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GENERIC PHARMACEUTICALS: MARKETPLACE ACCESS AND CONSUMER ISSUES

HEARING

BEFORE THE

COMMITTEE ON COMMERCE, SCIENCE, AND TRANSPORTATION UNITED STATES SENATE

ONE HUNDRED SEVENTH CONGRESS

SECOND SESSION

APRIL 23, 2002

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SENATE COMMITTEE ON COMMERCE, SCIENCE, AND TRANSPORTATION

ONE HUNDRED SEVENTH CONGRESS

SECOND SESSION

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GENERIC PHARMACEUTICALS: MARKETPLACE ACCESS AND CONSUMER ISSUES

TUESDAY, APRIL 23, 2002

U.S. SENATE,
COMMITTEE ON COMMERCE, SCIENCE, AND TRANSPORTATION,
Washington, DC.

The Committee met, pursuant to notice, at 9:30 a.m. in room SR–253, Russell Senate Office Building, Hon. Byron L. Dorgan, presiding.

OPENING STATEMENT OF HON. BYRON L. DORGAN, U.S. SENATOR FROM NORTH DAKOTA

Senator DORGAN. This is a Senate Commerce Committee hearing that we are holding today on the subject of prescription drugs. This will the first in a series of three hearings on the subject of prescription drug prices, costs, and other related issues.

The hearing this morning will take a look at the issue of generic drugs. Let me put a chart up, if I might, as I begin to tell you that most of us now have seen the information that prescription drug costs—in this case, spending—but costs have risen by 17 percent in the last year. There are estimates by some reliable concerns that costs will continue to increase by more than 12 percent per year over the next 10 years. A substantial portion of this increase is due to the utilization—an increased utilization and also price inflation. We're going to have a series of hearings exploring why prescription drug spending is rising as fast as it is and what Congress might do to address that issue.

Why generics? Well, today's hearing will look at how a more competitive generic drug industry might help save consumers money. Generic drugs are safe, effective and a lower-cost alternative to brand-name prescription drugs. It has been estimated that a greater use of generics, when they are available, could save consumers 8 to 10 billion dollars a year. A recent study has suggested that a Medicare prescription drug benefit could cost 50 billion to 100 billion dollars less over 10 years if the use of generic drugs is encouraged.

The next chart shows the examples of the dramatic savings that can be realized by generic drugs. If you were to walk into your corner drugstore with a prescription for the blood-pressure drug Cardizem, you would pay $1.45 per pill compared with $.22 for the equally safe and equally effective generic version, a savings of 85 percent. The chart also shows the generic version of Hytrin, which is a blood pressure medicine, is $1.82; Vasotec, $1.08, the generic is $.45; and Prozac, $2.61, the generic is $1.41.

Some states, businesses, consumers, and insurance companies have raised concerns that there are loopholes in the Hatch-Waxman law, which was created to spur generic drug competition, and that these loopholes are being used to keep generic drugs off the market for a longer period than Congress intended. One of the purposes of this hearing is to examine some of the alleged abuses. We want to know if there is anything Congress can do to bring generic drugs to the market sooner, while at the same time not harming the innovators and those who are creating new drugs.

For instance, proponents of the Hatch-Waxman reform argue that brand-name pharmaceutical companies file frivolous patent infringement lawsuits simply to trigger the 30-month hold required in the Hatch-Waxman law before final approval can be granted for the marketing of generic drugs. That has the effect of keeping generic drugs off the market for a much longer period of time.

In addition, there have been examples of brand-name manufacturers entering into agreements with generic manufacturers in which the generic drug manufacturer withholds its product from the market in return for a payment from the brand-name manufacturer. Getting to the bottom of these allegations is timely and important. Within the next few years, patent protection will expire on 21 of the best-selling brand-name drugs with combined sales in the U.S. of about $20 billion.

I support the right of pharmaceutical manufacturers to have their legitimate patents protected and to make a profit with them. But these allegations that some drug companies file frivolous patents and/or infringement suits with the intent to delay generic competition and extend brand-name monopolies are serious. And, if true, we need to level the playing field for the American consumer.

I look forward to hearing from today's witnesses about these important issues. Senator Schumer, our first witness, has introduced legislation with Senator McCain. Let me call on Senator McCain, the ranking member.

STATEMENT OF HON. JOHN MCCAIN,
U.S. SENATOR FROM ARIZONA

Senator MCCAIN. Thank you, Mr. Chairman. I thank you for holding this hearing and providing the Committee an opportunity to examine the role of pharmaceutical companies, including generic companies, in anti-competitive activities that are unfairly restraining trade and impeding access to affordable medications for many consumers, especially senior citizens and working Americans who don't have health insurance and cannot afford to get their prescriptions filled.

Mr. Chairman, I don't want to duplicate what you just said but there are allegations of anti-competitive behavior in the marketplace, and they're always disturbing. But it's particularly galling today, given what ails our nation's healthcare system.

Just last week, the nation's largest public provider of healthcare CalPERS, California Public Employees Retirement System, announced that they would have to increase their members' premium by 25 percent next year. According to CalPERS's assistant executive officer for health benefits, quote, "In the past 2 or 3 years, pharmaceutical costs have increased more than any other compo-

nent in our CalPERS health rates, and our Medicare Choice/Supplemental Plan pharmacy trend can account for over 50 percent of the increase in premium rates that we see in our retiree plans from 1 year to the next."

I hope that our witnesses, including the chairman of the FTC, recognize the dramatic and drastic impact that the increase of costs of prescription drugs is having on the skyrocketing costs of healthcare in America. If our witnesses ignore that and don't agree that it's a problem and believe that this should go unfettered, then I don't believe that they are doing their job.

There are many factors that contribute to the rapid growth in our nation's healthcare costs, and drug costs are among them. I hope that each of our witnesses will help my colleagues and me understand how the current structure for prescription drug patents works and what in that structure should be strengthened, eliminated, or replaced so that consumers are not penalized by anti-competitive actions of name-brand and generic drug companies.

I'm very pleased to join with my friend, Senator Schumer, in trying to get enacted a piece of legislation that would have a modest but beneficial effect by allowing generic drugs to become available as rapidly as possible, as the chairman's chart points out.

Also, Mr. Chairman, it's interesting to me that in the March 14, 2002, *Bloomberg News Report,* Pfizer's chairman and chief executive officer Harry McKinill's bonus doubled to $2.8 million in 2001, his first year as head of the world's biggest drug maker. His compensation increased as Pfizer's net income increased. Shares of New-York-based Pfizer fell 13 percent last year. McKinill, CEO since January of last year and chairman since May, was awarded options valued at as much as $57.8 million if the shares rise 10 percent over the life of 10-year grant. The CEO, Mr. McKinill, exercised options valued at $11.4 million last year.

Is this really what drug company CEOs should be doing at a time when costs of drugs are dramatically increasing for average Americans? And today, as we speak, seniors are being faced with a choice between their health and their income because they can't afford prescription drugs. And the CEO of Pfizer gets stock options that can be valued as much as $57.8 million, last year exercising options at $11.4 million? Something's wrong here, Mr. Chairman, something is really wrong.

I thank you, Mr. Chairman.

[The prepared statement of Senator McCain follows:]

PREPARED STATEMENT OF HON. JOHN MCCAIN, U.S. SENATOR FROM ARIZONA

Mr. Chairman, thank you for holding this hearing and providing the Committee an opportunity to examine the role of pharmaceutical companies, including generic companies, in anti-competitive activities that are unfairly restraining trade and impeding access to affordable medications for many consumers—especially senior citizens and working Americans who don't have health insurance and cannot afford to get their prescriptions filled.

I look forward to hearing from each of the witnesses and learning more about what is actually happening in the marketplace, as well as what can be done to help improve the current system and counter efforts by drug manufacturers to unfairly prolong their patents, eliminate fair competition and delay access to lower-priced generic versions of prescription drugs.

In 1984, Congress enacted the Hatch-Waxman Act to spur generic competition while providing incentives for brand name drug companies to continue research and

development into new and more advanced drugs. Hatch-Waxman has succeeded in helping bring new lower-cost alternatives to consumers and investment in U.S. pharmaceutical research and development has increased from $3 billion to $21 billion over the last 15 years. But the full potential of Hatch-Waxman appears to be stymied, and today, abuses of the current system appear to be delaying generic products from coming to market in a timely manner.

Allegations of anti-competitive behavior in the marketplace are always disturbing, but it is particularly galling today given what ails our nation's health care system. Health care costs are skyrocketing, insurance premiums are rising and the number of uninsured in our country is probably going to continue growing as many businesses no longer can afford providing coverage for their employees and their families.

Without question, the high cost of prescription drugs plays a significant part in the financial problems plaguing our health care system.

Just last week the nation's largest public provider of health care, CalPERS (California Public Employee's Retirement System) announced that they would have to increase their members' premiums by 25 percent next year. According to CalPERS' Assistant Executive Officer for Health Benefits Allen Feezor, "In two of the past three years, pharmaceutical costs have increased more than any other component in our CalPERS health rates. In our Medicare Choice/Supplemental plans, pharmacy trend can account for over 50 percent of the increase in premium rates that we see in our retiree plans one year to the next. It should be noted that in both our hospital and Rx trends, a measurable portion of the trend is due to increased utilization by our enrollees but this can not take away from the extraordinarily high trends in both pharmacy and hospital pricing."

Prescription drug costs also play a significant role in the rising financial cost providing health care coverage to employees in the private sector, as demonstrated by General Motors coverage program, According to General Motors, "GM is the largest private provider of health care coverage, spending over $4 billion a year insuring over 1.2 million active workers, retirees and their families. Of that, GM spends $1.3 billion for prescription drugs. The cost of prescription drugs is rising between 15–20 percent a year in GM's plan even though the company employs state of the art management techniques to assure appropriate and most cost effective use."

There are many factors that contribute to the rapid growth in our nation's health care costs. Drug costs is clearly among them, and I believe that we must work to make prescription drugs more affordable, by among other things, ensuring consumer access to generics after patents have expired, and before clever attorneys have manipulated the current system.

And so it is my sincere hope that each of our witnesses will be able to help my colleagues and me understand how the current structure for prescription drug patents works, and what in that structure does not work and should be strengthened, eliminated, or replaced so that consumers are not penalized by anti-competitive actions of name brand and generic drug companies. I hope that we can be educated on what we can do to help increase access to affordable, quality, medications without impeding science, research, or new technology.

I also believe that we must start looking at the bigger picture—and begin developing a bipartisan solution for ensuring access to affordable and quality health care for all Americans. And this can't be done by imposing price controls or creating a universal, government-run health care system. To fix what ails our health care system, we must build upon as many strengths it offers the highest quality care in the world—while addressing its weaknesses.

A balance must be found and I'm hopeful that today's hearing will be a step in that direction and will also help provide us the information necessary to protect intellectual property without allowing those protections to be manipulated for excessive profits at the expense of America's consumers.

Senator DORGAN. Senator McCain, thank you. Senator Wyden?

STATEMENT OF HON. RON WYDEN, U.S. SENATOR FROM OREGON

Senator WYDEN. Thank you, Mr. Chairman. I appreciate your holding this hearing, because ever since my days as co-director of the Oregon Gray Panthers, this issue has triggered a bare-knuckles fight between the brand-name drug companies and generic drug companies. For just a minute or two, before the brawl starts, I'd

like to talk about what this really means for seniors, patients and families.

First, both seniors and patients want to get the new cures for the serious illnesses that they face. They're understandably up in arms because they can't even afford the costs of the old medicines, let alone the new cures. Congress wrote the Hatch-Waxman law to help on both counts. Patent protection would provide an incentive for companies to be productive and more innovative, and then medicine would be more affordable as generics were sped to the market.

But since the passage of Hatch-Waxman, there have been problems on both ends. The drug companies were quoted in *the New York Times* last week as saying that they have experienced a clear fall in productivity, and I would ask unanimous consent that article be put into the record, Mr. Chairman.

Senator DORGAN. Without objection.

[The information referred to follows:]

ARTICLE FROM THE NEW YORK TIMES, SUBMITTED FOR THE RECORD

THE NEW YORK TIMES

Despite Billions for Discoveries, Pipeline of Drugs Is Far From Full

By Andrew Pollack

April 19, 2002

This should be the golden age for pharmaceutical scientists. The deciphering of the human genome is laying bare the blueprint of human life. Medical research has increased understanding of disease. Robots and computers are turning drug discovery from a mixing of chemicals in a test tube to an industrialized, automated process.

Yet if industrialization normally means higher speed and lower costs, the pharmaceutical industry has been experiencing the opposite—a "clear fall in productivity," according to Dr. Frank L. Douglas, the chief scientific officer of *Aventis.* Instead of narrowing the list of compounds that might be useful in drugs, automation has broadened it—greatly increasing the number of formulas tested without yet delivering commensurate growth in safe and effective drugs. The industry's output of new drugs has risen only modestly in the last two decades despite a more than sixfold increase, after adjusting for inflation, in research and development spending, to more than $30 billion annually. In the last few years, the output has actually declined.

"It makes you wonder: what are they doing?" said John Borzilleri, a health sciences portfolio manager at State Street Research and Management in Boston. "Are they spinning their wheels or is it just a matter of time?"

The perceived paucity of new drugs in company pipelines has become a preoccupation of the industry and of Wall Street. Bristol-Myers Squibb, *Merck* and other drug makers have said earnings will be lower than expected this year, in part because there are not enough new products to offset declining sales of old ones that lose patent protection and face competition from generic versions.

The industry mantra is now "it's the pipeline, stupid," said Dr. Steven M. Paul, group vice president for discovery research at Eli Lilly in Indianapolis. But no one has yet found a reliable way to fill the pipeline.

With drugs not coming fast enough to sustain the double-digit growth in earnings and revenue that Wall Street has come to expect, more companies might merge, to bolster earnings through reduced costs, analysts say. Companies are also trying to increase revenue from the drugs they do have by raising prices, advertising heavily to consumers and scrambling to extend their patents, actions that have embroiled the companies in controversy.

Over the last 25 years, a parade of technologies has promised to transform drug development: genetic engineering, rational drug design, combinatorial chemistry, improved screening—and now, genomics.

Yet the time spent to develop a drug, not counting the months consumed by government review, has lengthened to more than 11 years from about 9 years in the 1980's, according to the Tufts Center for the Study of Drug Development, and the

cost has more than doubled, after adjusting for inflation, to $800 million. Critics, who note that the Tufts Center gets money from drug companies, say those figures are inflated to justify high drug costs.

Still, the industry's failure rate, a big part of its costs, has not declined. Only one in about 5,000 early drug candidates and only one in five drugs that enter clinical trials ever make it to market, experts say. The remainder drop out because they do not work or are toxic.

"The odds are just dreadful, and they seem to be getting worse," Julie A. Olson, a vice president for licensing at *Pfizer,* told a recent biotechnology conference.

Some executives say that given the long development period, genomics and some other technologies are too new to have made a difference. Recent increases in research spending should lead to more drugs 10 years from now, they say.

"We're beginning to tackle all sorts of diseases we couldn't before," said Dr. Goran Ando, head of research and development at *Pharmacia* in Peapack, N.J. But, he added, "it won't happen overnight."

To be sure, looking at just the number of drugs getting to market can be misleading because the companies are producing better-selling drugs. C. Anthony Butler, an analyst at *Lehman Brothers,* said the industry's pipeline in 1995 contained 450 drugs, of which he projected that only 15 would have peak annual sales exceeding $800 million. In 2001, he said, the pipeline had about the same number of drugs but 92 of them were potential $800 million products.

Maintaining that pace, however, will not be easy. "In some ways the easy drugs have been done," said Dr. Robert H. Rubin, a professor of health sciences and technology and of medicine at Harvard.

Drug development is a cumbersome process. Companies usually start by identifying a target, often a protein in the body that is thought to play a role in some disease. Then they try to either design or find a compound that can attach itself to the target protein, thereby changing the course of the disease. They must make sure the compound is otherwise suitable—that it can be made into a pill, for example. It is then tested in animals for toxicity. Only then can it be tested on humans.

Technology has helped with the early part of the process, the discovery of compounds, but not as much with the costliest and most time-consuming portion of drug development—clinical trials. Scientists still cannot tell whether a drug will work or be toxic until they test it. "The slowest parts of drug discovery and development are pretty much the same," said Peter S. Kim, the executive vice president for research and development at Merck.

But even in the early part of drug development there has been disappointment. In the 1990's, a new technology called combinatorial chemistry allowed companies to create hundreds of thousands of compounds by mixing chemical building blocks in different combinations. Drug makers then developed robots to screen this wealth of compounds.

But many of the compounds created this way lacked characteristics that would make them suitable for use as drugs.

Still, there has been progress. Bristol-Myers, for example, increased the number of compounds coming out of its early discovery stage to 14 a year late in the 1990's from 6 a year early in the decade after spending $50 million to install an advanced "screen machine."

The newest technology, genomics, could increase the number of targets in much the way combinatorial chemistry increased the number of chemicals. Until now, virtually all drugs have been directed at an estimated 500 proteins in the body. But by sifting through the human genome, companies are finding thousands of genes that produce previously unknown proteins that might be involved in the disease.

In the long run, that is expected to open vast horizons, and perhaps even let companies reduce failure rates in animal testing and in clinical trials by enabling them to predict toxicity and effectiveness by studying how a drug affects genes. But in the short run, it has left the industry inundated with targets and data that may increase the failure rate by leading companies to start trials before they fully understand what the new data are telling them.

As Jerry Karabelas, a former head of pharmaceuticals at Novartis, once put it: "Data, data everywhere, and not a drug, I think."

To bolster their output in the meantime, big drug companies are turning to biotechnology companies for products and technology, typically spending about 30 percent of their research budgets on outside collaborations. There can be fierce bidding and rising prices for drugs that are close to reaching market, raising the risks for drug companies. Last fall, Bristol-Myers agreed to pay $2 billion to *ImClone Systems* for an ownership stake and the rights to market a cancer drug. But approval of the drug has since been delayed.

By contrast, some analysts and executives say, the drug companies are becoming more cautious about paying for basic technology because they are disappointed that what they have acquired so far has not led to more drugs.

Some analysts say the drug industry is undergoing a transition similar to the computer industry's move from vertical integration, exemplified by I.B.M., to a horizontal structure—with Intel making chips, Microsoft making software and others specializing in manufacturing or sales. Drug companies, these analysts say, will increasingly become the marketers and coordinators of work done by others.

"We think the old model of having everything under your own roof, a completely integrated monolithic organization, is not feasible," said Pradip K. Banerjee, a partner at *Accenture,* the consulting company.

Because biotechnology companies are smaller and more focused, they can often move faster than the big drug companies. *Vertex Pharmaceuticals,* based in Cambridge, Mass., said it spent about $50 million on each of seven drugs to get them into the second phase of clinical trials, a fraction of the usual costs. Joshua S. Boger, the chief executive of Vertex, said his biotechnology company was organized from scratch to take advantage of new technologies. If new technology is just put into the existing process, "you're just going to move the bottleneck to another place," he said.

But as biotechnology companies have moved from making well-known compounds like insulin to more complex challenges, many of them are experiencing failures in clinical trials or at the Food and Drug Administration. *Amgen,* the largest biotechology company, went 10 years without a new drug until last year. It is now growing by using the tactics of bigger drug companies—introducing improved versions of its drugs and buying another company, in its case *Immunex.*

In any case, executives say they had little choice but to try new technology. "Had we not had these technologies," said Dr. Douglas of Aventis, "I think the situation would have been much worse."

Senator WYDEN. And in addition to that drug company statement, of course, the seniors are having increasing problems with paying for other medicine.

Now, in my view, a drug company that produces a miracle cure is like a goose who lays a golden egg, and obviously the companies are saying that they're not laying as many golden eggs these days. With fewer of these golden eggs and consumers unable to afford many of their medicines now, these are important hearings, because Congress should look, in effect, at whether the goose is the problem or the problem is the law that is supposed to provide the nourishment. We're going to have to find a way to strike a balance here, protect consumer rights, and speed these new cures to market. That's why these hearings are important. Mr. Chairman, I'm glad you're holding them.

