

**Statement of the Gray Panthers**  
**regarding pharmaceutical manufacturer's abuse**  
**of the Hatch - Waxman Act**  
**Presented to the U.S. Senate Commerce Committee**  
**April 23, 2002**

Thank you for the opportunity to present the views of Gray Panthers and the "Stop Patient Abuse Now" SPAN coalition regarding the effect on consumers of anti-competitive practices by pharmaceutical manufacturers, and the need to reform the Hatch-Waxman Act.

This Statement is presented to the Senate Commerce Committee by Marion Wolff, long time Gray Panther member and Tim Fuller, National Executive Director of the Gray Panthers and founder of the "Stop Patient Abuse Now Coalition" SPAN coalition.

**About Gray Panthers and SPAN**

Gray Panthers is a grassroots organization of over 25,000 activist leaders in 50 chapters across the country. The national office develops and coordinates national campaigns in which chapter members organize local alliances for effective public education and action. Currently, the Gray Panthers are initiating a national and state-based pharmaceutical reform campaign named *RePhorma*. This campaign is exposing abuses of Hatch-Waxman Act through public education forums and media events, filing class action law suits asking for triple damages, and pin pointing specific aspects of the industry's manipulations of the public trust.

In support of the national *RePhorma* campaign, Gray Panthers has organized national partners in forming the "Stop Patient Abuse Now" SPAN coalition.

SPAN includes 125 senior and consumer organizations from 28 states that was founded last year specifically to respond to aggressive efforts by drug manufacturers that prevent timely access by consumers to safe and affordable medicine.

**The Pharmaceutical Market Needs Reform**

Consumers are extremely frustrated that Congress has refused over the past few years to address significant shortcomings in the 1984 Drug Price Competition and Patent Term Restoration Act ("Hatch-Waxman Act"), despite a clearly growing trend by drug manufacturers to abuse specific provisions of the act.

Specifically, we are appalled that the so-called "30-month stay" provision of the Hatch-Waxman Act is used by brand drug companies to routinely extend their market exclusivities without regard to the intent of the law. We are similarly appalled that among the thousands of

patents listed in the FDA Orange Book, the majority have nothing to do with the discovery of new chemical entities or new methods of use as intended by Congress.

Today, the Hatch-Waxman Act provides a regulatory scheme by which brand drug manufacturers ensure that generic drugs cannot compete with brand products for many years after original patents on the drugs expire. While it is true that the Hatch-Waxman Act led to significantly larger investments in drug research and a significantly expanded generic drug industry since 1984, in recent years the act has cost American consumers and other purchasers—including taxpayers—billions of dollars in lost savings.

As a result, the Gray Panthers and our SPAN coalition allies joins many other important senior and consumer groups in the country and a growing list of Governors, employers, and other institutional purchasers, in supporting legislation to close loopholes in the Hatch-Waxman Act. We applaud Senators Schumer and McCain for their efforts, and are grateful for the efforts of many other members of Congress who are also now taking time to understand the problems with the Hatch-Waxman Act.

### **The Hatch-Waxman Act Impedes Competition**

The Hatch-Waxman Act worked by providing brand manufacturers with 17 years of patent protection and other market exclusivity protections, which ensured huge profits on successful drug applications. The Act also worked by streamlining the generic drug approval process to ensure competition from lower-cost alternatives as soon as patents expired. The brand industry will point out that their investments for new drugs have increased dramatically as a result of the Act, and that generics now make up over 40 percent of the market. These facts are a testament to the Act's effectiveness for a period of time after 1984.

The brand industry will also state that only six percent of all generic applications since 1984 have been delayed as a result of brand industry efforts. The fact is, nearly all generic applications over the past few years have faced such delays, and *all* generic applications for blockbuster drugs have faced delay.

What the industry will not tell us is that the six percent of generic products that have been delayed were to have replaced brand drugs that generate more than half of the industry's total profits. In other words, generics that threaten to erode market share for blockbuster drugs will *always* face delays, and consumers—including 40 million uninsured Americans who pay out of pocket for these drugs—will be forced to wait months or years longer than intended by Congress for price breaks.

### **No Regulatory Avenue for Relief**

It must be understood that the Hatch-Waxman Act allows brand drug companies to unlawfully delay competition with impunity. How many members of Congress are aware that Bristol-Myers Squibb obtained a secondary patent last year for its Buspar® anti-anxiety drug (buspirone) by telling the patent office the new patent did *not* cover already approved uses of

the drug, but then turning around and telling the FDA that the patent *only* covered approved uses of the drug? How many members of Congress are aware that Bristol could not possibly have obtained its new patent if the patent did, in fact, cover already approved uses of the drug, and that it could not possibly have listed the patent in the Orange Book if it, in fact, did not cover approved uses of the drug?

How many members of Congress are aware that Bristol listed its new patent in the Orange Book *on the very day* its original patent expired, and that this action prevented shipment of millions of dollars worth of generic products that would have otherwise been available to consumers that afternoon? And how many members of Congress are aware that this simple effort cost consumers nearly \$300 million?

Finally, how many members of Congress are aware that the FDA did not do a single thing to stop this abuse of the public trust, and that consumers had no regulatory avenue for relief?

### **Consumers are Taking Independent Action**

In fact, we know that most members of Congress have been swayed by the brand drug industry to avoid any effort to improve the Hatch-Waxman Act. As a result of inaction by Congress, consumers have taken matters into their own hands to respond to these abusive tactics.

