years, the average number of patents listed for each blockbuster has increased from 2 to about 10. The time and cost associated with challenging and litigating these patents in order to bring affordable products to consumers is extraordinary.
- Blockage of generic competition by inappropriate manipulation of Hatch-Waxman exclusivity protections. Brand name manufacturers delay generic entry by distorting the intended purpose of the Hatch-Waxman 3-year exclusivity provision. FDA has granted exclusivity to brand manufacturers for

minor product and labeling changes that present no therapeutic benefit over the predecessor product. These changes are hardly the type of "innovation" that Congress intended to reward when it enacted Hatch-Waxman, and are clearly not worth the price that the public is paying for them.

A recent example involves labeling changes that resulted after Bristol Myers Squibb conducted pediatric clinical trials on Buspar (for anxiety) and Glucophage (for adult onset diabetes). Information derived from these limited studies yielded minor labeling changes. Bristol used the outcome of minor pediatric studies to delay generic versions of each product. Bristol argued that FDA's pediatric labeling regulation requires the "pediatric information" to be disclosed in drug product labeling; yet, this data is protected by three years of exclusivity which precludes generic firms from having that information on their product label.

The modest Buspar pediatric studies determined that "safety and effectiveness were not established in patients 6 to 17 years of age... at doses recommended for use in adults." Bristol sought: (1) six months of pediatric exclusivity for the study, and (2) three years of exclusivity for qualifying its negative pediatric labeling statement.

The limited Glucophage pediatric studies (72 subjects) resulted in the development of certain pediatric information. Bristol had received six months of exclusivity for conducting the study. Bristol also received three years of exclusivity for changing its labeling to include this "new" pediatric information, which in turn yielded a second six month pediatric extension for the labeling change. By preventing generic products from coming to the market consumers were denied significant savings offered by affordable generic products. Bristol ultimately lost its fight, but its tactics delayed generic competition for six months, creating a windfall for them on a drug with annual sales in excess of \$1 billion a year. The cost of this 7 month delay at \$ 2 million dollars a day, conservatively cost the system including the consumers at least \$420 million.

- Brand migration to extend product life cycles. Brand companies exploit patent and exclusivity strategies to delay competition. These tactics provide the brand companies with the time needed to focus on marketing efforts such as converting patients to patent protected products that often provide little or no therapeutic advantage to consumers.

- Questionable timing and use of FDA citizen petition process. A Citizen Petition "stops the clock" on the approval of a generic product, often for a minimum of several months. Brand Citizen Petitions are typically filed late in the review process and frequently raise highly questionable scientific issues and, as a consequence, these petitions can delay market entry of legitimate high quality generic competitors.

The Generic Pharmaceutical Association believes that modest legislative fixes could stop abuses and restore the balance between innovation, competition and access originally sought in the Hatch-Waxman. Enactment of legislation could help restore the type of fair competition that the authors of Hatch-Waxman originally intended while ensuring that the brand pharmaceutical companies have every ability to enforce and protect their innovations prior to the launch of competing products. Legislation could achieve this balance through elimination of the loopholes and the clarification of current law. Specifically any legislation solution should consider the following:

1. Eliminate the 30-month automatic stay. The 30-month automatic stay that frequently prevents generic entry must be eliminated in order to prevent gaming of the system. If this financial windfall to brand industry were eliminated, patent holders would still be entitled to sue generic companies but -- like all other industries -- they would have to obtain a preliminary injunction from the court to stay generic drug approvals. Indeed, eliminating the 30-month stay provision would infuse legal discipline and accountability into the system.

Many examples demonstrate the need to eliminate the 30-month stay. For example, the application of multiple, successive 30-month stays of generic approval during patent litigation. As noted, this practice is costing America consumers billions of dollars.

The original 30-month stay for the blockbuster antidepressant drug Paxil®, with annual sales of \$1.9 billion, (paroxetine HCl) expired in November of 2000. Yet, the application of multiple 30-month stays has delayed the availability of generic Paxil® availability until at least 2003. Abuses such as these are repeated continuously and lead to tens of millions of dollars in excessive expenditures.

2. Remove legal barriers that undermine the value of incentives for generic patent challengers. We support efforts to preserve and strengthen incentives for firms that undertake extremely costly challenges to complicated patents by ensuring that the reward, 180-day exclusivity, is just that -- a reward that could commence with a successful non-appealable court decision.
3. Prevent brand firms from hiding behind questionable patents. One way to achieve this is to allow generic firms to challenge patents during the review process. If successful, such challenges would expedite consumer access to affordable medicines.
4. Limiting 3-year exclusivity to only meaningful product innovations that are supported by substantial clinical studies. Minor labeling changes, rather than true innovations, should not be allowed to block the access by consumers, employers, insurers and taxpayers to the substantial savings offered by generic products.