Senator DORGAN. Senator Wyden, thank you. Senator Carnahan?

STATEMENT OF HON. JEAN CARNAHAN, U.S. SENATOR FROM MISSOURI

Senator CARNAHAN. Thank you, Mr. Chairman.

It will come as no surprise to anyone here that the number one issue that I hear about from Missouri seniors is the high cost of prescription drugs. Missouri seniors are struggling daily to afford their prescriptions and medications while making ends meet on a fixed income. I had one man come up to me just this weekend right after I spoke. He said, "I am HIV positive. It costs me $3,000 a month for my medication."

This picture is—something is wrong in this picture when people like this and people who are seniors all over this country have to make tough choices about how to pay for life-saving medications and also meet the other expenses in their lives. These are choices that no one should have to make.

Let me contrast that image with another one. Earlier this month, Fortune Magazine did a comparison of U.S. industries to see how profitable they were in the past year. Do you know which ranked first in all three of Fortune's profitability measures? That's right, it was the pharmaceutical companies. I agree that federal policy should not hamper investments in research and development of new pharmaceuticals; however, when seniors cannot afford food because of the price of prescription drugs, and when Missouri's Medicaid program is seeing increases of 14 percent for prescription drug spending, and when the average price for the 50 most prescribed drugs for seniors rose at over the twice the rate of inflation last year, and when the rate for private health-insurance plans rose over 20 percent last year, something needs to be changed. Something needs to be changed soon.

Congress needs to pass a comprehensive Medicare prescription drug benefit. I supported setting aside sufficient funding in the budget to create a meaningful, affordable, and voluntary senior prescription drug benefit for all seniors, and I will continue to push the Senate to enact that benefit this year.

While supporting a Medicare drug benefit will continue to be one of my top priorities, I believe there are complementary steps that can be taken to address the prescription drug crisis. Reforms should include two other essential pieces: lowering the price of drugs and preventing the need for medications in the first place. These additional measures will help to improve seniors' health, lower the overall cost of prescription drugs, and decrease the need for drug usage.

To accomplish these goals, I want to announce my support for two important pieces of legislation. The first bill addresses the topic of today's hearing, reforming the 1984 law referred to as the Hatch-Waxman Act. I plan to cosponsor the Greater Access to Pharmaceuticals Act, because it will help us improve competition in the marketplace between generics and brand-name drugs. There are loopholes in the current law preventing generics from entering the market. This bill will make a significant difference in lowering the cost of prescription drugs for consumers.

The average price for a brand-name drug is approximately three times the price of a generic. Missourians are outraged, and rightly so, when they hear of the maneuvers used to prevent generics from coming on the market. They are even further outraged when a drug company cuts a deal with a generic manufacturer to keep a generic off the market. These tactics are not only abusive, they erode the faith of our citizens in our legal and healthcare system.

The second bill is the Medicare Medical Nutrition Therapy Amendment Act, which would extend Medicare coverage of nutrition therapy services to individuals with cardiovascular diseases.

Mr. Chairman, I want to thank you for calling this hearing today. It focuses on a timely matter that has the potential to make a real difference in millions of lives of Americans, and I encourage the Senate to move forward on a Medicare prescription drug benefit, the Greater Access to Pharmaceuticals Act, and the Medicare Medical Nutrition Therapy Amendment Act this year. Thank you very much.

Senator DORGAN. Senator Carnahan, thank you very much.

I mentioned when we started that I'm going to be holding a series of three hearings on the subject of prescription drug prices. I recognize there's been a great deal of interest by virtually all of us in the Congress to attach some kind of prescription drug benefit to the Medicare program. I also believe if we don't put some downward pressure on prescription drug prices, and just attach a prescription drug benefit to Medicare, doing so will just break the bank. So we have to evaluate what can we do about prices. You can't have double-digit—in last year's case, 17 percent—increases in costs every year.

And the next hearing will be about reimportation. A group of us will announce tomorrow a new piece of legislation we shall introduce with respect to reimportation of prescription drugs. And then we'll have a third hearing, as well, on pricing.

Let me ask, if I can—I'm going to ask Senator Schumer to testify, but I want, at the same time, to call to the table the Honorable Timothy Muris, the Chairman of the Federal Trade Commission, and the Honorable Jeanne Shaheen, Governor of the State of New Hampshire. If you would come to the table, then I'm going to ask Senator Schumer to present his testimony. I will ask Governor Shaheen to present her testimony and the Chairman of the Federal Trade Commission to present his testimony.

That will represent the first panel. Then we will go to Panel II. We have a cloture vote today, I believe at 11:30, on the floor of the Senate, and I expect this hearing will take some time.

So let me ask Senator Schumer, why don't you continue with your testimony? Your entire statement will be made a part of the permanent record, and you may summarize.

STATEMENT OF HON. CHARLES SCHUMER,
U.S. SENATOR FROM NEW YORK

Senator SCHUMER. Well, thank you. And, first, let me thank you, Mr. Chairman, for holding this hearing. I want to thank Chairman Hollings, as well, who has shown great interest, and, of course, my colleague and cosponsor of our legislation, Senator McCain, who has had such success in taking on special interests that get in the way of what people want. And let's hope we can repeat that success here. And I want to thank you, Mr. Chairman. Your leadership on this issue has been enormous. And the fact that you are really the first to hold a hearing on this issue shows your commitment.

I agree with you, we have to very much—I'm all for getting prescription drugs added to Medicare and other plans. That's our first priority. But you're right, if we don't bring the price down, it is going to break the bank. And, therefore, doing generic drugs, which helps people of all ages but will reduce government costs now and even more in the future, is an important part of that.

I also want to thank my colleague, Senator Wyden. He's been talking about this issue since when we came to the Congress together in 1980, and thank him for his leadership here, as well as Senator Carnahan, who has really emerged in a short time as one of the true leaders in our entire Senate on bringing the costs of drugs down, and prescription drugs to senior citizens as part of Medicare, and I thank you for your cosponsorship of our measure today.

Now, let me just say that I hope that this hearing is a first step in bringing this legislation to fruition and to law. And, as I say, it goes side by side with other pieces of legislation to bring prices down and would make it easier for us to enact a prescription drug plan as part of Medicare.

An ad in the Washington Post yesterday, paid for by the pharmaceutical industry, reported that 75 percent of all physicians agree that patent laws are very important to the future of America's medicines. Well, I'm not a doctor, much to the chagrin of my mother——

[Laughter.]

Senator SCHUMER.—but I couldn't agree more. Continued innovation in pharmaceutical development is key to ensuring that patients have access to life-saving drugs when we need them, and everyone of us knows somebody whose life is much better because they have access and they have been given these drugs.

But the PhRMA ad only tells part of the story. It implies that patent laws were put in place to benefit consumers solely by protecting innovation. That's one important part, but there's a flip side. Our patent laws aren't just meant to stimulate innovation. They're also intended to bring scientific knowledge into the public domain, to eventually spur competition and keep the drug companies from holding a never-ending monopoly over the heads of consumers. There are two sides to it. And there's always been a balance. I believe that balance has been shifted out of whack.

In the world of the drug industry right now, brand companies are extending their monopolies long beyond what was ever envisioned, much to the detriment of consumers. These companies—we know what's happening. They've had record profitability, as both Senator Carnahan and Senator Dorgan have mentioned. And all of a sudden, lots of their prized drugs are coming off patent, and yet they don't have new ones that they think are going to be just as profitable. And so they're desperate, and they've been finding ways around the 1984 Hatch-Waxman law. Not having new blockbuster drugs, they want to extend the patents of the old ones, which does nothing to benefit consumers. Absolute nothing.

They're trying other things, as well—the advertising: we never saw a prescription drug advertised on an NFL football game 5 years ago. We do now. It's still, for the love of me—that may be another topic of another hearing, but, for the love of me, if we have prescriptions, why are we advertising to consumers? Want to get rid of prescriptions? Advertise to consumers. But if you have prescriptions—it's sort of a contradiction.

But the pharmaceutical industries are doing a number of things to try and keep that profitability high, when the best way they can do that is develop new drugs. And if they can't, well, we have to—they've got to try a little harder.

Now, there are a number of loopholes in the patent law, Mr. Chairman, which drug companies exploit every day to block their low-cost competitors from breaking into the marketplace. Take, for example, Paxil, a drug with $2.1 billion in sales used to treat obsessive-compulsive disorder. Glaxo-Smith-Kline sued the first generic applicant, Apotex, in 1998 over a patent intended to expire in 2006. This move automatically delayed competition for 30

months and has continued to prevent competition while the litigation is ongoing. Even if companies come to resolution on this patent, Glaxo has listed nine additional patents on this same drug, which already has a patent, during the intervening years since the first lawsuit began—patents on slightly different chemical substances, which have never been approved for marketing by the FDA, but which the company claims are relevant to Paxil, as well as patents on different formulations on these drugs. The last of the patents expires in 2021.

It's getting to the point where they're going to file for a 30-month automatic extension by changing the color of the pill from blue to red or changing it from a capsule to a tablet. The law is being perverted.

And most of these new patents, of course, will, and already have, invoked additional multiple 30-month stays which, as you all know, is automatic, against generic competition for Paxil. Each year generic competition is delayed costs consumers, on this one drug, $500 million.

What happened here is simple. The drug company saw its original patents about to expire and then created new ones to maintain its control over the market. They didn't create a new drug which would have brought new benefits. Instead, they just tried to create a new patent.

These kinds of practices have unfortunately now become the norm for the drug industry. These companies figure out a new way to keep dollars rolling in, and they're stooping to new lows every day to maintain exclusivity rights.

I've just learned the latest low blow that big pharmaceutical companies are stooping to do to block the entry of low-cost generic drugs. They have now begun to seek patents on information related to safety. The FDA has long determined that safety information should be part of the public record, and it shouldn't prevent generic versions of approved drugs from coming to the market. But now, in the case of the pain medication, Ultram, five generic versions of it were about to be approved in January of this year. But in February, Ortho-McNeil filed a patent on a slightly altered dosing schedule, a schedule which is obvious to most pharmacists, but one which they claim is essential to the safety of the drug. Under Hatch-Waxman, patenting this information would, at the very least, automatically keep the generic drug off the market for 30 months. If the patent's upheld in the courts, it prevents competition until 2019. With sales of $690 million a year, these delays cost consumers $3 million a week.

Prescription drug expenditures are throwing insurers, corporations, and State Medicaid agencies into a tailspin as they attempt to craft high-quality healthcare benefits that are within the realm of affordability. The bill that Senator McCain and I have introduced has the support of the UAW and General Motors as well as a long list of other groups; the problem is getting as great as it is. What's happening is, the pharmaceutical industry, when they do this, are crippling consumers and seniors who can't afford to purchase their drugs or take them every day as prescribed.

I agree that patent protection is key to saving lives. But I'm sure the doctors surveyed by PhRMA would also agree that a drug can

do no good if it's financially out of the reach of patients who depend on it. So with this in mind, I want to be clear about what Senator McCain's legislation and mine is not about. It's not about robbing pharmaceutical companies of legitimate patent protection. It's not about theft of innovation, and it's not about taking steps to enact laws that are not in the best interests of consumers. In fact, it's just the opposite. It's about examining competition in today's marketplace and revisiting a compromise which was struck nearly 18 years ago, but is now out of balance.

In 1984, Hatch-Waxman was one of the least appreciated and most pro-consumer laws passed in the Congress in the last two decades. Hatch-Waxman saved billions of dollars on pharmaceuticals while helping brand-name companies to stay profitable and innovative. And as a result, generic drugs have captured over 44 percent of the market in terms of prescriptions written. Pharmaceutical research and development since Hatch-Waxman has increased sevenfold, from $4.1 billion to $26.4 billion. Pharmaceutical industry has once again topped the Fortune 500 list of most profitable industries.

But in recent years, Mr. Chairman, as the profits and stakes have become higher, drug industry lawyers have picked the Hatch-Waxman law clean. Companies are pursuing these aggressive extended monopolies through filing weaker, invalid patents and engaging in deals which the FTC is increasingly scrutinizing for anticompetitive practices. We have to put an end to these abuses.

Just one other drug I want to mention. Prozac went off patent. One year, it's saving—the generic is out—$1.8 billion is being saved by consumers this year—same amount of Prozac, probably a little more, but at a much lower cost.

So I would urge you to look, Mr. Chairman, at the Greater Access to Pharmaceuticals, or GAP, Act that seeks to breathe new life into Hatch-Waxman, not by redrawing ideological battle lines but by restoring the intent of our patent law. Our intention is not to cutoff innovators at the knees, it isn't a freebie for the generic drug industry. We come down on the generic companies that make these deals to prevent the generic from coming to market. It's pro-consumer. That's what we're trying to do here.

And I have other cases here, which I'd like to put in the record. I know you're trying to hurry things along. But I just hope, Mr. Chairman, that we can consider this legislation or generic drug legislation of some type, because we desperately need it as drugs become more expensive but more necessary to so many American families.

Thank you.

Senator DORGAN. Senator Schumer, thank you very much for your testimony.

Next we will hear from Governor Shaheen. Governor, your entire statement will made a part of the record and you may summarize. Thank you for being here.

STATEMENT OF HON. JEANNE SHAHEEN,
GOVERNOR, STATE OF NEW HAMPSHIRE

Governor SHAHEEN. Thank you, Mr. Chairman and Members of the Committee. I appreciate the opportunity to appear before you

this morning and certainly appreciate the efforts of Senator Schumer and Senator McCain to move us in a direction that closes the loopholes in the Hatch-Waxman Act.

As Senator Carnahan pointed out, the high cost of prescription drugs is a huge issue for seniors in New Hampshire, as well. I was at a forum in our state's largest city recently where a man stood up and said that he was over 80 and that he had to take a job as a janitor cleaning toilets in order to afford medication for himself and his wife. That should not happen.

But more importantly, it is also an issue for business in this country. And as I go around the state, the issue that I hear more than any other from businesses in New Hampshire is that they can't afford the increasing costs of premiums to cover healthcare for their employees.

It's also an issue, as you all know, for states as we try and provide Medicaid coverage for our citizens. In 1996, the year that I was elected Governor in New Hampshire, the state spent $41.7 million on prescription drugs. In 2001, the state spent $88 million on prescription drugs for our Medicaid program.

We've been working to contain those costs. We have a very comprehensive pharmacy benefits management program in New Hampshire, one that we entered into with Vermont and Maine, but we need your help. We need your help in closing those loopholes that force businesses, families, and seniors to spend millions more than they should on brand-name drugs.

There are 17 drugs that are used in Medicaid programs throughout the country whose patents are due to expire in the next 3 years. Those 17 drugs cost 46 states' Medicaid programs $1.2 billion in 2001. If we could see competition from lower-cost generic drugs, we could see an average savings of 50 percent on those drugs. In New Hampshire alone last year, we spent $4.9 million on 15 of those 17 drugs in our Medicaid program. If those patents expire on time, we could save $2.4 million a year.

Now, that doesn't sound like a lot for those of you from big states. But let me tell you what that $2.4 million could buy us in coverage to improve the health of the citizens of New Hampshire. We could provide prenatal and post-birth visits for 3,437 new babies and their mothers. We could provide dental coverage, something that is very difficult to cover through the Medicaid program, for 8,723 children. We could provide well child checkups for 44,642 children. And we could give Meals on Wheels to seniors 5 days a week to 59,524 seniors. It would make a huge difference in our ability to provide healthcare for the people of New Hampshire.

Now, in an effort to address concerns about the loopholes in the Hatch-Waxman Act, I have joined a coalition of Governors, of businesses and labor called Business for Affordable Medicine. The 17 drugs that I mentioned earlier are costing the ten businesses that are part of BAM $132 million a year.

I certainly, as I heard Senator Schumer say, support the original intent of the Hatch-Waxman Act. I do believe it's important for us to encourage companies to continue their research and development efforts. I do think it has helped to bring generic drugs into competition. But I think it's currently being undermined by the loopholes that exist.

Prilosec is one of the most popular drugs in our Medicaid program. It costs, at a pharmacy in a small town in New Hampshire—Henniker, New Hampshire—you pay $152 a month for Prilosec. Senator Dorgan and I know that, in our states which border Canada, our citizens could go across the border and buy that drug for over 50 percent less.

The patent on Prilosec was supposed to expire in October of last year, but they sued their generic competitor and triggered that automatic 30-month extension. In the 6-months since Prilosec was supposed to expire, New Hampshire has spent over $600,000 on just that one drug through our Medicaid program.

There has been some concern raised by the pharmaceutical industry that if changes were made in Hatch-Waxman, that we would see less research. In fact, a report by the Kaiser Family Foundation indicated that between 1990 and 2000, the pharmaceutical industry spent twice as much on marketing and administration as they did on research and development. I don't believe we would see a decrease in research and development. I would see that the original intent of the act, which was to encourage research and development, is what would happen if, in fact, they were required to focus on research and bringing forward new drugs rather than being allowed to extend their patents in ways that weren't imagined by the original act.

It's very clear that the drug companies have been benefiting from the loopholes in the Hatch-Waxman Act. Unfortunately, the taxpayers, the families, the seniors, the businesses who need healthcare coverage have not. I urge this Committee to carefully consider ways to address these loopholes and provide better access to prescription drugs at an affordable cost for the people of my state, New Hampshire, and the country.

Thank you.

[The prepared statement of Governor Shaheen follows:]

PREPARED STATEMENT OF JEANNE SHAHEEN,
GOVERNOR, STATE OF NEW HAMPSHIRE

Thank you, Mr. Chairman. I am Jeanne Shaheen, Governor of the State of New Hampshire. I appreciate this opportunity to appear before you, and I am honored to be on this panel with Federal Trade Commission Chairman Timothy Muris. I want to thank you for devoting so much time to the issue before us today. Few other issues can rival the skyrocketing cost of prescription drugs in terms of its impact on the health of our families, the bottom line of our businesses, and the solvency of state budgets.

Today I am here to testify about how the skyrocketing cost of prescription drugs is making it increasingly difficult for governors to provide high quality Medicaid coverage to children, seniors and people with disabilities without breaking the backs of taxpayers.

In 1996, New Hampshire spent $41.7 million on prescription drugs as part of our Medicaid program. In fiscal year 2001, New Hampshire spent $88 million. We cannot afford that type of continued growth in our Medicaid prescription drug costs. Like other governors across the country, I am working to address the high cost of prescription drugs in a number of ways, including a comprehensive pharmacy benefits management program, which, as you might expect, is opposed by the PhRMA.

Governors need your help in this effort. The loopholes in the Hatch-Waxman Act are forcing state governments, seniors, and businesses to spend hundreds of millions of dollars unnecessarily on brand name prescription drugs.

There are 17 drugs that are supposed to go off patent in the next two and a half years. State Medicaid agencies across the country spent more than $1.2 billion last

year on those 17 drugs alone.[1] Under the original intent of the Hatch-Waxman Act, states should expect to save an average of 50 percent on these 17 drugs as lower-cost alternatives become available after patents expire.[2]

Last year, New Hampshire's Medicaid program spent over $4.9 million on 15 brand name drugs that face patent expiration between April 2002 and December 2004. If we see timely market competition on those 15 medications, a small state like mine, New Hampshire, could save an estimated $2.5 million annually in Medicaid prescription drug costs by 2005.

I know that $2.5 million might not seem like a lot of money to those of you who represent big states. But in New Hampshire $2.5 million would make a big difference for our taxpayers and the children, seniors and other vulnerable citizens who depend on state services. For example, with $2.5 million, the state of New Hampshire could provide pre-natal and post birth home visits for 3,437 new babies and their mothers, dental coverage to 8,723 kids, check-ups for 44,642 children, or 59,524 seniors with meals 5 days a week through Meals on Wheels.

That's why I am part of the Business for Affordable Medicine Coalition. This is a coalition of businesses, labor unions, and governors, both Democrats and Republicans[3] that has come together over the last several months. BAM's principle focus is to prevail upon Congress to close the loopholes in the Hatch-Waxman Act.