For example, Gray Panthers filed the first class action lawsuit against Bristol-Myers Squibb last year to recover damages that resulted from the company's anti-competitive efforts to delay generic competition for Buspar. Gray Panthers and SPAN members first petitioned the Federal Trade Commission and state Attorneys General to investigate the company's actions. Our goal was to make a claim against Bristol on grounds that the company violated anti-trust and competitiveness laws, and therefore should face treble damages.

The FTC and 29 state Attorneys General subsequently filed suit against the company, and numerous class action suits have been consolidated in a single court. As a result, we anticipate that Bristol-Myers Squibb will ultimately be forced to spend far more than it stood to gain by its actions.

Gray Panthes and SPAN coalition has since initiated similar actions against Biovail corporation for its efforts to delay generic competition for the heart drug Tiazac®, against AstraZeneca for its efforts to delay generic Prilosec® (an ulcer drug), and against Bristol-Myers Squibb for its efforts to delay generic Taxol® (a cancer drug). Gray Panthers and SPAN is also preparing new actions against other drug companies.

These actions have led to similar efforts by numerous other groups—all of which have concluded they must now take matters into their own hands to deter drug company actions that prevent competition and delay timely access to lower-priced drugs.

### **Inaction by Congress is Costing Taxpayers and Consumers Billions of Dollars**

It is critical that Congress act quickly to close loopholes in the Hatch-Waxman Act. The Act includes favors for the brand drug industry that are not afforded by any other law to any other industry. For example, brand manufacturers may sue generic manufacturers for alleged patent infringement under the act, but are under no obligation to post a bond to do so. They also face no penalty under the act for frivolous suits. Meanwhile, the simple filing of such a suit ensures a 30-month delay in the generic approval.

Congress' decision to let brand manufacturers avoid any disincentive to sue generic manufacturers establishes a perverted system in which generic competition is certain to be delayed for all blockbuster drugs.

For example, AstraZeneca sued 13 generic manufacturers for alleged patent infringement against its Prilosec® heartburn drug, the best-selling drug in the world. The company stopped generic approvals for 2-1/2 years as a result. The FDA finally granted approval to generic alternatives, months after the approval should have been granted, and only after pressure from consumers, including an unprecedented letter from 18 governors insisting on immediate action.

Despite the approval, AstraZeneca is now pressing its claims in court, which continues to prevent generic manufacturers from marketing their products. The Gray Panthers has no objection to the right of drug companies to go to court to protect their intellectual property. We do object, however, to AstraZeneca's strategy of delaying the court case in order to prevent competition.

In fact, the judge in that case, Honorable Barbara Jones, issued an order to AstraZeneca, in which she found the company had intentionally withheld critical material from defendants, and had taken other steps to delay the case.

How many members of Congress know that AstraZeneca makes \$11 million from Prilosec sales every day it can delay competition? How many members of Congress know that this has so far cost U.S. consumers and taxpayers nearly \$1 billion in extra prescription drug costs this year alone?

And how many members of Congress know that AstraZeneca has switched 35 percent of all Prilosec patients to its next-generation Nexium® product—many without their knowledge according to lawsuits filed against AstraZeneca—despite the fact the FDA has found the drug to be no better for the vast majority of patients than either Prilosec or less expensive generic forms of Prilosec (*see* letter from Gray Panthers to DDMAC, dated January 15, 2002.)

### **Congress Must Act This Year to Reform the Hatch-Waxman Act**

The Hatch-Waxman Act promoted pharmaceutical competition at one time. Today, it results in a system of anarchy in the pharmaceutical market where brand manufacturers prevent competition with impunity, generic manufacturers must cut deals to stay alive, and consumers and other drug purchasers become litigants to force fairness in the system.

The brand industry has stated it will oppose reform of the Hatch-Waxman act “with every ounce of its strength.” This is no surprise to any pharmaceutical purchaser—PhRMA has a sweetheart system under the Act that allows it to stifle generic competition. For example:

- Brand companies can use the Act to avoid scrutiny by the FDA for blatantly false and unlawful patent listings because the agency interprets its role under the act as only ministerial;
- Brand companies can initiate litigation under terms of the Act in order to avoid posting bonds or facing penalties for losing such cases;
- Brand companies can even get away with pressing non-Hatch-Waxman Act claims under the Act in order to simply trigger a 30-month stay on generic approvals.

## **Conclusion**

We believe that, while the Hatch-Waxman Act was well intentioned, it long ago ceased to be effective or fair. It is clear today that the Act is stifling rather than promoting competition. And it is clear that certain provisions in the Act actually encourage drug manufacturers to prevent the very competition intended by the Act, at an annual cost of billions of dollars to consumers, taxpayers, and other pharmaceutical purchasers.

As a result, a system of anarchy prevails under the Hatch-Waxman Act, where brand drug manufacturers subvert the intent of the Act to prevent competition, and generic manufacturers and purchasers must find ways to work outside the Act to preserve competition.

The situation will only get worse unless Congress acts quickly to fix the system. Consumer groups are no longer content to wait for systemic change. Rather, they are initiating expensive class action litigation and are lobbying the FTC and states to write new rules to govern the pharmaceutical market outside—or on top of—the Hatch-Waxman Act.

We encourage action by this committee and others in Congress to close the loopholes in the Hatch-Waxman Act this year. Hatch-Waxman reform is the best way to help all Americans afford prescription medicine, and is critical to restore the congressional intent of the 1984 initiative.

Thank you.

Timothy Fuller  
Marion Wolff

Gray Panthers