The watering down of the qualifying criteria for the 3-year market exclusivity provision is costing American consumers billions of dollars. The painkiller Ultram® (tramadol HCl) is protected by **two** 3-year exclusivity periods covering minor details of the drug's dosing regimen (i.e., one exclusivity for increasing the dose in 25mg increments, and another for increasing at 50mg increments). Congress never intended for such minor labeling changes to block access to generic drugs. Yet, the Ultram® exclusivity periods could cost consumers, their employers, as well as public and private insurers at least \$727 million dollars. Abuses such as these are repeated continuously and lead to tens of millions of dollars in excessive expenditures.

5. Create a rolling generic drug exclusivity that will increase incentives for more timely generic entry. The 180-day exclusivity provision now available to the first generic challenger should become available to any other subsequent challenger if – for whatever reason – the initial challenger does not go to market. In addition, reform should ensure the forfeiture of the exclusivity period for a range of other actions by the first challenger that effectively delays market access to generics.

Some opponents of reforming Hatch-Waxman have focused on the 180-day generic exclusivity provision related to patent challenges, arguing that this incentive is unnecessary. We believe that there are several reasons why this

incentive should be protected, and why some in the brand industry might want this incentive to be abolished.

There are many examples of how the 180-day exclusivity provision has benefited consumers. Perhaps the most visible, and recent example, involves Eli Lilly's Prozac®. In August 2001, a generic firm successfully concluded a patent challenge as prescribed under Hatch-Waxman, and introduced a generic version of this blockbuster drug. The company enjoyed six months of exclusivity. On January 29, 2002, the firm's period of exclusivity ended, and multiple generic versions of Prozac entered the marketplace. Rapidly and predictably, the price of Prozac dropped from approximately \$2.70 per dose for the brand to less than 10 cents per dose for generic versions at the wholesale level.

That challenge ultimately opened the market to generic competition 2 ½ years early, at a savings to U.S. consumers of over \$2.5 billion. Those cost savings from generic Prozac competition have benefited all Americans, and reduced costs to insurers, employers, and government health care programs.

There are a number of other examples where the 180-day generic exclusivity provision has generated significant savings for consumers. These include:

- Generic Zantac® entered the market over 4 years early at a conservative savings to consumers of \$ 2.45 billion dollars.
- Generic Taxol® entered the market over 11 years early at a savings to consumers of \$3.5 billion dollars. Generic Relafen® entered the market 3 years early at a savings to consumers of \$109 million dollars.
- Generic Platinol® entered the market over 11 years early at a savings to consumers of \$1 billion dollars.

The 180-day generic exclusivity provision works for consumers. Clearly it provides the incentive that Congress intended for the generic company. The only party who may be deemed a non-beneficiary is the brand company.

Removing the 180-day exclusivity provision will hurt consumers by removing the incentive for generic companies to provide the adversarial check and balance that the U.S. Patents and Trademark Office does not provide.

GPHA believes that these reforms will help achieve the objective of restoring the balance to Hatch-Waxman, and revitalizing it for the 21st century.

Why is reform critical now? Twenty blockbuster drugs, with sales greater than \$500 million, are scheduled to lose patent or market exclusivity in the next 10 years. A total of 45 of the 100 most prescribed drugs should face first-time generic competition within the next 5 years. Financial analysts project that brand products accounting for more than \$40 billion in annual sales should lose patent protection and should be available for generic competition. This should generate consumer and system savings in excess of 30 billion dollars. Of course, the brand industry would like to forestall this event as long as possible. Without refining the system, there is no guarantee that the nation's health care system and consumers can realize these benefits.

The battle over modernization of Hatch-Waxman must be understood in the context of the enormous savings available to the American public through generic utilization. The brand pharmaceutical industry would have Congress believe that the system isn't broken, so it doesn't need fixing. The brand industry would have Congress and the American public believe that the patent challenge provisions of Hatch-Waxman, with their 180-day generic exclusivity incentive, result in increased litigation and deserve to be discarded. The brand pharmaceutical industry would have Congress and the public believe that generic competition is a threat to the next cure or blockbuster treatment.

We must consider the source of these arguments. They are made by international and domestic corporations that recognize that billions of dollars in sales and windfall profits are at stake because generic competition works at lowering drug costs. We would argue that competition spurs true innovation.

GPHA encourages Congress to embrace reforms of Hatch-Waxman that close loopholes, encourage competition, reward true product innovation, and provide consumers with date-certain savings on their drug costs. Our industry is prepared to work with Congress on meaningful reform that expands the savings offered by generic medicines. Thank you. I would be happy to respond to any questions you may have.