Like governors who are trying to identify healthcare cost savings at a time when budgets are extremely tight, businesses that provide health coverage to their workers are anxious to have full access to lower-cost generic alternatives as soon as brand patents expire. Last year the corporate members of BAM alone spent more than $132 million on the 17 brand name drugs that face patent expiration before 2004.

I am very supportive of intellectual property rights. I support the original purpose of the 1984 Hatch-Waxman Act, which was designed both to promote the growth of a generic drug industry and provide additional patent protection for research-based brand-name drugs. However, the Act has been seriously undermined by loopholes that have allowed brand-name drug makers to delay competition from lower-cost alternatives for years.

For example, the patent for Prilosec, which is one of the most popular drugs in America, expired last October. A 1-month supply of Prilosec costs a senior $152 at a drugstore in Henniker, New Hampshire. It's now been seven months since the patent on Prilosec expired, but there's still no generic on the market because, AstraZeneca, the company that makes Prilosec, followed the now all too common strategy of brand-name manufacturers—it sued its generic competitor, triggering an automatic 30-month stay on the FDA's approval of the generic. Meanwhile, AstraZeneca is using its marketing prowess to quickly get Prilosec users to switch over to another drug it makes, Nexium. And my state Medicaid program has spent over $600,000 on Prilosec since its patent expired.

I know you will hear from PhRMA and the big drug companies that if Hatch-Waxman is reformed, there will be less innovation, less research and development of new drugs. However, according to the Kaiser Family Foundation, brand-name drug companies spent more than twice as much on advertising, marketing and administration as they did on research and development in every year from 1990 through 2000.[4]

Let me be clear that I am not here today as a cheerleader for the generic drug industry. Unfortunately, there is increasing evidence that some generic companies engage in collusion with brand name companies to take advantage of Hatch-Waxman loopholes for their mutual benefit and successfully delay entry of lower-priced generic products.

Brand name drug companies and many generic companies are doing quite well under the current Hatch-Waxman Act. State taxpayers, seniors and businesses are not.

I encourage this Committee and all of Congress to act this year to stop the anti-competitive practices that result from loopholes in the Hatch-Waxman Act.

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[1] State Medicaid Survey, Business for Affordable Medicine, January 2002. Every state except for four, Arizona, Kentucky, Michigan, and Rhode Island, participated.

[2] Generic drugs save consumers an estimated 30 to 70 percent. The U.S. Food and Drug Administration, Center for Drug Evaluation and Research, February 21, 1997.

[3] Alabama Governor Don Siegelman, Alaska Governor Tony Knowles, Hawaii Governor Benjamin Cayetano, Louisiana Governor Mike Foster, Missouri Governor Bob Holden, New Hampshire Governor Jeanne Shaheen, South Dakota Governor William Janklow, Vermont Governor Howard Dean, M.D., Washington Governor Gary Locke, West Virginia Governor Bob Wise.

[4] *Prescription Drug Trends,* The Henry J. Kaiser Family Foundation, November 2001.

New Hampshire Prescription Drug Costs

Scheduled Patent Expiration	Drug	Indication	FY 2001 Expenditures	Generic Savings 50%
2002				
April	Axid	Gastrointestinal	$ 173,197.07	$ 86,598.54
June	Claritin	Allergy	$ 973,089.42	$ 486,544.71
December	Augmentin	Infection	$ 594,320.09	$ 297,160.05
December	Intron A	Hepatitis-C	$ 14,307.19	$ 7,153.60
December	Relaten	Arthritis	$ 147,625.44	$ 73,812.72
				$ -
2003				$ -
February	Singulair	Asthma	$ 320,739.27	$ 160,369.64
November	Flovent	Asthma	$ 562,797.67	$ 281,398.84
November	Flonase	Allergy	$ 213,730.82	$ 106,865.41
November	Cipro	Infection	$ 379,390.24	$ 189,695.12
December	Energix-B	Hepatitis-B	$ 11,929.44	$ 5,964.72
				$ -
2004				$ -
January	Diflucan	Infection	$ 82,901.13	$ 41,450.57
July	Lamisil	Tenia Pedis	$ 89,420.70	$ 44,710.35
August	Wellbutrin SR	Depression	$ 988,643.22	$ 494,321.61
October	Lupron	Cancer	$ 175,159.37	$ 87,579.69
December	Lovenonx	Deep Vein Thrombosis	$ 239,828.16	$ 119,914.08
				$ -
		Total	**$ 4,967,079.23**	**$ 2,483,539.62**

[1]The U.S. Food and Drug Administration estimates that generic drugs save consumers 30 to 70%. Center for Drug Evaluation and Research, February 1997.

Business for Affordable Medicine
1620 L Street NW, Suite 1210 • Washington, D.C. 20036
Phone: 202-966-0440 • Fax: 202-966-3336

State Medicaid Spending Levels (2001)

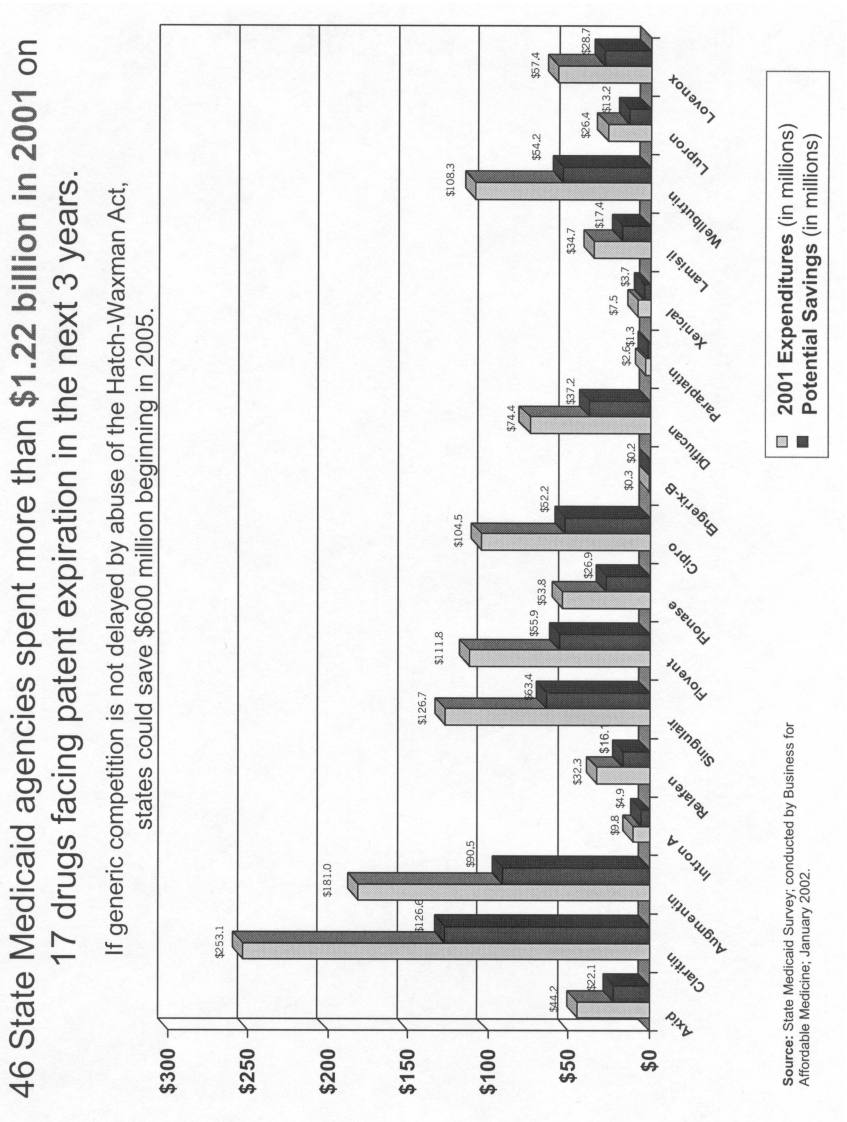
Name:	Stefanie Johnson
Title:	Senior Management Analyst
State:	New Hampshire
Phone:	603/271-4295
Email:	sjohnson@dhhs.state.nh.us
Number of state residents eligible for Medicaid in 2001:	Average Monthly enrollment for SFY 2001is 82,488

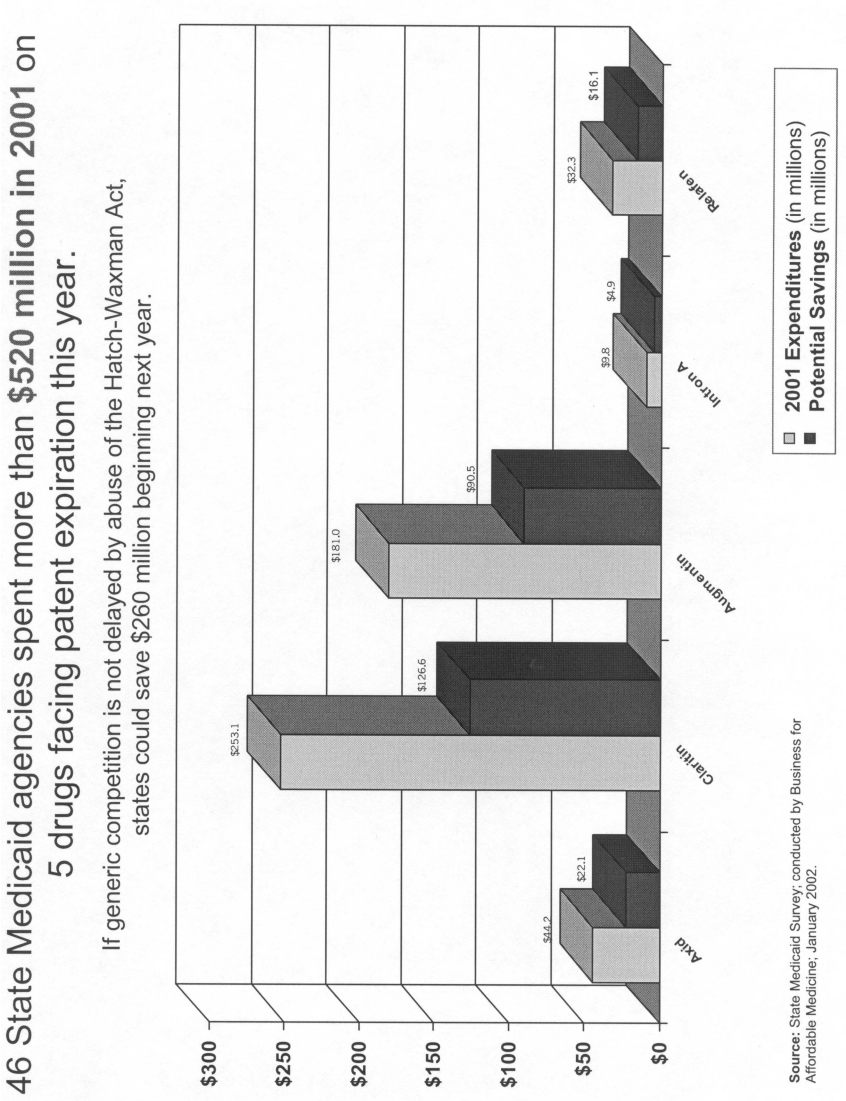
Patent Expiration Date	Drug	Indication	2001 Expenditures	
2002			State Fiscal Year (7/1/00-6/30/01)	
April	Axid	Gastrointestinal	$	173,197.07
June	Claritin	Allergy	$	973,089.42
December	Augmentin	Infection	$	594,320.09
December	Intron A*	Hepatitis-C	$	14,307.19
December	Relaten	Arthritis	$	147,625.44
2003				
February	Singulair	Asthma	$	320,739.27
November	Flovent	Asthma	$	562,797.67
November	Flonase	Allergy	$	213,730.82
November	Cipro	Infection	$	379,390.24
December	Engerix-B*	Hepatitis-B	$	11,929.44
2004				
January	Diflucan	Infection		$82,901.13
April	Paraplatin***	Cancer	N/A	
June	Xenicial	Obesity	Not Covered during this time	
July	Lamisil	Tenia Pedis	$	89,420.70
August	Wellbutrin SR**	Depression	$	988,643.22
October	Lupron*	Cancer	$	175,159.37
December	Lovenox*	Deep Vein Thrombosis	$	239,828.16
		Total Expenditures	$	4,967,079.23

*Rough estimate as these drugs are not always paid by NDC and are not always specific to pharmacy claims

** Only Wellbutrin Sustained Release (SR) is still under patent.

***Billed through Oncology offices and Hopitals


46 State Medicaid agencies spent more than $1.22 billion in 2001 on 17 drugs facing patent expiration in the next 3 years.
If generic competition is not delayed by abuse of the Hatch-Waxman Act, states could save $600 million beginning in 2005.
$300
$250
$200
$150
$100
$50
$0
Axid
Claritin
Augmentin
Intron A
Relafen
Singulair
Floxent
Flonase
Cipro
Engerix-B
Diflucan
Paraplatin
Xenical
Lamisil
Wellbutrin
Lupron
Lovenox
$44.2
$22.1
$253.1
$126.4
$181.0
$90.5
$9.8
$4.9
$32.3
$16.1
$126.7
$63.4
$111.8
$55.9
$53.8
$26.9
$104.5
$52.2
$0.3
$0.2
$74.4
$37.2
$2.6
$1.3
$7.5
$3.7
$34.7
$17.4
$108.3
$54.2
$26.4
$13.2
$57.4
$28.7
2001 Expenditures (in millions)
Potential Savings (in millions)
Source: State Medicaid Survey; conducted by Business for Affordable Medicine; January 2002.



Senator DORGAN. Governor Shaheen, thank you very much for your testimony. Next we will hear from the Chairman of the Federal Trade Commission, Mr. Muris. Mr. Chairman?

STATEMENT OF HON. TIMOTHY MURIS, CHAIRMAN, FEDERAL TRADE COMMISSION

Mr. MURIS. Thank you very much, Senator. This is an important subject, and I am pleased to be here to testify today on behalf of the Commission regarding competition in pharmaceuticals. As others have stated, it's clear that the innovations in pharmaceuticals

are providing more and more benefits to consumers, but it's also clear that the costs are exploding.

The Hatch-Waxman Act represented a compromise. To a large degree, the law has succeeded. By purchasing generics, consumers have saved billions. Many branded drugs are set to have their patents expire in the next 4 years. There should be an increase in the substantial savings.

Because of the significance of pharmaceutical expenditures, the Commission has been very active in this area. We have investigated abuses of the Hatch-Waxman amendments to delay generic entry. We also identify and analyze and report on a wide range of competition issues, including in the pharmaceutical area.

In terms of law enforcement, we have what I refer to as two categories of cases. The first generation of cases involves agreements between makers of brand-name drugs and generic drugs. In essence, the branded company pays the generic company not to compete. The Commission has brought three such cases. Part of one is currently in litigation. We settled part of that litigation very recently with American Home Products. Under the Commission's order, American Home Products cannot enter agreements in which the branded manufacturer pays the generic for delayed entry, or in which the generic agrees not to enter with a non-infringing product. This settlement is very similar to one that we achieved involving Abbott and Geneva in 2000 and a settlement with Hoechst and Andrx in 2001.

The second generation involves unilateral action by branded manufacturers to delay generic competition. For example, as has been described here this morning, some branded firms list additional patents with the FDA in Orange Book, often shortly before the original patents expire. These branded manufacturers then launch patent infringement suits against firms that are poised to enter the market. Under Hatch-Waxman, such litigation triggers an automatic 30-month stay.

I'm pleased to announce today the Commission's first enforcement action in this area, a settlement with Biovail Corporation. The complaint alleges that Biovail unlawfully acquired an exclusive patent license to protect its monopoly in the market for Tiazac and generic versions of Tiazac. This is a drug that's used to treat high blood pressure and chronic chest pain. The acquired license was for a patent on a unique formulation of the active ingredient in the drug. We also allege that Biovail maintained its monopoly by wrongfully listing the acquired patent in the Orange Book and making misleading statements to the FDA.

To resolve these charges, Biovail must divest part of its exclusive patent rights. The order also prohibits Biovail from wrongfully listing any patents in the Orange Book. It prevents any action by Biovail that would trigger a statutory stay on generic entry, and it also requires Biovail to notify us prior to acquiring patents that will be listed in the Orange Book.

Through an amicus brief, we also helped achieve an important result in another Orange Book listing case, this one involving Bristol-Meyers. In February, a federal district court judge ruled that listings in the Orange Book were not petitions to the government. This is an extremely important ruling, because if Orange Book list-

ings are petitions, they could be exempt from antitrust under the Noerr-Pennington Doctrine, which is an issue of longstanding interest to me.

Finally, to complement our law enforcement, we are studying competition in the sale of prescription drugs and the impact of generic competition under the Hatch-Waxman Act. We're examining the business relationships between brand name and generic drug manufacturers. Last April, 6 months after our request to OMB, we received clearance to conduct the study. Pursuant to Section 6(b) of the Federal Trade Commission Act, the Commission has since issued nearly 90 special orders to branded and generic manufacturers. We did not have the bulk of this compliance until the end of last year. We're compiling the information. We expect that the study will soon be completed with a report detailing its findings.

There are, however, a few tentative observations that are possible based on our initial review of the data. First, some pharmaceutical companies, including both brands and generics, employ potentially anti-competitive strategies involving Paragraph IV certifications. These strategies have evolved following the FTC's announcement of consent orders in the first-generation cases that I mentioned.

Second, the FDA's grant of the 180-day marketing exclusivity provision has increased substantially since the courts eased the rules governing how the FDA grants such exclusivity. Third, interim payment agreements that were used in our two initial first-generation cases appear to be uncommon. Finally, the majority of patents subject to Paragraph IV certifications that result in patent infringement litigation involve formulation and method of use. These are not the patents on the active ingredient contained in the drug product.

We will continue to be very active in protecting consumers from anti-competitive practices that inflate drug prices. Indeed, since my arrival, we've dramatically increased our resources on non-merger healthcare and pharmaceuticals, in particular, but also in other healthcare areas. We look forward to working closely with the Committee, as we have in the past. I want to thank you, on behalf of the Commission, for your support of our work.

[The prepared statement of Mr. Muris follows:]

PREPARED STATEMENT OF TIMOTHY MURIS,
CHAIRMAN, FEDERAL TRADE COMMISSION

I. Introduction

Mr. Chairman, I am Timothy J. Muris, Chairman of the Federal Trade Commission. I am pleased to appear before the Committee today to testify on behalf of the Commission regarding competition 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, which has an impact on the prices of prescription drugs. Likewise, the development of generic drugs also can be risky and costly. Expenditures on pharmaceutical products continue to grow. According to the Employee Benefit Research Institute, such expenditures increased 92 percent over the past five years, to $116.9 billion.[2] Pharmaceutical expenditures are thus a concern not only to individual consumers, but to government payers, private health plans, and employers as well.

To address the issue of escalating drug expenditures, and to ensure that the benefits of pharmaceutical innovation would be available to the broadest group of healthcare consumers possible, Congress passed the Hatch-Waxman Amendments[3] to the Food, Drug and Cosmetic Act ("FDC Act").[4] The Hatch-Waxman Amendments were intended to promote robust competition in the pharmaceutical industry and, to a large degree, have succeeded.[5] The Congressional Budget Office estimates that, by purchasing generic equivalents of brand name drugs, consumers saved $8–10 billion on retail purchases of prescription drugs in 1994 alone.[6] With patents on branded drugs having combined U.S. sales of almost $20 billion set to expire within the next four years,[7] these already substantial savings are likely to increase dramatically.

Yet, in spite of this remarkable record of success, the Hatch-Waxman Amendments have also been subject to abuse. Although many drug manufacturers—including both branded companies and generics—have acted in good faith, some have attempted to "game" the system, securing greater profits for themselves without providing a corresponding benefit to consumers. It is these anticompetitive efforts that the Federal Trade Commission has addressed. The nature of that response, both past and present, is the principal subject of this testimony.

Over time, the Commission has developed significant expertise regarding competition in the pharmaceutical industry. The Commission has, for example, brought antitrust enforcement actions affecting both branded and generic drug manufacturers.[8] The Commission has also conducted empirical analyses of competition in the pharmaceutical industry, including in-depth studies by the staff of the Bureau of Economics.[9] The Commission's efforts have included filing comments with the Food and Drug Administration ("FDA") regarding the competitive aspects of Hatch-Waxman implementation,[10] as well as previous testimony before Congress.[11] Furthermore, individual Commissioners have addressed the subject of pharmaceutical competition before a variety of audiences, both to solicit input from affected parties and to promote dialogue regarding practical solutions.[12]

The subject of this testimony, however, is more limited. This testimony addresses the Commission's efforts to ensure efficient operation of the Hatch-Waxman process directly through vigorous enforcement of the antitrust laws. To date, these efforts principally have entailed litigation relating to settlements between brands and generics alleged to be anticompetitive; this testimony refers to those as "first generation litigation." More recently, the Commission has progressed to "second generation litigation," involving issues such as allegedly improper Orange Book listings. We are also examining potentially anticompetitive settlements between generics themselves. This testimony will also briefly address the Commission's non-litigation efforts, which include an ongoing industry-wide study of pharmaceutical competition, as well as continuing inter-agency discussions with the FDA.

II. Regulatory Background: The Hatch-Waxman Drug Approval Process

A.The Hatch-Waxman Balance

The stated purpose of the Hatch-Waxman Amendments is to "make available more low cost generic drugs."[13] The concern that the FDA's lengthy drug approval process was unduly delaying market entry by low-cost generic versions of brand-name prescription drugs motivated Congress's passage of the Amendments. Because a generic drug manufacturer was required to obtain FDA approval before selling its product, and could not begin the approval process until any conflicting patents on the relevant branded product expired, the FDA approval process essentially functioned to extend the term of the branded manufacturer's patent monopoly. To correct this problem, Congress provided in the Amendments that certain conduct related to obtaining FDA approval, which would otherwise constitute patent infringement, would be exempted from the patent laws.

This limited objective, however, was in no way intended to undermine fundamental intellectual property rights. Congress continued to regard patent protection as critical to pharmaceutical innovation, and as an important priority in its own right. The Hatch-Waxman Amendments thus represented a compromise: an expedited FDA approval process to speed generic entry balanced by additional intellectual property protections to ensure continuing innovation. As one federal appellate judge explained, the Amendments "emerged from Congress's efforts to balance two conflicting policy objectives: to induce brand-name pharmaceutical firms to make the investments necessary to research and develop new drug products, while simultaneously enabling competitors to bring cheaper, generic copies of those drugs to market."[14]

Pursuant to the FDC Act, a branded drug manufacturer seeking to market a new drug product must first obtain FDA approval by filing a New Drug Application ("NDA"). At the time the NDA is filed, the NDA filer must also provide the FDA

with certain categories of information regarding patents that cover the drug that is the subject of its NDA.[15] 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."[16]

Rather than requiring a generic manufacturer to repeat the costly and time-consuming NDA process, the Amendments permit the company to file an Abbreviated New Drug Application ("ANDA"), which incorporates data that the "pioneer" manufacturer has already submitted to the FDA regarding the branded drug's safety and efficacy. The object of the ANDA process is to demonstrate that the generic drug is "bioequivalent" to the relevant branded product.[17] The ANDA must contain, among other things, a certification regarding each patent listed in the Orange Book in conjunction with the relevant NDA.[18] One way to satisfy this requirement is to provide a "Paragraph IV certification," asserting that the patent in question is invalid or not infringed.[19]

Filing a Paragraph IV certification potentially has significant regulatory implications, as it is a prerequisite to operation of two significant provisions of the statute. The first of these is the automatic "30-month stay" protection afforded patents. An ANDA filer that makes a Paragraph IV certification must provide notice, including a detailed statement of the factual and legal basis for the ANDA filer's assertion that the patent is invalid or not infringed, to both the patent holder and the NDA filer.[20] 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.[21] If the patent holder does not bring suit within 45 days, the FDA must approve the ANDA immediately, if other regulatory conditions are fulfilled.[22] If the patent holder does bring suit, however, the filing of that suit triggers an automatic 30-month stay of FDA approval of the ANDA.[23] During this period, unless the patent litigation is resolved in the generic's favor, the generic cannot enter the market.

The second significant component of the Hatch-Waxman Amendments is the "180-day period of exclusivity." The Amendments provide that the first generic manufacturer 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.[24] Through this 180-day provision, the Amendments provide an incentive for companies to challenge patents and develop alternative forms of patented drugs.[25] The 180-day period is calculated from the date of the first commercial marketing of the generic drug product or the date of a court decision declaring the patent invalid or not infringed, whichever is sooner.[26] The 180-day exclusivity period increases the economic incentives for a generic company to be the first to file an ANDA and get to market.[27] Of course, during the 180 days, the generic would compete with the branded product. After the 180 days, subject to regulatory approvals and determination of the outcomes of any patent suits, other generics can enter the market.

B. Competitive Implications

The "30-month stay" and the "180-day period of exclusivity" were both a part of the Hatch-Waxman balance. The imposition of a stay in some cases could forestall generic competition for a substantial period of time. The 180-day period of exclusivity can, in some circumstances, limit the number of generic competitors during this period.[28] Over the past few years we have learned that some branded and generic drug manufacturers have "gamed" the system, attempting to restrict competition beyond what the Hatch-Waxman Amendments intended. This testimony will now discuss our efforts to investigate vigorously and to prosecute such abuses.

III. Promoting Competition through Antitrust Enforcement

A. First Generation FTC Litigation: Settlements Between Brands and Generics

Studies of the pharmaceutical industry indicate that the first generic competitor typically enters the market at a significantly lower price than its branded counterpart, and gains substantial share from the branded product.[29] Subsequent generic entrants typically bring prices down even further.[30] The policies of many health plans, both public and private, which require generic substitution whenever possible, accelerate this trend. These are the consumer benefits of the competition that the Hatch-Waxman Amendments were meant to facilitate. This competition substantially erodes the profits of branded pharmaceutical products. Although successful generics are profitable, their gain is substantially less than the loss of profits by the branded product, because of the difference in prices between branded and generic products. As a result, both parties can have economic incentives to collude to delay generic entry. By blocking entry, the branded manufacturer can preserve its monopoly profits. A portion of these profits, in turn, can be used to fund payments

to the generic manufacturer to induce it to forgo the profits it could have realized by selling its product. Furthermore, by delaying the first generic's entry—and with it, the triggering of the 180 days of exclusivity—the branded and first-filing generic firms can sometimes forestall the entry of other generics. Patent infringement litigation settlement agreements between the branded manufacturer and the first-filing generic could be one method to effect such a collusive scheme.

The Commission's first generation litigation focused on patent settlement agreements between brands and generics that the Commission alleged had delayed the entry of one or more generics. Resolving patent infringement litigation through settlement can be efficient and procompetitive. Certain patent settlements between brands and generics, however, drew the Commission's attention when it appeared that their terms may have maintained monopolies through abuses of the Hatch-Waxman regime.

Two leading cases illustrate the Commission's efforts in the area: *Abbott/Geneva* and *Hoechst/Andrx.* The first of these cases involved an agreement between Abbott Laboratories and Geneva Pharmaceuticals, Inc. relating to Abbott's branded drug Hytrin. The Commission's complaint alleged that Abbott paid Geneva approximately $4.5 million per month to delay the entry of its generic Hytrin product, potentially costing consumers hundreds of millions of dollars a year.[31] The complaint further alleged that Geneva agreed not to enter the market with *any* generic Hytrin product—including a non-infringing product—until: (1) final resolution of the patent infringement litigation involving Geneva's generic Hytrin tablets, or (2) market entry by another generic Hytrin manufacturer. Geneva also allegedly agreed not to transfer its 180-day marketing exclusivity rights.

The second case involved an agreement between Hoechst Marion Roussel and Andrx Corp. relating to Hoechst's branded drug Cardizem CD. The Commission's complaint alleged that Hoechst paid Andrx over $80 million, during the pendency of patent litigation, to refrain from entering the market with its generic Cardizem CD product.[32] As in the *Abbott/Geneva* case, the Commission also asserted that the agreement called for Andrx, as the first ANDA filer, to use its 180-day exclusivity rights to impede entry by other generic competitors.

Both cases were resolved by consent order.[33] The orders prohibited the respondent companies from entering into brand/generic agreements pursuant to which a generic company that is the first ANDA filer with respect to a particular drug agrees not to: (1) enter the market with a non-infringing product, or (2) transfer its 180-day marketing exclusivity rights. In addition, the companies were required to obtain court approval for any agreements made in the context of an interim settlement of a patent infringement action, that provided for payments to the generic to stay off the market, with advance notice to the Commission to allow it time to present its views to the court. Advance notice to the Commission was also required before the respondents could enter into such agreements in non-litigation contexts.

Although the specific terms of the brand/generic settlement agreements challenged by the Commission in these two cases were particular to these cases, the cases highlight the Commission's concern about settlements whose primary effect appears to be to *delay generic entry,* leading to less vigorous competition and higher prices for consumers. Of course, not all settlements are problematic. While the Commission has not attempted to set forth a comprehensive list of potentially objectionable settlement provisions, it is possible to identify from the Commission's reported cases a few types of provisions that, within the Hatch-Waxman context, have drawn antitrust scrutiny. These include:

- *Provisions that provide for "reverse" payments.* "Reverse" payments (*i.e.,* payments from the patent holder to the alleged infringer) may merit antitrust scrutiny, since they may represent an anticompetitive division of monopoly profits.
- *Provisions that restrict the generic's ability to enter with non-infringing products.* Such provisions can extend the boundaries of the patent monopoly without providing any additional public disclosure or incentive to innovate, and therefore have the potential to run afoul of the principles of antitrust law.[34]
- *Provisions that restrict the generic's ability to assign or waive its 180-day marketing exclusivity rights.* Because a second ANDA filer may not enter the market until the first filer's 180-day period of marketing exclusivity has expired, restrictions on assignment or waiver of the exclusivity period can function as a bottleneck, potentially delaying subsequent generic entry for an extended period.[35]

B. Second Generation FTC Litigation: Improper Orange Book Listings

1. *In re Buspirone*

One of the principal focuses of the Commission's second generation litigation has been improper Orange Book listings.[36] Unlike the settlement cases discussed above, which typically involve collusion between private parties, an improper Orange Book listing strategy involves abuse of the Hatch-Waxman process itself to restrain trade. Such conduct has raised *Noerr-Pennington* issues—an area of longstanding Commission interest.

The *Noerr* doctrine—first articulated as an interpretation of the Sherman Act in *Eastern R.R. Presidents Conf. v. Noerr Motor Freight, Inc.*[37] and *United Mine Workers of America v. Pennington*[38]—provides antitrust immunity for individuals "petitioning" government. While the *Noerr* doctrine is an important limitation on the antitrust laws that protects the right of individuals to communicate with government entities, some courts have interpreted the doctrine too broadly in ways that are inconsistent with Supreme Court precedent. The *Noerr* doctrine was never intended to protect what Robert Bork has characterized as "[p]redation through the misuse of government processes."[39]

One matter that arose from such a "misuse of government processes" was the Commission's *U-Haul* case.[40] That case involved a bankruptcy situation in which U-Haul, as a creditor, was presented with an opportunity to participate in the reorganization of its largest competitor. Rather than acting in good faith, the Commission alleged, U-Haul used the bankruptcy proceeding to undermine its rival and sought to delay the reorganization in a plainly anticompetitive manner.

To address the concern that *Noerr* doctrine was being interpreted too expansively, potentially resulting in the extension of immunity to misuses of government processes, we convened a *Noerr-Pennington* Task Force of Commission staff in June 2001. One of the objectives of the Task Force was to clarify existing aspects of the *Noerr* doctrine, such as the scope of "petitioning" conduct and the continuing existence of a misrepresentation exception to *Noerr* immunity. Another was to identify ongoing misuses of governmental processes that would potentially subject the participants to antitrust liability.

One of the first potential abuses the Task Force considered was the improper listing of patents in the FDA's Orange Book. Pursuant to current policy, the FDA does not review patents presented for listing in the Orange Book to determine whether they do, in fact, claim the drug product described in the relevant NDA.[41] Instead, the FDA takes at face value the declaration of the NDA filer that listing is appropriate. As a result, an NDA filer acting in bad faith can successfully list patents that do not satisfy the statutory listing criteria. Once listed in the Orange Book, these patents have the same power to trigger a 30-month stay of ANDA approval as any validly listed patent, thereby delaying generic entry and potentially costing consumers millions, or even billions, of dollars without valid cause.

In January of this year, lawsuits relating to Bristol-Myers's alleged monopolization through improper listing of a patent on its branded drug BuSpar—consolidated in the Southern District of New York as *In re Buspirone*[42]—presented the Commission with an opportunity to clarify the *Noerr* doctrine and to have a significant impact on the Commission's ongoing pharmaceutical cases. Specifically, plaintiffs alleged that, through fraudulent patent filings with the FDA, Bristol-Myers caused the agency to list the patent in question in the Orange Book, thereby blocking generic competition with its BuSpar product, in violation of Section 2 of the Sherman Act.[43]

As anticipated, Bristol-Myers responded to these allegations by filing a motion to dismiss that raised, principally, a claim of *Noerr-Pennington* immunity. Given the importance of the issue to competition in the pharmaceutical industry, as well as to the Commission's ongoing investigations, the Commission filed an *amicus* brief, opposing the motion to dismiss.[44] On February 14, 2002, the court issued an opinion denying Bristol-Myers's immunity claim and accepting most of the Commission's reasoning on the *Noerr-Pennington* issue.[45]

The court's order was broad, rejecting Bristol-Myers's claim of *Noerr-Pennington* immunity on three independent and alternative grounds. The first, and perhaps most important, of these grounds was that Orange Book filings simply do not constitute protected "petitioning." The court agreed with the Commission's argument that an Orange Book filing is analogous to a tariff filing. In both cases, "the government does not perform an independent review of the validity of the statements, does not make or issue an intervening judgment, and instead acts in direct reliance on the private party's representations."[46] The court also agreed that an Orange Book filing is not incidental to petitioning, holding that Bristol-Myers could have listed its patent in the Orange Book "without subsequently bringing infringement suits

. . . [and] could have brought these suits without relying on its Orange Book listing."[47]

The court further concluded that, even if Orange Book filings were to constitute "petitioning," application of two specific exceptions to the *Noerr* doctrine—the *Walker Process* and "sham" exceptions—would preclude a finding of antitrust immunity. Under *Walker Process,*,[48] a patent holder may be subject to antitrust liability for attempting to enforce a patent procured through fraudulent misrepresentations to the Patent and Trademark Office ("PTO"). The *Buspirone* court concluded that the Orange Book listing and patent prosecution processes were sufficiently analogous to warrant extension of the *Noerr* exception beyond the PTO context, and that plaintiffs' allegations satisfied *Walker Process.*[49]

Under the "sham" exception, the opponent of *Noerr* immunity must demonstrate that defendant's petitioning conduct—in this case, Bristol Myers's patent filing with the FDA—was "objectively baseless."[50] After an examination of the prosecution history of Bristol-Myers's patent, as well as the specification and claims, the *Buspirone* court concluded that the filing was, indeed, "objectively baseless." The court further observed that Bristol-Myers's argument to the contrary "ignores the law and tries to justify taking property that belongs to the public."[51]

In light of the *Buspirone* decision, and the underlying force of the court's reasoning, the *Noerr-Pennington* doctrine may not prove as large an obstacle to using the antitrust laws to remedy improper Orange Book filings as some may have anticipated. It is worth noting, and indeed emphasizing, that *Buspirone* does not mean that all improper Orange Book filings will give rise to antitrust liability. Any antitrust liability must necessarily be predicated on a clear showing of a violation of substantive antitrust law. But, under *Buspirone,* Orange Book filings are not *immune* from those laws or exempt from their scrutiny.

2. *Biovail (Tiazac)*

Today, the Commission is announcing that it has accepted for public comment an agreement and proposed consent order with Biovail Corporation,[52] settling charges that Biovail illegally acquired an exclusive patent license and wrongfully listed that patent in the Orange Book for the purpose of blocking generic competition to its branded drug Tiazac. This is the Commission's first enforcement action to remedy the effects of an allegedly anticompetitive Orange Book listing.

Prior to the events giving rise to the Commission's complaint, Biovail had already triggered a 30-month stay of FDA final approval of Andrx's generic Tiazac product, by commencing an infringement lawsuit against Andrx. Andrx prevailed in the courts, however, so that by February 2001, the stay would have been lifted. According to the Commission's complaint,[53] Biovail, in anticipation of pending competition from Andrx, undertook a series of anticompetitive actions to trigger a new stay and maintain its Tiazac monopoly. Just before the stay was to terminate, Biovail acquired a newly issued patent from a third party and listed it in the Orange Book as claiming Tiazac—thereby requiring Andrx to re-certify to the FDA under Paragraph IV, and opening the door to Biovail's suit against Andrx for infringement of the new patent and commencement of a second 30-month stay.

According to the Commission's complaint, Biovail knew that the new patent did *not* claim the form of Tiazac that it had been marketing, and Biovail did not need this new patent to continue marketing Tiazac without infringement risk. In fact, the FDA later learned that Biovail's position was that the newly listed patent covered a new formulation of Tiazac that Biovail had developed only after it acquired and listed the patent. The newly listed patent did not cover the version of Tiazac that the FDA had approved and that Biovail had been marketing. FDA told Biovail that the new Tiazac formulation therefore lacked FDA approval and that it would delist the patent from the Orange Book unless Biovail certified that the patent claimed the approved version of Tiazac.

The Commission alleges that Biovail misleadingly represented to the FDA that the new patent claimed existing-and-approved, rather than revised-and-unapproved, Tiazac, to avoid de-listing from the Orange Book and termination of the stay against Andrx.[54] The Commission alleges that Biovail's patent acquisition, wrongful Orange Book listing, and misleading conduct before the FDA were acts in unlawful maintenance of its Tiazac monopoly, in violation of Section 5 of the FTC Act,[55] and that the acquisition also violated Section 7 of the Clayton Act[56] and Section 5 of the FTC Act.

The proposed consent order would require Biovail to divest the illegally acquired patent to its original owner, except as to new product developments outside the Tiazac market; to dismiss its infringement case against Andrx, which would end the stay, thereby allowing entry of generic Tiazac to the benefit of consumers; and to refrain from any action that would trigger another 30-month stay on generic Tiazac

entry. Further, the order prohibits Biovail from unlawfully listing patents in the Orange Book and requires Biovail to give the Commission prior notice of acquisitions of patents that it will list in the Orange Book for Biovail's FDA-approved products. These measures should not only remedy Biovail's allegedly unlawful conduct, but also send a strong message that the Commission will act decisively to eliminate anticompetitive practices in the pharmaceutical industry.

C. Settlements Between Generics

Although agreements between first and second generic entrants have attracted significantly less attention to date, they too can raise competitive concerns and may draw antitrust scrutiny in the future. As in the case of agreements between brands and generics, the economic incentives to collude can be strong. Studies indicate that the first generic typically enters the market at 70–80 percent of the price of the corresponding brand,[57] 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. Collusion between the generics 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.

Two potentially competition-reducing categories of agreements are worth noting. The first involves exclusive distributorship arrangements. A second generic entrant, rather than bringing a competing product to market, might agree to become the exclusive distributor of the first entrant. Such an arrangement would essentially grant the second entrant an agreed-upon share of the market, rather than requiring it to secure that share at the expense of the first entrant through aggressive price competition.

The second involves potential division of market segments. The first entrant might agree to market its product exclusively in one strength, while the second entrant agrees to market its product exclusively in another. Like the exclusive distributorship arrangement, the objective of such an agreement would appear to be *less* vigorous competition, as the agreement would simply grant each company a reciprocal market segment that would otherwise need to be secured through competition on price and other terms.

As with any antitrust case, the analysis would depend on the actual facts, but, at a minimum, such arrangements would arouse significant interest at the Commission.

IV. Other Commission Efforts to Promote Competition

A. The Commission's 6(b) Study

In light of the serious questions raised by its various generic drug investigations, in October 2000, the Commission proposed a focused industry-wide study of generic drug competition. This study is designed to examine more closely the business relationships between brand-name and generic drug manufacturers in order to understand better the nature and extent of any anticompetitive impediments to the process of bringing new, low-cost generic alternatives to the marketplace and into the hands of consumers. The study will provide a more complete picture of how generic drug competition has developed under the Hatch-Waxman Amendments, including whether agreements between branded and generic drug manufacturers of the types challenged by the Commission are isolated instances or are more typical of industry practices. In addition, the Commission will examine whether particular provisions of the Hatch-Waxman Amendments have operated as intended or have unintentionally enabled anticompetitive strategies that delay or deter the entry of generic drugs into the market.

Last April, the Commission received clearance from the Office of Management and Budget ("OMB") to conduct the study.[58] The Commission has since issued nearly 90 special orders—pursuant to Section 6(b) of the Federal Trade Commission Act[59]—to branded and generic drug manufacturers, seeking information about certain practices that were outlined in the Federal Register notices that preceded OMB clearance to pursue the study.[60] The Commission staff focused each special order on a specific branded pharmaceutical that was the subject of Paragraph IV certifications filed by a potential generic competitor, and, for generic manufacturers, on a specific drug product for which the company had filed an ANDA containing a Paragraph IV certification. Responses from the companies were generally completed by the end of 2001. The Commission staff is currently compiling the information received to provide a factual description of how the 180-day marketing exclusivity and 30-month stay provisions have influenced the development of generic drug competition. We expect that the 6(b) study will be completed, and a report detailing its findings released, sometime this summer.

Among other areas of interest, the Commission staff is also analyzing how often the 180-day marketing exclusivity provision has been used,[61] how it has been triggered (*i.e.,* by commercial marketing or court orders),[62] the frequency with which branded manufacturers have initiated patent litigation, and the frequency with which patent litigation has been settled or litigated to a final court decision. The Commission will use the agreements provided, along with underlying documentation of the reasons for executing the agreement, to examine whether agreements between branded and generic drug manufacturers—or between generics—may have operated to delay generic drug competition. In addition, the study will provide evidence about branded manufacturers' patent listings in the Orange Book, the timeliness of the listings, and how frequently generics challenge those listings. Finally, the study will examine whether the size of a drug product's sales affects the likelihood that a particular strategy will be used to delay generic competition.

A few tentative observations can be made based on the ongoing review of the data received by the Commission, including:

- *The types of potentially anticompetitive practices employed by pharmaceutical companies have changed direction following recent FTC enforcement actions.* The results of the Commission's study, to date, suggest that some pharmaceutical companies—including both brands and generics—have employed a variety of potentially anticompetitive strategies involving Paragraph IV certifications, and that these strategies have changed direction after the FTC's announcement of consent orders in *Abbott/Geneva* and *Hoechst/Andrx.*
- *Grants of marketing exclusivity have increased since the D.C. Circuit's decision in Mova Pharmaceutical Corp. v. Shalala.* The FDA's grant of the 180-day marketing exclusivity has increased substantially since *Mova,* which eased the rules governing how the FDA grants the exclusivity to generic companies.[63] From 1998 to 2001, the FDA has granted the 180-day marketing exclusivity substantially more often than it did from 1984 to 1998.
- *Interim patent agreements*[64] *appear to be uncommon.* The two patent infringement settlement agreements discussed above—the Abbott/Geneva and Hoechst/Andrx agreements—were interim agreements. The data reviewed by the Commission to date suggest that this is not the norm. Most agreements have been final agreements that resolve patent litigation.
- *Formulation and method of use patents are the most frequently challenged.* The majority of patents subject to Paragraph IV certifications that result in patent infringement litigation involve formulation and method of use. These are not the patents on the active ingredient contained in the drug product, but the patents on how the product is formulated—for example, into tablets—or how the product will be used to treat certain health problems.

B. Continuing Discussions with FDA

In addition to its independent efforts, the Commission continues to work with FDA to ensure robust competition from generic drugs. Most recently, these efforts have included a Citizen Petition filed by Commission staff to clarify the proper content of Orange Book listings. The Commission staff also participated in the FDA's January 30, 2002, "symposium" on Hatch-Waxman. This event provided a forum for representatives from the leading trade associations of branded and generic drug manufacturers—the Pharmaceutical Researchers and Manufacturers of America ("PhRMA") and the Generic Pharmaceuticals Association ("GPhA")—to present their concerns to FDA and advocate specific regulatory reforms. The Commission staff participated in the questioning of the PhRMA and GPhA representatives and discussed with FDA the potential competitive impact of various regulatory approaches. Finally, the Commission staff continues to bring concerns to the attention of the FDA informally in order to encourage the implementation of the Hatch-Waxman drug approval process with an eye toward competition and consumer welfare (in addition to the traditional goals of safety and efficacy).

V. Conclusion

Thank you for this opportunity to share the Commission's views on competition in the pharmaceutical industry. As you can see from this testimony, the Commission has been and will continue to be very active in protecting consumers from anticompetitive practices that inflate drug prices. 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. In keeping with this objective, the Commission will likewise endeavor to ensure that the careful Hatch-

Waxman balance—between promoting innovation and speeding generic entry—is scrupulously maintained.

ENDNOTES

[1] The 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 other Commissioner.

[2] Milt Freudenheim and Melody Peterson, *The Drug Price Express Runs into a Wall,* N.Y. Times, Dec. 23, 2001.

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

[4] 21 U.S.C. § 301 *et seq.*

[5] The Hatch-Waxman Amendments also were intended to encourage pharmaceutical innovation through patent term extensions. *See infra* note 14 and accompanying text.

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

[7] *Id.* at 3. *See also* Amy Barrett, *Crunch Time in Pill Land,* Business Week 52 (Nov. 22, 1999).

[8] *See, e.g., FTC v. Mylan Laboratories, Inc. et al,.* 62 F. Supp. 2d 25 (D.D.C. 1999); *Roche Holding Ltd.,* 125 F.T.C. 919 (1998) (consent order); *Ciba-Geigy Ltd.,* 123 F.T.C. 842 (1997) (consent order).

[9] 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>*; David Reiffen and 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>.*

[10] *FDA: Citizen Petition*, Comment of the Staff of the Bureau of Competition and 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-Day Marketing Exclusivity for Generic Drugs,* Comment of the Staff of the Bureau of Competition and 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).

[11] Testimony of 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>.*

[12] *See, e.g.,* Sheila F. Anthony, *Riddles and Lessons from the Prescription Drug Wars: Antitrust Implications of Certain Types of Agreements Involving Intellectual Property* (June 1, 2000) *available at <http://www.ftc.gov/speeches/anthony/sfip000601.htm>*; Thomas B. Leary, *Antitrust Issues in Settlement of Pharmaceutical Patent Disputes* (Nov. 3, 2000) *available at <http://www.ftc.gov/speeches/leary/learypharma.htm>*; Thomas B. Leary, *Antitrust Issues in the Settlement of Pharmaceutical Patent Disputes, Part II* (May 17, 2001) *available at <http://www.ftc.gov/speeches/leary/learypharmaceutical—settlement.htm>*; 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>.*

[13] H.R. Rep. No. 98–857, pt. 1, at 14 (1984), *reprinted in* 1984 U.S.C.C.A.N. 2647, 2647.

[14] *Abbott Labs. v. Young,* 920 F.2d 984, 991 (D.C. Cir. 1990) (Edwards, J., dissenting) (citations omitted).

[15] 21 U.S.C. § 355(b)(1).

[16] *Id.* at § 355(j)(7)(A).

[17] *Id.* at § 355(j)(2)(A)(iv).

[18] *Id.* at § 355(j)(2)(A)(vii).

[19] *Id.* at § 355(j)(2)(A)(vii)(IV).

[20] *Id.* at § 355(j)(2)(B). Although the patent holder and the NDA filer are often 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 Or-

ange Book. Occasionally, this requires an NDA filer to list a patent that it does not own.

[21] *Id.* at § 355(j)(5)(B)(iii).

[22] *Id.* For example, the statute requires the ANDA applicant to establish bioequivalence. *See supra* note 17.

[23] 21 U.S.C. at § 355(j)(5)(B)(iii).

[24] *Id.* at § 355(j)(5)(B)(iv).

[25] *See Granutec, Inc. v. Shalala,* 139 F.3d 889, 891 (4th Cir. 1998).

[26] 21 U.S.C. § 355(j)(5)(B)(iv).

[27] There has been litigation over what acts trigger the 180-day period of exclusivity. *See infra* note 63.

[28] These circumstances occur when other generic firms had products ready to market, were tentatively approved by the FDA, and were not impeded by patent litigation.

[29] *See* CBO Study, *supra* note 6; *see generally* Reiffen and Ward, *supra* note 9.

[30] *See* CBO Study, *supra* note 6; Reiffen and Ward, *supra* note 9, at 4.

[31] *Abbott Laboratories*, No. C–3945 (May 22, 2000) (consent order), complaint *available at <http://www.ftc.gov/os/2000/05/c3945complaint.htm>*, and *Geneva Pharmaceuticals, Inc.,* No. C–3946 (May 22, 2000) (consent order), complaint *available at <http://www.ftc.gov/os/2000/05/c3946complaint.htm>*.

[32] *See Hoechst Marion Roussel, Inc.,* No. 9293 (May 8, 2001) (consent order), complaint *available at <http://www.ftc.gov/os/2000/03/hoechstandrxcomplaint.htm>*.

[33] 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.pdf>*. Similar issues are raised by another case—*Schering-Plough*—that is still in litigation. *See Schering-Plough Corp.,* No. 9297 (complaint issued Mar. 30, 2001), *available at <http://www.ftc.gov/os/2001/04/scheringpart3cmp.pdf>*. On April 2, 2002, the Commission resolved all claims against one of the three respondents, American Home Products ("AHP"), by issuing a final consent order. Pursuant to that order, AHP is prohibited from entering into two categories of agreements: (1) those in which the brand makes a payment to the generic in return for delayed entry, and (2) those in which the generic agrees not to enter the market with a non-infringing product. *See Schering-Plough Corp.,* No. 9297 (consent order as to AHP issued Apr. 2, 2002), *available at <http://www.ftc.gov/os/2002/04/scheringplough_*do.htm>.

[34] *Cf. Brulotte v. Thys Co.,* 379 U.S. 29, 33 (1964) (holding that "enlarg[ing] the monopoly of the patent" by collecting post-expiration royalties constitutes patent misuse).

[35] *But see* Leary, Part II, *supra* note 12, at 7 (arguing that agreements regarding waiver of 180-day exclusivity period may have no anticompetitive effect absent reverse payment).

[36] The Commission first raised concerns about the potential anticompetitive impact of improper Orange Book listings in *American Bioscience, Inc. v. Bristol-Myers Squibb Co., et al.,* Dkt. No. CV–00–08577 (C.D. Cal. Sept. 7, 2000). *See* Federal Trade Commission Brief as *amicus curiae available at <http://www.ftc.gov/os/2000/09/amicusbrief.pdf>*. In that case, the parties sought court approval of a settlement containing a specific factual finding that Bristol-Myers was required to list American Bioscience's patent of Bristol-Myers's branded drug Taxol in the Orange Book. The Commission was concerned that the court's approval of the settlement would amount to a judicial finding that the patent met the statutory requirements for listing in the Orange Book and would prejudice parties who may later challenge the listing.

[37] 365 U.S. 127 (1961).

[38] 381 U.S. 657 (1965).

[39] Robert H. Bork, The Antitrust Paradox: A Policy at War with Itself 364 (Free Press 1993) (1978).

[40] *AMERCO, et al.,* 109 F.T.C. 135 (1987).

[41] *See* 21 C.F.R. § 314.53(f). *See also* Abbreviated New Drug Application Regulations—Patent and Exclusivity Provisions, 59 Fed. Reg. 50338, 50343 (1994) ("FDA does not have the expertise to review patent information. The agency believes that its resources would be better utilized in reviewing applications rather than reviewing patent claims."); Abbreviated New Drug Application Regulations, 54 Fed. Reg. 28872, 28910 (1989) ("In deciding whether a claim of patent infringement could reasonably be asserted . . . the agency will defer to the information submitted by the NDA applicant.").

[42] *In re Buspirone Patent Litigation/In re Buspirone Antitrust Litigation*, 185 F. Supp. 2d 363 (S.D.N.Y. 2002) ("*In re Buspirone*"). Some of the same plaintiffs had

previously brought suit under the FDC Act, requesting that the court issue an order compelling Bristol-Myers to de-list the objectionable patent. Although plaintiffs prevailed at the district court level, the Federal Circuit reversed that decision, holding that the FDC Act did not provide a private right of action to compel de-listing of a patent from the Orange Book. *See Mylan Pharmaceuticals, Inc. v. Thompson*, 268 F.3d 1323, 1331–32 (Fed. Cir. 2001).

[43] 15 U.S.C. § 2.

[44] Memorandum of Law of *Amicus Curiae* the Federal Trade Commission in Opposition to Defendant's Motion to Dismiss *available at <http://www.ftc.gov/os/2002/01/busparbrief.pdf>*.

[45] *In re Buspirone, supra* note 42.

[46] 185 F. Supp. 2d at 370.

[47] *Id.* at 372.

[48] *Walker Process Equipment, Inc. v. Food Machinery & Chemical Corp.,* 382 U.S. 172 (1965).

[49] *In re Buspirone, supra* note 42, at 372–75. Notably, the *Buspirone* court's decision is one of the first to apply the *Walker Process* exception outside the narrow PTO context

[50] *Professional Real Estate Investors, Inc. v. Columbia Pictures Industries, Inc.,* 508 U.S. 49, 60 (1993).

[51] *In re Buspirone, supra* note 42, at 376.

[52] *Biovail Corp.* (consent order accepted for public comment, Apr. 19, 2002).

[53] The Commission's complaint against Biovail is available on the FTC's Web site, *<http://www.ftc.gov>*.

[54] After learning that Biovail had taken the position that its newly acquired patent covered a formulation of Tiazac developed after acquisition of the patent, the FDA contacted Biovail to determine whether this formulation was the same as the formulation approved under the Tiazac NDA. In response, Biovail submitted a declaration stating simply that its newly acquired patent claimed Tiazac and, therefore, was eligible for listing in the Orange Book. The Commission asserts that this declaration was misleading, because it did not clarify whether the term "Tiazac" as used by Biovail meant FDA-approved Tiazac (as the FDA required) or Biovail's revised form of the product.

[55] 15 U.S.C. § 45.

[56] *Id.* at § 18.

[57] *See* CBO Study, *supra* note 6; Reiffen and Ward, *supra* note 9, at 22.

[58] The Commission was required to obtain OMB clearance before it could begin the study, because the number of special orders to be sent triggered the requirements of the Paperwork Reduction Act of 1995, 44 U.S.C. Ch. 35, as amended.

[59] 15 U.S.C. § 46(b).

[60] *See* 65 Fed. Reg. 61334 (Oct. 17, 2000); 66 Fed. Reg. 12512 (Feb. 27, 2001).

[61] Commission staff commented to the FDA on the 180-exclusivity issue in connection with a proposed rulemaking. *See* Marketing Exclusivity Comment, *supra* note 10.

[62] 21 U.S.C. § 355(j)(5)(B)(iv).

[63] *Mova Pharmaceutical Corp. v. Shalala,* 140 F.3d 1060 (D.C. Cir. 1998); *see Granutec, Inc. v. Shalala,* 139 F.3d 889 (4th Cir. 1998). In implementing the 180-day marketing exclusivity provision in the past, the FDA added a requirement that the first ANDA applicant have "successfully defended against a suit for patent infringement" before the applicant is eligible for the 180-day marketing exclusivity period. *Mova* and *Granutec,* however, held that the FDA had exceeded its statutory authority in imposing the "successful-defense requirement" as a prerequisite to obtaining the 180-day marketing exclusivity.

[64] An interim agreement is an agreement in effect until the final determination of the patent litigation.

Senator DORGAN. Chairman Muris, thank you very much. Senator Schumer, thank you for being willing to stay.

Let me just ask a brief question on the subject that Mr. Muris just covered. Senator Schumer, you indicated in your testimony that you felt that the ability to slide through the cracks here of Hatch-Waxman was substantial. And Mr. Muris just described a number of circumstances where the FTC is taking enforcement actions because of that. In fact, in his testimony, he's talking about the branded drug, Hytrin. One company paid another $4.5 million

per month to delay the entry of the generic product, costing consumers hundred of millions of dollars a year.

I'd ask each of you: we have some examples of specifics. How substantial is this? How often is it happening? Is it an epidemic out there, in terms of this kind of behavior and action to keep generics off the market?

Senator SCHUMER. Well, I think that's well put. It is an epidemic. It started very recently, as the pharmaceutical industry was looking for ways, with so many blockbuster drugs' patents expiring, they were looking for ways to extend them. And many of the parts of Hatch-Waxman have been twisted and used far beyond what the sponsors thought. The 30-month automatic extension, no one thought that would be used, when it was passed, routinely on even frivolous filings to just get an extra two and a half years of the drug.

No one even imagined when Hatch-Waxman passed that the drug company and the generic company—the pharmaceutical, the brand name, and the generic would make a deal and use the 180-day exclusivity to prevent other generic drug companies from coming.

So, yes, this has reached an epidemic, I would say, Mr. Chairman. It is prevalent everywhere. I salute the FTC for taking some enforcement actions, but there's—first, the law prevents them from doing certain things, like the 30-month automatic stay, and, second, they'll always be playing catch-up ball. I think that's why we need to change the law.

Senator DORGAN. And, Mr. Muris, is this becoming a customary business practice, to try to keep your competition out of the market? And do you have the resources to deal with it if it is becoming a customary business practice?

Mr. MURIS. Mr. Chairman, there are certainly many practices that we have seen to attempt to restrict competition. The practices are evolving. We have identified some agreements between the branded and generics, and, at least in the circumstances of the settlements that we've reached, I believe they're clearly illegal. We've recently found a decrease in those practices, but an increase in other practices.

I believe we have the resources we need to investigate these practices. We have dramatically increased, as I mentioned, our resources in non-merger healthcare. Assuming that the Congress grants our budget request for fiscal 2003, I believe we will have adequate resources.

Senator DORGAN. Mr. Muris, the pharmaceutical manufacturers will testify later today. They essentially say you and Mr. Schumer are all wet. I mean, they say, "What are you talking about here? What we have is Hatch-Waxman, which is working just fine. It promotes competition while still protecting those that have legitimate patent rights. You're all wet," they say. Respond to that, please.

Mr. MURIS. Hatch-Waxman was a compromise. It had important benefits for both branded and generic companies. But at the margin, as economists like to say, there's activity that violates the antitrust laws and harms consumers. We've been aggressive in attacking that activity, and, as I said, we're increasing our scrutiny.

Senator DORGAN. How substantially are you increasing your scrutiny? And as I asked previously, do you have the resources to do that in a way that gives us the assurance that people are protected?

Mr. MURIS. We have increased our security—for this fiscal year, we will spend about 50 percent more resources in non-merger healthcare. The vast bulk of that will be in the pharmaceutical area, although we're also finding problems in other areas in healthcare and have recently announced cases. This is an area where there are problems, as I've mentioned. At the moment, I believe we have adequate resources.

Senator DORGAN. One final quick question. Governor Shaheen, you come from a state that's close to Canada, and I do, as well. We both know that for personal use, many of our constituents go across the border and access the same pill put in the same bottle by the same company. The only difference is price, and they pay a much lower price in Canada. It is also true, however, that your pharmacist in your state is not able to go across the border to access the lower-priced drug, FDA-approved drug, and pass those savings along to the consumer. Is that not correct?

Governor SHAHEEN. That's absolutely correct. And I heard you say earlier that reimportation is one of the other issues that you'll be looking at, and I would urge you to do that, because it's not just a question of, you know, people not having access to those drugs. But they look at what's going on and the fact that if they went into Canada, they could get them so much cheaper, and they see it as an issue of fairness, that why can't we, in the United States, get those drugs at the same prices that they can get them in Canada.

Senator DORGAN. I might say, it's not my intention to have American consumers buying prescription drugs in Canada. It is my intention to try to find a way to break the back of the price controls that exist here that are unfair to consumers, and one way to do that would be to allow reimportation of FDA-approved drugs that have a chain of custody and allow pharmacists and licensed distributors to access those drugs from Canada. And we'll be introducing some legislation, or announcing some legislation, on that tomorrow.

Senator McCain.

Senator MCCAIN. Thank you, Mr. Chairman. Just to followup, Governor Shaheen, have you ever received an explanation from anyone as to why your citizens can drive to Canada, and mine to Mexico, as they do by the busload, and purchase the exact same drugs for half the price?

Governor SHAHEEN. I've never had an explanation that I thought was acceptable.

Senator MCCAIN. Mr. Muris?

Mr. MURIS. We've not studied that issue at the Commission, and, quite frankly, I've seen empirical literature on both sides of the issue. Until I, saw——

Senator MCCAIN. If you need any evidence, just visit New Hampshire, my state, any state that has a border on Mexico or Canada. I don't think it'll be very hard to garner. And, frankly, my constituents do not understand that. They simply do not, nor do I. And I think it's a gross inequity, and I hope that the FTC will look at it.

I want to thank Senator Schumer for his passionate, eloquent and informed presentation. Thank you, Senator Schumer. I guess citizens of New York have the same cross-border experiences as others.

Mr. Muris, of the cases the FTC has looked at, in how many have you concluded that the pharmaceutical industry was attempting to either prohibit or delay the entry of generic drugs into the marketplace?

Mr. MURIS. We've been involved in five cases publicly where the Commission alleged or filed an amicus brief where we thought generic entry was being delayed. Sometimes it was with agreements with the generics, sometimes it was a unilateral action by the brand, and we have many other non-public investigations underway where we're looking at those sorts of charges.

Senator MCCAIN. Well, in the five, then, how many of those have you concluded that the pharmaceutical industry was attempting to either prohibit or delay the entry of generic drugs into the marketplace?

Mr. MURIS. One of those is still under litigation, but, in the other four, that was the conclusion of the Commission.

Senator DORGAN. Would you yield on that point? Mr. Muris, you said five that you were involved in publicly. That implies that there are many more that you're involved in that have not become public. Can you describe that?

Mr. MURIS. Yes, Senator. We have numerous investigations—non-public investigations; under our rules until we take an enforcement action, the facts remain non-public—where we are investigating serious charges, and we anticipate we will take additional enforcement actions, when there have been efforts to delay generic competition that we believe violate the antitrust laws.

Senator MCCAIN. Have you found evidence of continuing anticompetitive practices or strategies?

Mr. MURIS. Yes, we have. It is very hard under the antitrust laws to bring a pattern case, but we are looking at some of those situations. I've had a longstanding interest in stopping the use of government processes to restrict your competitors in ways that were illegal under the antitrust laws. When I arrived at the FTC in June, we started a task force to look at that issue, the Noerr-Pennington defense, and we've put many more resources in analyzing Noerr-Pennington issues than had been used before I arrived.

Senator MCCAIN. And you mention in your testimony the so-called Orange Book issue that you're just getting into. How serious do you think that problem is?

Mr. MURIS. The Orange Book problem appears to be serious. The problem of subsequent or consecutive 30-month stays, I think, was unintended by the Hatch-Waxman Act. I think that's a very serious problem. There have been several allusions to cases that involve that this morning. That, indeed, I believe, is a very serious problem.

Senator Schumer?

Senator SCHUMER. Yeah, I was just going to say, I don't think anyone who wrote Hatch-Waxman, as in the case I mentioned today, would think that if you change the dosage slightly, that you

should get another 20 years. And that's been—that was one of the things that was just filed. I mean, they're way out of line. No one would ever have imagined that this would happen.

Senator MCCAIN. Mr. Muris, I think that Governor Shaheen speaks for my Governor and the other 48 Governors when she says that this issue of prescription drug costs is of dramatic importance, and I hope that the FTC understands the priority that this issue needs to be given. As I mentioned in my opening statement, we do have seniors all over America today who are making a choice between their health and their income, and I don't think Americans should be forced to make that decision.

Where would you rank this issue, Governor Shaheen, as to its importance to your citizens, particularly senior citizens, today?

Governor SHAHEEN. It's the number one issue. It's the issue that I hear more as I go around the state. It is the cost of healthcare. And if you look at what's driving the cost of healthcare, as Senator Dorgan pointed out in his initial remarks, it's the cost of prescription drugs.

Senator MCCAIN. It certainly was the case made by the CalPERS people who, as I mentioned in my statement, have had to enact the greatest increase in healthcare premiums in their history.

I want to thank the witnesses. Mr. Muris, I want to thank you for your efforts, and I hope you'll redouble those. We will redouble ours to try to get some legislation through, at least in the short term, to help the generic situation. Then, Congress and the American people are going to have to move on to the larger issue. I thank you. I thank the witnesses.

Thank you, Mr. Chairman.

Senator DORGAN. Senator Schumer, I understand you have to leave. We'll excuse you. Thank you for your presence today. Senator Wyden?

Senator WYDEN. Thank you, Mr. Chairman, and I want to thank Senator Schumer and Governor Shaheen and start with you, Mr. Muris.

It's clear that through your office now, the Federal Government is putting substantial resources and bringing a significant number of settlement actions in this area. It seems to me that you're trying to send a powerful message to industry to stop gaming the system. Is that a fair characterization?

Mr. MURIS. Yes, Senator. I have two substantial priorities where we have announced a dramatic increase in resources. One is the healthcare area, particularly pharmaceuticals. The other is protecting consumers' privacy.

Senator WYDEN. Tell me, if you would, what you see as the biggest problems now with the 180-day marketing exclusivity section and the 30-month stay provisions? I know you've got your study coming out this summer, but that goes right to the heart, it seems to me, of how we look at reforms. I've said that I think this is a bare-knuckles brawl, and it's always been between the brand-name companies and the generic companies. But right now, things don't seem to be working on either end. The seniors can't afford the old medicines, let alone the new cures. And, of course, the companies are talking publicly about a decline in productivity. So I think it would be helpful if you'd tell us what you think are the biggest

problems today, recognizing your study is still to come out, with those two key provisions, 180-day marketing exclusivity and the 30-month stay.

Mr. MURIS. As you're implying, the Commission has yet to take a position, so let me speak somewhat tentatively. It's clear, as I just mentioned, however, that the consecutive 30-month stay provision is a serious problem. I think there is no doubt about that. We have seen very late-listed patents in the Orange Book, and in some cases we thought that was very suspicious.

On the 180-day provision, we are still evaluating to see the extent to which a generic sitting on the 180-days is really preventing other generics from entering. We're reviewing our data to see how prevalent that situation is. Under the old FDA interpretation, in essence, the FDA rewarded the 180 days as a prize if the generic successfully defended a lawsuit. When the courts struck that interpretation down, we've now had many more 180 days handed out by the FDA, and we are studying the data to see just what sort of problems that's caused, if any. We hope to have that analysis done soon.

Senator WYDEN. As far as the consumer is concerned, we're facing the end of patent protection for a long stream of medicines. The companies have been noting that there aren't a whole lot of drugs in the pipeline. Are you convinced that we'll see more efforts to game the system, more maneuvers, if nothing's done?

Mr. MURIS. We are certainly seeing a large number of efforts to game the system. The efforts are evolving. I believe that the FTC's agressive enforcement of the antitrust laws has appeared to have put a stop to these agreements between branded and generics to delay entry of the generics. There are new tactics being used. I am hoping that court decisions, like in the Buspar case that said that Orange Book listing is not petitioning, will open the way to use antitrust to prevent the games that are anti-competitive.

Senator WYDEN. Tell me, if you will, about the new tactics, because I think that's one of the reasons why a lot of us think we ought to look at making some changes in the law, and at both ends, with respect to patents and generics. What do you think the new tactics are likely to be in terms of trying to get around the system?

Mr. MURIS. The issue that we've seen more prevalent recently relates to late listing of patents and in triggering another 30-month stay, and we think there are cases in which those patents are not properly listed in the Orange Book. Something else I mentioned in my testimony is possible collusion between generics. The evidence shows that one generic will lower prices; the addition of an additional generic will lower prices even more. And another possibility, what we call a second-generation case, would involve collusion between generics.

Senator WYDEN. How many of those generic collusion cases are you looking at now?

Mr. MURIS. Well, we are looking at some—I'm very reluctant to talk about non-public investigations.

Senator WYDEN. So just numbers. Just numbers.

Mr. MURIS. We are looking at some such cases.

Senator WYDEN. A significant number of cases?

Mr. MURIS. I wouldn't say a significant number, but we are looking at some.

Senator WYDEN. Mr. Chairman, I don't have any further questions at this point. But, Mr. Muris, I think it is very important that you all continue to work. I gather you feel you've got significant resources and you don't need additional resources for the healthcare inquiries now?

Mr. MURIS. We have dramatically improved our resources. The merger wave has receded, and Congress increased our budget last year, and we've asked for an increase for fiscal 2003. I believe that if that increase is granted, we will have enough.

Senator WYDEN. Thank you, Mr. Chairman.

Senator DORGAN. Senator Wyden, thank you very much. Governor Shaheen, are you able to stay?

Governor SHAHEEN. Yes.

Senator DORGAN. Okay. Let me call on Senator Carnahan for inquiry.

Senator CARNAHAN. Thank you, Mr. Chairman.

Mr. Muris, I receive a great number of letters from constituents who tell me that they have family members who are dying of diseases which they feel could be helped if they were able to access generics. They have a common theme in these letters, that medicine should be available by generics, but had been held up because of what are referred to as "sweetheart deals." This is when a drug company pays a generic manufacturer to hold off putting a generic on the market. A deal has been reached that makes it more profitable for the generic company simply to hold off on bringing the drug to market.

What authority does the FTC have to prevent sweetheart deals, and what efforts are you taking to prevent those?

Mr. MURIS. Under certain circumstances, such deals can violate the antitrust laws. The Commission has brought three such cases. In two of them, we accepted consent agreements. In the third, we accepted a consent agreement very recently against one of the parties, and the rest of that case is in litigation.

Senator CARNAHAN. Could you possibly provide me with a specific list of all the sweetheart deals that you have investigated within the last 2 years? Would that be possible?

Mr. MURIS. Yes. Yes, Senator.

Senator CARNAHAN. Thank you.

Governor Shaheen, I recently received a letter from Governor Holden of Missouri, who asked me to be here today because he felt this issue was so very important to the people of our state. I know that the Governors across the nation are struggling to keep up with the rapidly rising cost of prescription drugs in Medicaid. Could you discuss what impact enacting a Medicare senior prescription drug benefit would have on the Medicaid program?

Governor SHAHEEN. Obviously, it would relieve much of the cost pressure on the program in a way that would be very helpful to states. As I indicated in my testimony, last year, 46 states were surveyed as to the cost of medications that had their patents due to expire in the next 3 years. And the cost of those 17 medications for 46 states was $1.2 billion. So it's a significant cost that states are paying for Medicaid. It's the fastest-growing part of New

Hampshire's State budget. I think that's true for almost all of the states.

This is an issue that is of such concern, with respect just to the loopholes in Hatch-Waxman, that the Governors, when we met in February, passed a resolution calling on Congress to hold hearings into those loopholes and to take some action if it were deemed appropriate. So it's a very big issues, and we frankly need help from you in Congress with how we're going to continue to pick up the costs of Medicaid.

Senator CARNAHAN. Well, if the Schumer-McCain bill does not pass, what options do you have to meet the high costs of prescription drugs?

Governor SHAHEEN. Well, we will continue to struggle. One of the things that states are doing, as we are in New Hampshire, is trying to address the issue in a variety of ways. In New Hampshire, we've had a waiver pending before the Centers for Medicaid and Medicare since the fall of 2000 which would allow us to pass along the cost of—our costs for drugs purchased through Medicaid to those people in need. In New Hampshire, we have a very comprehensive pharmacy benefits management program, one that I would say was lobbied and has been lobbied very heavily against by PhRMA and the drug industry to keep us from putting that program in place.

Senator CARNAHAN. Thank you very much. Thank you, Mr. Chairman.

Senator DORGAN. Senator Breaux?

STATEMENT OF HON. JOHN B. BREAUX,
U.S. SENATOR FROM LOUISIANA

Senator BREAUX. Thank you very much, Mr. Chairman, and I thank Governor Shaheen for being with us, and, Chairman Muris, thank you for being with us, as well.

I think that history is always a very eloquent teacher and somewhat a predictor of the future. And I think if you look at the history of Hatch-Waxman, Mr. Chairman, it was intended, obviously, to try and bring a greater degree of balance to the question of how drugs are bought in this country, whether it was going to be brand-name drugs or whether it was going to be generics. And it was sort of the purpose to try and reach a balance. It was a very difficult debate. Many of us in this Committee were involved in it in other capacities.

I remember, in 1984, when Hatch-Waxman was first adopted, generics constituted about 19 percent of the total market for prescription drugs. I understand that last year, the year 2001, it's up to about 49 percent.

It would seem to me that, by any measure of whether Hatch-Waxman did the job of getting a greater utilization of generics, those statistics tell a very clear story. Generics are now about 49 percent of all the drugs that are bought in this country. It used to be 19. So I think if we look at Hatch-Waxman and ask the question, did it move the utilization of generics to the American public, the answer is clearly yes, it has done so.

I'd like to ask you, Mr. Chairman, about the role that you have in your agency with regard to regulating this area. My information is that, since Hatch-Waxman, there have been about 8,000 new ge-

neric drugs that brought onto the market. And of the 8,000 that have been brought on the market, probably around 500 have had some patent disputes with regard to them. And you're telling this Committee this morning that of the 8,000 new drugs, there's been approximately three cases that have actually been brought to this point of being litigated or are disputed in a court settlement. Is that about right?

Mr. MURIS. The Commission itself has been involved in five cases. There are other cases in the private sector. Under the antitrust laws, Senator, as you're aware, private individuals can sue as well. As I stated in my oral statement and in my written testimony, I do believe the Hatch-Waxman Act has had significant success in increasing competition from generics.

Senator BREAUX. That's the point, to put this in perspective. We had 19 percent of the market was generics. Now we've got 49 percent of the market is generics. Eight thousand new generics have been brought onto the marketplace since Hatch-Waxman was passed, and 3—or 5, I'm sorry—5 have been pursued aggressively by the FTC. I think, by any standard of patent disputes and other products that are always being litigated, that is a pretty astounding record, I think, for having a system that seems to be working, I think, quite well.

It's not easy to bring a balance here. I mean, you can look at the 30-day extension as being a system that the brand names try to game to keep their patents extended for a little bit longer, although my understanding is that the 30-day extension does not in any way involve a patent extension. Can it not only be brought during the life of a patent?

Mr. MURIS. Well, the problem——

Senator BREAUX. It's still in place when the 30-day extension is applied. Is that correct?

Mr. MURIS. Yes. There are really two issues that are raised on the 30-month extension issue. One is——

Senator BREAUX. 30-month, I'm sorry. Excuse me.

Mr. MURIS. One is whether it was intended at the time Hatch-Waxman passed that there could be successive 30-month stays. The other issue, the issue that we deal with more directly, are these efforts that Senator Wyden talked about to game the system in ways that violate the antitrust laws by the very late listing of additional patents or new patents when a generic is poised to enter. The Biovail settlement that we're announcing today involved just such a case. We allege two violations of the antitrust laws in attempting to deter competition from generics.

Senator BREAUX. What about the 180-day? That allows a generic, what, to come into the market if that is granted, without any other generic competing?

Mr. MURIS. Yes, Senator, as part of the compromise, it's meant to be a sweetener or an inducement for generics.

Senator BREAUX. Well, I think that you all are probably doing a very good job. I mean, this is a very complicated, very detailed, lawyers all over the place trying to engage in these multibillion-dollar battles, and I just happen to think that Hatch-Waxman was an incredible effort, and a lot of people said it would never work. I think the evidence clearly indicates that it, in fact, has worked very

well. When you increase the market share from 19 percent to almost 50 percent of every drug sold in this country, I think, by any standard, that is a remarkable achievement.

And I know that the answer to the prescription drug costs in this country is to make, for seniors, a portion of Medicare cover prescription drugs and try to reform an outdated program, like Medicare, at the same time. I think that truly is the answer.

The fact that prescription drugs now make up 16 percent of all the healthcare costs in this country is not that alarming if prescription drugs are used to keep people out of hospitals in the first place or keep them in hospitals for a shorter period of time. That is a wise utilization of the health dollars in this country.

And so, anyway, I just think Hatch-Waxman has been pretty effective, and I yield back my time.

Senator DORGAN. Senator Edwards?

STATEMENT OF HON. JOHN EDWARDS,
U.S. SENATOR FROM NORTH CAROLINA

Senator EDWARDS. Thank you, Mr. Chairman.

Let me say, first of all, that I think that our drug industry is the most creative in the world. I think they're entitled to profit from that creativity. I think all of us have, in fact, profited from that creativity. We have, in my State of North Carolina, in the Research Triangle, Glaxo, who has done groundbreaking work in a lot of different areas.

But I think it's also clear, at the same time, that legal maneuvers and loopholes have been used in an abusive way. And unfortunately, it's the American consumer, and particularly the seniors citizens, that are paying the price for that. I think that Senator McCain and Senator Schumer have a terrific bill that has some very good ideas in it.

I do think there are three areas, two of which they address, one that they don't, that could stand some additional work. First, deterring meritless patent filings, FDA listings, and patent lawsuits. Second, making sure drug companies don't abuse the exclusivity period they get when they develop new uses for drugs. And third, streamlining the patent adjudication process. And in addition to the work this Committee's doing, which is so important, as a member of the Health Committee, my intention is to make sure that these loopholes are closed, if at all possible, by the end of this year because of the effect it's having on people.

Mr. Muris, I want to ask you about this Orange Book problem, because at least in my legal experience, there seems to be a serious problem. As I understand it, the way this process works, if a brand claims that a patent applies to a particular drug, the FDA basically takes their word for it and they list it. And they can say, you know, this is a new patent for Drug X even though the patent is actually for Drug X. And the FDA just sticks it in the book if they say that. Is that basically the way the process works?

Mr. MURIS. Yes, Senator. The FDA does not, for the most part, do an independent evaluation of the patents, and that's given rise to some of the problems.

Senator BREAUX. And then, once it's listed in the book through that process, from the brand just saying it should be listed, then

what happens is, in order for the generic to come to the market, in order for there to be competition in the market, they have to challenge the patent. And once a challenge to the patent is brought, through litigation, then there's an automatic 30-month stay. Is that right?

Mr. MURIS. Yes. It's the shorter of 30 months or until the district court decision, and sometimes the district courts take longer than that.

Senator EDWARDS. It's at least 30 months, though.

Mr. MURIS. Well, it could be shorter if the district court decides——

Senator EDWARDS. In less than 30 months.

Mr. MURIS.—in less than 30 months, right.

Senator EDWARDS. All right. Well, just in my experience, I can't think of another example where, by filing a lawsuit, somebody gets two and a half years of relief, no matter how much merited or meritless the lawsuit is.

And here's my concern. Is there not a way to set up a process whereby the FDA exercises at least more information-gathering authority over this listing process? I understand there can be a debate about whether they ought to have the discretionary authority, and I know that, I guess, abuts against the Noerr-Pennington problem that you talked about earlier. But my concern is, there not a way for them to ask for more specific information so that they can, in fact, -provide and make better information available about whether this particular drug ought to be listed in the way that the brand claims it should be listed in the Orange Book?

Mr. MURIS. I certainly don't want to pretend to speak for the FDA, but let me address a couple of developments that are occurring. The FDA did recently hold a session, in which we participated, with representatives from generics and from branded drug companies, where they talked about some of the issues under Hatch-Waxman. I personally believe that there are at least a few issues where the FDA could provide clearer guidance without having to second-guess the validity of patents and becoming patent lawyers.

Senator EDWARDS. Well, my concern with this is it seems to me that the way we're doing it now is, we're leaving it to litigation in the courts, which is a very expensive, time-consuming process. I think it would be a better process if the FDA had more oversight and we left less of it to the litigation process. That's basically my notion. Can you comment about that?

Mr. MURIS. Well, I do believe that there are some areas where that is, indeed, the case, and I think that the fact that the FDA held the session to talk about the issues indicates some willingness on their part to move in the direction that you're talking about.

Senator EDWARDS. Thank you. Governor, thank you for being here. Thank you for the leadership you've shown on this particular issue. We have the same problems in North Carolina that you have in New Hampshire, and I wonder, you mentioned this briefly in your testimony and in answer to a previous question, but I wonder if you could talk a little more expansively about your waiver request, what your plan is, what it is you hope to accomplish, be-

cause I think all of us are looking for creative solutions to the dilemma we find ourselves in.

Governor SHAHEEN. I'd be happy to do that, Senator. If I might, though, go back to the issue that was raised earlier, first, about the share of the generic market that is now out there since Hatch-Waxman, because I would certainly agree with Senator Breaux and others who have talked about the success of the Hatch-Waxman Act in bringing new generics onto the market. And it has been very successful. The number that was cited to me by PhRMA was that the rate has increased from 18 percent to 45 percent of the market. But the fact it's been that 45 percent of the market for the last 8 years, and the brand-name industry makes up fully 92 percent of expenditures, of all expenditures, on pharmaceuticals. So while we've seen a dramatic increase, I think we still have a long way to go in terms of providing real competition to the brand-name drugs.

To go back to your question about what are we doing with the waiver, we followed the very positive lead of Maine and Vermont, who put in programs that allowed them to pass along the savings that they were able to make from the states purchase of Medicaid drugs, because we can get those drugs at a lower cost than people can get them on the market. And what we wanted to do was to pass along those savings to people who were income-eligible in our state, up to about 200 percent of the poverty level.

We put in a waiver that was modeled on the successful programs in Maine and Vermont that had been approved. About the time we did that, the Vermont program was sued by the pharmaceutical industry. The Vermont program lost in court to the industry, and our waiver has been on hold since then.

What we would have been able to do, had that been approved, would be to provide up to about a 35-percent discount on the cost of prescription drugs for the senior citizens of New Hampshire who were income-eligible.

Senator EDWARDS. In the Maine program, they were taken to court and they won their case in court, as I understand it. Is that correct?

Governor SHAHEEN. That's correct. The Maine program had a different component that they were successfully able to argue in court.

Senator EDWARDS. And just one last question, Mr. Chairman. Mr. Muris, when you all bring these cases, based on these companies engaging an anti-competitive behavior, and assuming they've made millions and millions of dollars in profits as a result, are you able to make them disgorge those millions of dollars in profits in your action?

Mr. MURIS. The Commission has the authority to bring disgorgement actions. Thus far, there have been follow-on private actions, which are still underway. We've just received comments on the situations in which the Commission should use disgorgement, and I hope we can announce the——

Senator EDWARDS. But you haven't been doing that in the past. Is that correct?

Mr. MURIS. Not in the drug cases, no.

Senator EDWARDS. Okay. Thank you, Mr. Chairman.

Senator DORGAN. Senator Rockefeller?

STATEMENT OF HON. JOHN D. ROCKEFELLER IV,
U.S. SENATOR FROM WEST VIRGINIA

Senator ROCKEFELLER. Thank you, Mr. Chairman.

I just wanted to clarify further, because I think this needs to be stated and understood, what Governor Shaheen said, and that is that of the 50 leading brand drugs last year, I think five made it into the generic in 2001 category, into the generic category. And it is true that generic drugs make up 42, 45, 49 percent, whatever it is. But of the $141 billion that was spent at the retail level to get those, only about $8 billion or 8 percent came from generic drugs. And if you put that another way, 58 percent of all prescriptions accounted for—of the brand-drug names, 92 percent of the total retail costs came from prescription drugs, brand drug. So there's two sides to this. One is the percentage, and second is the cost. And what you have been talking about primarily is the difficulties that you have in dealing with cost.

And that leads me to ask you: you have, in your statement, indicated that your Medicaid program spent almost $5 million, on 15 brand-name drugs that faced patent expiration between 2002 and December 2004. Now, if there were timely market competition on those 15 drugs, you could save approximately $2.5 million annually in Medicare drug costs.

John asked this question—Senator Edwards asked this question, but it bears hearing by all. You know, that's called a big repercussion. When we passed the $100 billion tax cut, our most recent one, that cost my state, which, like yours, is small and rural, $86 million in Medicaid, in essence. It means it gives the Governor the choice, but it's very hard to go to a lot of different places. So that's $86 million over 3 years, and we're not facing up to FMAP, which would put back, if we did that, under, frankly, a bill I had, put back more money into West Virginia and your state. Not everybody is burdened with this problem—California and some others. But we are. And so that whole question of Medicaid money and the cost of it and how you do your budgeting in small states like ours is huge.

And I don't think you need to make additional comments, but I wanted to make that clear.

Governor SHAHEEN. Thank you.

Senator ROCKEFELLER. Mr. Muris, on the Orange Book question, again, Senator Edwards asked this question. And there are ways of dealing with this. But they don't exist now. And there really isn't any authority or power that either the FDA or the FTC has to deal with the Orange Book question at the present moment. So if you are to, for example, look to that Orange Book wherein any patent can be entered without scrutiny, you're going to need a change in legislation or a change in your authority unless the FDA can do it on its own. And I don't think that's the case.

So is there any power at this point, either through rules and regulations or through legislation, for anybody to do anything about frivolous lawsuits, which Senator Edwards referred to, in terms of the Orange Book, which is all-powerful and totally unknown to the American people?

Mr. MURIS. In some circumstances, I believe there is.

Let me just amend the record in a response to Senator Edwards' question. We did have one disgorgement case that didn't involved Hatch-Waxman but did involve drugs. In the Mylan case, the Commission obtained $121 million, but it was not a Hatch-Waxman case.

Frivolous lawsuits, under certain circumstances, can violate the antitrust laws. The amicus brief that I mentioned and the case that we're announcing today are both cases where we believe there were wrongful listings, in violation of the antitrust laws, in the Orange Book. Also, I believe that, under its current authority, there are some steps that the FDA could take.

But your general point, Senator, in terms of, for example, the consecutive 30-month stay issue, you would need new legislation to address that issue.

Senator ROCKEFELLER. The FDA could scrub the Orange Book if it had legislation. There could be the inability to repeat 30-day stays. There could be the eventual elimination of 30-day stays. Would those require legislation?

Mr. MURIS. Yes, Senator. As I said, there are some steps that could be taken without new legislation, but the steps that you suggest would require legislation.

Senator ROCKEFELLER. One of the things that I'm pleased to say, Mr. Chairman, is that Senator McCain and Senator Schumer have introduced a bill, as have I, and they work together quite well in being able to handle a number of these problems. And I think it's incredibly important, in anybody's analysis of the scheme of things, that generic drugs make a dent in the retail cost to users. Because the percentage of what they represent, as opposed to brand names, is only important as we have hearings of this sort. What's important to consumers is what it costs and, therefore, what they're going to buy. And I think, under the present situation, you have—under the Orange Book situation, you—I mean, they can literally break, brand-name manufacturers can break these down into what's called metabolite items: the color of the pill, the splitting of the pill, all kinds of things can become subjects for suits and, hence, the 30-month stay.

I don't think it takes a wizard to figure that this is a loophole and one which should be closed. And I think doing it intelligently and, as Senator Edwards indicated, not in a manner to be punitive to pharmaceutical companies, who do, in fact, have to make profits in order to keep the 30,000 or so researchers which they have hard at work, but which also gives people the opportunity to afford the prescription drugs which they need in order to live. And particularly where you're dealing with seniors who may have a total of $10,000 gross income, and they're spending $6,000 or $7,000 of that on prescription drugs. I mean, the whole concept of a generic, then, doesn't become academic, but becomes profoundly real.

Do you any comments, Governor?

Governor SHAHEEN. You stated it very well.

Senator ROCKEFELLER. Thank you, Mr. Chairman.

Senator DORGAN. Senator Rockefeller, thank you very much. Let me thank Chairman Muris and Governor Shaheen for your testimony today. It's very helpful. And your entire statement will be a

part of the permanent record. We will excuse you and we will ask the second panel to come forward.

The second panel consists of Ms. Marian Wolff; Dr. Greg Glover who represents the Pharmaceutical Research and Manufacturers of America organization; Ms. Kathleen Jaeger, president and chief executive officer of the Generic Pharmaceutical Association; Mr. Steven Martin, president and chief executive officer of Nebraska BlueCross and BlueShield; and Ms. Shelbie Oppenheimer, ALS Association. I did not mention Ms. Marian Wolff is accompanied by Mr. Tim Fuller, executive director of the Gray Panthers. If you would all come to the witness table and take seats.

Let me ask—thank you for closing the door. Why don't we begin?

I indicated to you that we have a vote that starts at 11:30 today. I do want to remind the witnesses that we provide 5 minutes for oral testimony. Your entire testimony will be made a part of the permanent record. If you would summarize, we would appreciate it, to be helpful to our schedule, as well.

We thank all of you for being here today. And let me begin in the order that I called you to the table. Ms. Marian Wolff is accompanied by Mr. Tim Fuller, the executive director of the Gray Panthers. Ms. Wolff, why don't you proceed? And if you'll pull the microphone very close to you, I would appreciate that.

STATEMENT OF MARIAN WOLFF, MEMBER, GRAY PANTHERS; ACCOMPANIED BY TIM FULLER, EXECUTIVE DIRECTOR, GRAY PANTHERS

Ms. WOLFF. My name is Marion Wolff, I am a——

Senator DORGAN. Excuse me. Can we have the door closed, please? Thank you very much.

Ms. WOLFF. I am a retired mathematics teacher, and I'm also a member of the Gray Panthers. In the early 1980's, I was diagnosed with gastritis and Barrett's disease of the esophagus. Barrett's is a lesion caused by reflux acid and, if left untreated, will lead to cancer of the esophagus. At that time, Prilosec was not yet available in the United States, and my doctor prescribed Zantac. For awhile my pain subsided, but then it returned. Prilosec had become available, and I was switched to 20 milligrams of Prilosec daily. In those days, my insurance covered the cost with a $20 copayment. Periodic endoscopies showed that the lesions in the esophagus were healing, although the gastritis persisted.

In September of 2001, I was informed by my insurance that it would cover the cost of only 90 capsules of Prilosec per year as the limit, with a $35 copayment. The rest that I needed—I take about 400 a year—had to be paid out of pocket by me. After some comparison shopping, I found that the AARP pharmacy charged $3.96 per capsule, while the local Giant pharmacy charged $4.27 per capsule, including a 10-percent senior discount. The yearly out-of-pocket cost for the required medication comes to about $1,174, or, in my case, close to $1,200.

I am fortunate that we have always lived frugally and have savings to buy the many medications that I must have to prevent cancer. I know of a number of friends who have to choose between buying medications which permit them to live active, productive lives

or living in constant pain. Generic drugs, of course, are the answer for patients who depend on drugs like Prilosec.

AstraZeneca is now promoting Nexium. It no longer provides free samples of Prilosec to physicians. Millions of dollars are spent on advertising to persuade patients to ask their doctors to prescribe Nexium. I find it unethical to have a TV commercial influence my medical treatment. It makes me angry when I see ads in the magazines telling me that I should buy name brands to finance research. Isn't that what NIH is doing?

It infuriates me to know that dozens of lawyers are busy exploiting legal loopholes in the patent laws to postpone the marketing of generic drugs at the expense of people like me.

I have brought some documentation of my case, and you are very welcome to take a look at the color photographs of my insides.

[Laughter.]

Ms. WOLFF. This was the latest endoscopy in July of last year, and it shows that I still have some Barrett's, and it shows the gastritis. So you see, I'm totally dependent on Prilosec.

What really give me heartburn is finding out that AstraZeneca is using every trick in the book to keep more affordable versions of Prilosec off the market. First, they sued 13 generic companies for alleged patent infringement, and that stopped generic approval for the next two and a half years. I hope I will still be around when there is a generic drug available. I'm not so sure.

When the FDA did finally grant approval for the generic alternative, it was months after it should have happened and only after pressure from consumers. Despite the approval, AstaZeneca is dragging out the court case that continues to prevent generics from getting on the market. My insurance company probably would not have cut my annual limit to 90 capsules last year if they were able to pay true competitive prices.

Did you know AstraZeneca makes $11 million from Prilosec sales for every day it can delay competition? Did you know that U.S. consumers have paid more than $1.2 billion extra for Prilosec since the patent expired last October? Did you know that AstraZeneca has switched 35 percent of all Prilosec patients to its next generation, Nexium, a product that, the FDA has found the drug to be no better for the vast majority of patients than either Prilosec or more affordable generic alternatives.

As you can see, I'm a Gray Panther, and the Gray Panthers have organized the 125-member Stop Patient Abuse Now, or SPAN, coalition which is filing class-action lawsuits against companies that exploit consumers and manipulate patent law. We are educating the public and the media about what's at stake with Prilosec and many other drugs, and we are asking Congress to do its part to close the loopholes in the Hatch-Waxman Act. Please return the law to its original intent of providing legitimate prices for the drugs that are so desperately needed by consumers like me.

We want to thank the chairman for holding this hearing and inviting the Gray Panthers to testify. We especially want to thank Senators Schumer and McCain for introducing their legislation. Whether we use the soap box or the ballot box, we must win affordable prescription drugs for all.

I want you all to know that I am really a very private person. But I feel so strongly about this issue that I consented to appear here today. Thank you.

Senator DORGAN. Ms. Wolff, thank you very much. I noted that no one on the panel sought a closer look at the esophagus pictures that you brought.

[Laughter.]

Senator DORGAN. But we wish you well, and we appreciate very much your testimony this morning.

Next we'll hear from Dr. Greg Glover, representing the Pharmaceutical Research and Manufacturers of America. Dr. Glover, you may proceed.

STATEMENT OF DR. GREG GLOVER, M.D., J.D., PHARMACEUTICAL RESEARCH AND MANUFACTURERS OF AMERICA

Dr. GLOVER. Thank you. Mr. Chairman and Members of the Committee, on behalf of the Pharmaceutical Research and Manufacturers of America, I am pleased to appear at this hearing on the Hatch-Waxman Act. I am a physician and an attorney with the law firm of Ropes & Gray specializing in intellectual property and FDA regulatory issues. My testimony will demonstrate that the Hatch-Waxman Act has promoted pharmaceutical innovation and competition, and that S. 812 would undermine this carefully crafted, delicately balanced regime.

The U.S. pharmaceutical market is robust, competitive and working to the benefit of consumers and patients. In fact, it is working as Congress intended when it passed the Drug Price Competition and Patent Term Restoration Act of 1984. Advocates of change have a heavy burden to show that the revisions are needed and that the proposed revisions would not upset the equilibrium of the existing statute.

The generic industry has flourished since Hatch-Waxman eliminated major barriers to market entry. It is today much easier, far less costly, and quicker for low-cost generic drug manufacturers to get their copies of innovator medicines to market following patent expiration. By contrast, the Hatch-Waxman Act provided the research-based pharmaceutical industry, the source of virtually all new drugs in the United States, with only limited incentives to innovate. The act provides, first, a limited period of protection for proprietary data, second, partial restoration of patent life lost during clinical trials and FDA review, and, third, diminished procedures for protecting patents which are presumed to be valid under U.S. law.

As a result of the Hatch-Waxman Act, consumers are receiving the benefits of access to low-cost generic copies as well as an expanding stream of more effective, precise, and sophisticated medicines.

One of the fundamental principles of the Hatch-Waxman Act is that a generic drug should not be able to enter the market if it infringes a valid patent. Moreover, under the Hatch-Waxman Act, the generic applicant is proposing to market a drug that is the same as the pioneers. Indeed, the sameness if the basis for the generic applicant to the use the pioneer's data to demonstrate safety

and effectiveness. If there is a patent-infringement suit, it is based on an effort to market a generic copy of a pioneer product that is covered by a presumptively valid patent.

Congress recognized that it would be preferable to resolve patent infringement disputes prior to FDA product approval for the generic. Accordingly, the act establishes patent litigation provisions that benefit both pioneer and generic manufacturers. These provisions provide for, first, patent listing to notify generics of patents that claim the pioneer's product; second, patent certification to inform pioneers of proposed generic products that may infringe their patents; third, up to a 30-month stay of product approval to allow for resolution of patent infringement claims; and, fourth, a grant of a 180-day period of market exclusivity to the first generic that challenges a listed patent.

We believe that S. 812 reflects unfounded arguments in support of proposals to amend the Hatch-Waxman Act. While these proposals are ostensibly intended to speed approval of generic drugs and enhance pharmaceutical competition, the bill is unlikely to promote either of these objectives. If adopted, S. 812 would substantially undermine the Hatch-Waxman compromise.

Data compiled by the FDA conclusively show that, in the overwhelming majority of cases, generic applications have not raised or encountered any patent issues that have delayed their approval. Out of more than 8,000 generic applications that have been filed with the FDA, fewer than 500 raised any patent issues. Of these, only three of the patent disputes settled between innovator and generic companies have reportedly been challenged by the Federal Trade Commission, an infinitesimally small percentage of all generic applications.

As to our specific concerns regarding S. 812, they are as follows. First, by eliminating the 30-month stay, the bill would severely impair, if not destroy, effective remedies for intellectual property protection by abolishing innovators' rights to litigate patent disputes prior to FDA approval of a generic product.

Second, the bill would also permit the approval of generics that do not duplicate their reference drugs, thereby violating the fundamental premise of the Hatch-Waxman Act that the generic drug must be the same as the innovator drug. And, third, the bill would inhibit submission of citizen petitions offered in good faith to inform the agency of legitimate concerns regarding a proposed generic drug product.

In summary, the Hatch-Waxman Act is one of the most successful pieces of consumer legislation in history. The law works. Contrary to assertions of proponents of S. 812, the bill would not close any purported loopholes. It would undermine the act's few critical protections for innovator intellectual property rights. Without these protections, there will be less innovation, fewer new drugs for generics to copy, and, more importantly, fewer new drugs to enhance treatment for patients.

I'll be pleased to answer any questions the Committee may have.

[The prepared statement of Dr. Glover follows:]

PREPARED STATEMENT OF DR. GREG GLOVER, M.D., J.D., PHARMACEUTICAL RESEARCH AND MANUFACTURERS OF AMERICA

Mr. Chairman and Members of the Committee:

On behalf of the Pharmaceutical Research and Manufacturers of America (PhRMA), I am pleased to appear at this hearing today on the Hatch-Waxman Act. I am a physician and an attorney with the law firm of Ropes & Gray, specializing in intellectual-property and food and drug regulatory issues. PhRMA represents the country's major research-based pharmaceutical and biotechnology companies, which are leading the way in the search for new cures and treatments that will enable patients to live longer, healthier, and more productive lives.

Today, I would like to offer testimony on the importance and success of the Hatch-Waxman Act for promotion of both pharmaceutical innovation and competition, and on why S.812 as currently drafted would undermine this carefully crafted, delicately balanced regime.

PhRMA strongly believes that the U.S. pharmaceutical market is robust, competitive, and working to the benefit of consumers and patients—is working, in fact, as Congress intended when it passed the Drug Price Competition and Patent Term Restoration Act of 1984 (commonly known as the Hatch-Waxman Act after its principal sponsors). We believe that advocates of change have a heavy burden to clearly show that change is needed and would not upset the careful balance achieved by Congress. They have not met that burden.

The U.S. pharmaceutical industry continues to lead the world in pharmaceutical innovation and makes a significant contribution to the country's economy. It is a substantial contributor to the $1.3 trillion health-care sector, which, overall, accounts for about 13 percent of the nation's economic output, is expected to reach 16 percent of output by 2010, and could exceed 20 percent by 2040.

Over the past 100 years, pharmaceutical research has helped transform health care, contributing substantially to an increase of nearly 30 years in life expectancy (from 47 years in 1900 to 76.5 years today). The death rate from disease has fallen by a third from 1.2 per 1,000 in 1920 to 0.8 in 1,000 per 1993, even as people live longer (sometimes succumbing to disease in later life, having benefited from control or elimination of diseases that previously struck earlier in life).

Pharmaceuticals have also brought better lives, conquering infection, making mental illness highly treatable, enhancing independence in old age, and making impressive inroads against cancer, heart disease, stroke and many other diseases. Pioneer pharmaceutical companies continue to play a critical role in addressing old and new challenges, including AIDS and Alzheimer's disease.

Not only are pharmaceuticals worth the cost, they are also cost-effective, adding little to the cost of health care and replacing less effective, more expensive treatments. Over nearly 30 years, total GDP spent on drugs rose little from only 0.84 percent in 1965 to 0.86 percent in 1992. As stated in the President's 2002 Economic Report, there is "a growing body of evidence that, for a wide range of diseases, the additional money spent on treatment is more than offset by savings in direct and indirect costs of the illnesses themselves. Indirect costs include lost productivity and, especially, poor health, which people are clearly willing to pay to avoid."

In a survey concluded this month, funded by PhRMA, of 400 physicians from throughout the country, over 90 percent considered the continuing development of new prescription drugs vital to patient care. In addition, 84 percent believed that prescription drugs have reduced the need for surgery, and 95 percent of these physicians thought that prescription drugs have shortened hospital stays. In addition, eight out of ten of those surveyed acknowledged brand name pharmaceutical companies as deserving the most credit for developing new prescription drugs and breakthrough cures.

The research-based pharmaceutical sector in the United States is, in fact, the single largest global player in the research and development of new drugs, both in terms of new drugs brought to market, and R&D expenditures. The research-based pharmaceutical industry in the United States is responsible for the discovery and development of over 90 percent of new drugs worldwide.

PhRMA companies spend an estimated 17.7 percent of sales on R & D, the highest percentage of any major U.S. industry. The pharmaceutical industry is more research intensive than the electronics, communications and aerospace industries. The typical PhRMA company spends more on research each year than such companies as Microsoft, Boeing, and IBM, as evidenced by a comparison of average research outlays reported publicly by PhRMA member companies and by Microsoft, Boeing, and IBM as stated in their annual reports. National Science Foundation studies have shown that while the pharmaceutical industry recorded only 2.5 percent of the domestic sales of companies that conducted R&D in 1998, it accounted for 8.7 per-

cent of all company-funded R&D, 18.7 percent of all company-funded basic research, and 4.8 percent of all research scientists and engineers.

Research-based pharmaceutical companies allocate nearly 78.5 percent of their R&D expenditures to the research and evaluation of new drug products. The remaining 21.5 percent is devoted to research into significant improvements and/or modifications to existing products. Such significant adjustments can include enhanced efficacy, improved dosage and delivery forms and patient-tailored therapies.

The Hatch-Waxman Act has played a critical role. On the one hand, the generic industry has flourished since the passage of the 1984 compromise law eliminated major barriers to market entry and made it much easier, far less costly, and quicker for low-cost generic drug manufacturers to get their copies of innovator medicines to market following patent expiration.

- Since 1984, the generic industry's share of the prescription-drug market has jumped from less than 20 percent to almost 50 percent.
- Before 1984, it took 3 to 5 years for a generic copy to enter the market after the expiration of an innovator's patent. Today, generic copies often come to market as soon as the patent on an innovator product expires, And sales of pioneer medicines typically drop by 40 percent or more within weeks after generic copies enter the market.
- Prior to 1984, only 35 percent of top-selling innovator medicines had generic competition after their patents expired. Today, almost all innovator medicines face such competition.

On the other hand, the Hatch-Waxman Act provided the research-based pharmaceutical industry—the source of virtually all new drugs in the U.S.—limited incentives to innovate, through restoration of part of the patent life lost by pioneer medicines as a result of regulatory review by the Food and Drug Administration (FDA) and litigation procedures to decrease the likelihood of patent infringing market entry of generic drug products. The research-based industry, spurred by accelerating scientific and technological advances, continues to increase its investment in R&D and to develop new, more advanced, and more effective medicines.

- The research-based industry's investment in pharmaceutical R&D has jumped from $3.6 billion in 1984 to more than $30 billion this year.
- During the 1990s, the research-based industry developed 370 new life-saving, cost-effective medicines—up from 239 in the previous decade.
- The research-based pharmaceutical industry now has more than 1,000 new medicines in development, either in human clinical trials or at FDA awaiting approval. These include more than 400 for cancer; more than 200 to meet the special needs of children; more than 100 each for heart disease and stroke, AIDS, and mental Illness; 26 for Alzheimer's disease; 25 for diabetes; 19 for arthritis; 16 for Parkinson's disease, and 14 for osteoporosis.

These data on generic market entry and pharmaceutical innovation demonstrate that the Hatch-Waxman compromise is both promoting competition and encouraging innovation. As a result, consumers are receiving the benefits of early access to low-cost generic copies and of an expanding stream of ever more effective and precise, sophisticated medicines.

How has the Hatch Waxman compromise both promoted competition and preserved incentives for innovation? A little history helps to explain.

Following amendments made to the Federal Food, Drug, and Cosmetic Act ("FCDA") in 1962, all new drugs had to satisfy strict pre-market approval requirements for both safety and efficacy, and, as a consequence, submit to lengthy FDA approval processes. The substantial safety and efficacy data needed to support the approval of a drug were considered to be trade-secret information that could not be used to approve competing, generic copies. Apart from repeating the long, costly clinical studies performed by an innovator company, a generic applicant could obtain approval only by using a literature-based (so-called "paper") New Drug Application (NDA), which was possible only when published scientific literature demonstrated a drug's safety and effectiveness. As a consequence, prior to 1984, there were few generic copies of pioneer drugs.

To permit the approval of generic copies of all post-1962 drugs, the Hatch-Waxman Act compromise in effect revoked the trade-secret status of innovators' safety and effectiveness information. Instead of proving safety and effectiveness, a generic manufacturer was allowed to show only that its copy is bioequivalent to a pioneer product and that FDA could, therefore, rely on the pioneer's safety and efficacy data

to approve the copy. Bioequivalence means that a copy's active ingredient is absorbed at the same rate and to the same extent as that of the pioneer medicine.

As a result of the Hatch-Waxman Act, generic manufacturers are able to avoid the huge cost (estimated at over $800 million on average) of discovering and developing a new drug. It costs only a very small fraction of that amount for generic manufacturers to demonstrate bioequivalence—which is why they can market their copies at reduced prices. The Act retains only a very limited vestige of the pioneer companies' former, complete proprietary rights in these extremely valuable data. Under the Act, FDA is prohibited from approving generic copies of a pioneer drug for 5 years after approval of an innovator product using a new chemical entities and for 3 years after approval of other pioneer drugs and innovations in existing drugs.

The Hatch-Waxman Act compromise also helped generic manufacturers by overruling the patent infringement standard articulated in a 1984 Court of Appeals decision in *Roche Products, Inc. v. Bolar Pharmaceutical Co.,* the *Bolar* case. In line with prior judicial patent law decisions, the Court had held that it constituted patent infringement for a generic company to manufacture and test a medicine before its patent expired, including for the purpose of preparing a marketing application to submit to FDA. In a unique exception to patent law, the Hatch-Waxman Act compromise allows generic manufacturers to use innovator medicines still under patent to obtain bioequivalency data for their FDA applications so they can be ready to market their copies as soon as the pioneer patents expire.

The Hatch-Waxman Act also sought to increase the number of generic copies by providing an incentive for generic manufacturers to challenge pioneer patents. The first generic manufacturer to certify to FDA that a patent on an innovator medicine is invalid or is not infringed by its product obtains 180 days of exclusive marketing rights if the copy is approved before the patent expires. During that 180-day period, the FDA cannot approve any other copies.

To attempt to balance the generic provisions, the Hatch-Waxman Act compromise provided limited incentives to pioneer companies to help spur innovation. The law restores part of the patent life—but not all—lost by innovator products as a result of FDA review:

- A pioneer drug receives a half-day in restored patent life for every day the product is in clinical trials prior to review by FDA.
- A pioneer drug receives day-for-day restoration of patent life for the time it is under FDA review.
- *However*, the effective patent life of a drug cannot exceed 14 years, regardless of how much time is lost in clinical testing and review. And the total time restored is limited to no more than 5 years (even if more than 5 years is lost during drug development and review).

As a consequence, innovator drugs introduced in the 1990s, even with patent restoration, enjoyed an average effective patent life of less than 11.5 years—substantially less than the 18.5 years enjoyed by inventors of other products. (The full patent term in the U.S., as with all member nations of the World Trade Organization, is now 20 years from the date a patent application is filed with the Patent and Trademark Office).

In addition to partial patent restoration, the law also creates procedures to facilitate the efficient resolution of patent disputes before FDA approves an allegedly infringing generic copy.

One of the fundamental principles of the Hatch-Waxman Act is that a generic drug should not be able to enter the market if it infringes a valid patent. Under U.S. law, patents are presumed to be valid, and this presumption can be overcome only by clear and convincing evidence to the contrary. Moreover, under the Hatch-Waxman Act, the generic applicant is proposing to market a drug that is the same as the pioneer's. Indeed, that "sameness" is the basis for the generic applicant to use the pioneer's data to demonstrate safety and effectiveness. If there is a patent infringement suit, it is based on an effort to market a generic copy of a pioneer product that is covered by a presumptively valid patent.

Failure to resolve patent issues prior to generic product approval presents problems for pioneer and generic manufacturers alike. The marketing of a product that is later determined to be infringing will severely and irreparably injure the pioneer's market at a magnitude that generally cannot be compensated by the infringing generic manufacturer. At the same time, the generic manufacturer is faced with the risk of having to pay crippling actual and enhanced damages for intentional infringement if it decides to market the approved product before the resolution of the patent infringement claim. In short, (in addition to being in the interest of physicians and patients who might otherwise have to address the difficulties associated

with switching from the pioneer to the generic product and back again) it is in the interest of both the pioneer and the generic company to resolve all patent issues before the generic product goes to market.

Congress recognized that it would be preferable to resolve patent infringement disputes prior to FDA product approval. Accordingly, the Act establishes patent litigation provisions to benefit both pioneer and generic manufacturers. These provisions provide for: (1) patent listing to notify generics of patents that claim the pioneer's product; (2) patent certification to inform pioneers of proposed generic products that may infringe their patents; (3) up to a 30-month stay of product approval to allow for resolution of patent infringement claims; and (4) the grant of a 180-day period of market exclusivity to the first generic that successfully challenges a listed patent.

An applicant who submits a New Drug Application ("NDA") must submit information on each patent that "claims the drug or a method of using the drug . . . and with respect to which a claim of patent infringement could reasonably be asserted if a person not licensed by the owner of the patent engaged in the manufacture, use, or sale" of the drug.

FDA publishes the submitted patent information in its official publication, *Approved Drug Products with Therapeutic Equivalence Evaluations* (the "Orange Book"). The purpose of the Orange Book listings is to provide clear notice to potential generic developers of the patents (other than process patents) that cover the product and may reasonably be asserted by the innovator against the generic drug manufacturer. In doing so, it serves to protect the interests of both pioneer and generic manufacturers.

Correspondingly, the need for patent certifications arises from the legislative intent: (1) to permit the marketing of generic copies of pioneer products immediately upon the expiration of any relevant patents; (2) to encourage generic challenges of innovator patents; (3) to provide a timely, effective mechanism for patent holders to protect rights in patents alleged to be invalid or not infringed by the generic product; and (4) to prohibit FDA's approval of any abbreviated application whose marketing would infringe a valid patent covering the pioneer product, until the parties have had a meaningful opportunity to attempt to resolve the issue.

The certification requirements determine the date on which approval of an ANDA can be made effective and, therefore, the date on which commercial marketing may begin. If the applicant makes either the first certification option (no patent information has been filed) or the second (the patent has expired), approval can be made effective immediately. Under the third certification option, (generic applicant does not intend to market the generic drug until the patent expires) approval of the application can be made effective on the date the patent expires. If, however, the applicant challenges the innovator's patent and makes the fourth certification (a "Paragraph IV" certification), the applicant is required to give notice to the holder of the patent alleged to be invalid or not infringed.

Approval of an ANDA containing the fourth certification may become effective immediately only if the patent owner has not initiated a patent infringement suit within 45 days of receiving notice of the certification. If the patent holder initiates a patent infringement action in response to a Paragraph IV Certification within 45 days of receiving notice of the certification, FDA cannot approve the ANDA for 30 months, unless either the action is resolved in favor of the generic applicant or the patent expires before that time.

The first follow-on (generic) product approved through an ANDA containing a Paragraph IV Certification receives 180 days of market exclusivity during which no subsequent ANDA for the same product can be approved. The purpose of the 180-Day ANDA exclusivity is to reward a generic drug manufacturer for the expense and effort involved in challenging a listed patent of the pioneer company. Despite these intentions, however, the 180-day provision has been at the heart of most controversies under the Hatch-Waxman Act.

Although the Hatch-Waxman compromise stimulates competition and provides only limited incentives for the innovation upon which pioneer and generic pharmaceutical companies alike depend for new products to offer to consumers, generic manufacturers are advocating major changes in the legislation. We believe that, in view of the balanced nature of the law, any proponent of change has a heavy burden to clearly demonstrate that change is necessary and would not upset the delicate compromise achieved in 1984. We do not believe this burden has been met with regard to any of the changes that have been proposed. Therefore, we strongly oppose such changes that would unfairly skew the law in favor of generic manufacturers and impede the ability of the research-based industry to realize in a timely way the promises that accelerating biomedical advances hold for patients in all parts of the world.

We believe that S. 812 as it stands, reflects the unfounded arguments in support of proposals to amend the Hatch-Waxman Act. While these proposals are, ostensibly intended to speed approval of generic drugs and enhance pharmaceutical competition, the bill is unlikely to promote either of these objectives, and, if adopted, would substantially undermine the Hatch-Waxman compromise that has proven so successful.

Specifically, as elaborated more fully below, S.812 would: (1) deny effective remedies to holders of patents infringed by generic drugs; (2) change the standards to allow FDA to approve generic drugs that could not be approved under current law because they are not, in fact, the same as the innovator drugs for which FDA has the data necessary to assess safety and efficacy; and (3) create new requirements designed to deter outside parties from submitting scientific information to FDA that could be adverse to generic drugs. In addition, the bill would revise the current system for rewarding generic companies that challenge patents on innovator drugs in a way that would result in unnecessary litigation and keep many generic drugs off the market for a 6-month period.

As an initial point, it is critical to understand that, despite arguments to the contrary, data compiled by FDA conclusively show that, in the overwhelming majority of cases, generic applications have not raised or encountered any patent issues that have delayed their approval. The facts speak far themselves:

- From 1984 through January 2001, *8,259 generic applications* were filed with FDA.
- Of these applications, 7,781—*94 percent*—raised no patent issues.
- Only 478 generic applications—*5.8 percent*—asserted a patent issue, either challenging a patent's validity or claiming non-infringement of a patent.

Further research shows that:

- Only 58 court decisions involving *just 47 patents* have been rendered resolving generic challenges to innovator patent's—a tiny fraction of the number of generic applications.
- *Only 3* of the patent disputes settled between innovator and generic companies have reportedly been challenged by the FTC—an infinitesimal percentage of the applications.

As to our specific concerns regarding the proposals made in S. 812, they are as follows:

First, the bill would severely impair, if not eliminate, effective remedies for patent infringement.

As explained above, under current law, FDA is barred for up to 30 months from approving a generic drug that is involved in timely initiated patent litigation. The Hatch-Waxman Act made it no longer an act of patent infringement for a generic company to use a pioneer company's patented product in preparing the marketing application for its generic copy of that product. (Such otherwise-infringing testing is not, in fact, permitted in any other U.S. industry.) Patent holders are not permitted to assert their rights against generic applicants during this period. Now, a claim for patent infringement cannot be brought until the generic company actually files its application. The 30-month stay increases the likelihood that a pioneer company will still be able to defend its patent rights before FDA approval enables an allegedly infringing generic product to come onto the market.

S. 812 would simply abolish the innovator's right to litigate patent disputes prior to FDA approval. Although an innovator could still theoretically seek a preliminary injunction from the court against the generic product, courts rarely grant preliminary injunctions in patent litigation, and such injunctions are especially difficult to obtain in the pharmaceutical patent context due to the highly complex and technical, fact-intensive claim analysis required. As a result, even though generic companies would continue to enjoy the benefits of the Hatch-Waxman Act that were created at the expense of innovator companies, the innovator industry would be denied the corresponding, necessary means provided in the Act to protect against patent infringement because of this unique privilege granted to generic companies.

The bill would also permit the approval of generic drugs that do not, in fact, duplicate their reference drugs. Present law prohibits the use of studies, other than bioequivalence data, to support an abbreviated new drug application for a generic drug. The premise of the law is that the generic drug must be the same as the innovator drug in all material respects, and therefore the only issue is showing that it is absorbed by the body at the same rate and to the same extent as the innovator drug. S. 812 would loosen the standards and allow FDA to approve generic drugs

that are not the same as the reference innovator drugs, substituting FDA judgment that some unspecified differences don't matter for the current objective requirement that generic drugs must be the same as the reference innovator drugs.

In light of problems that have arisen even with application of the existing bioequivalence standard, we are quite concerned by this proposal. In this regard, we would note that two-thirds of physicians surveyed, as discussed above, considered changing bioequivalence standards to be a bad idea, primarily because of the importance of maintaining the quality of the drugs and protecting the safety of their patients.

In addition, the bill would inhibit the submission of citizen petitions offered in good faith to inform the Agency of legitimate concerns regarding a proposed drug product.

S. 812 would impose new burdens on use of the citizen petition, which is the mechanism by which an outside party can request an official FDA decision on a scientific or other issue. Under the bill, it appears that the Federal Trade Commission (FTC) may be *required* to open an investigation of any person submitting a citizen petition to FDA if anyone alleges that the citizen petition has been submitted for an improper purpose.

Such mechanisms would deter persons from submitting citizen petitions to the FDA containing scientific or other relevant information regarding a competing product, since an FTC investigation, accompanied by a subpoena for documents, would seem to be the inevitable and immediate result. Congress and FDA should welcome a process for airing scientific issues, rather than trying to inhibit discussion. If a party were to submit a baseless citizen petition to achieve an anti-competitive effect, the existing anti-trust laws would provide ample bases for the FTC, or a private party, to bring an enforcement action. S. 812 would serve only to chill legitimate petitioning, to the detriment of the FDA approval process, undermining the legitimate economic interests of competitors and, potentially, putting consumers at risk.

The bill would as well revise the requirements for obtaining generic drug exclusivity in a manner that would keep more rival generic products off the market longer and promote unnecessary litigation. In an apparent inconsistency with its stated objective of speeding generic drug approvals, S. 812 would enhance the ability of the first generic drug company that challenges an innovator patent to keep all other generic products off the market for six months. A provision for six months of exclusivity exists in current law but has been made less capable of keeping other generics off the market. S. 812 would overrule those decisions.

In summary, the Hatch-Waxman Act is one of the most successful pieces of consumer legislation in history. The law works. Contrary to the assertions of others, S. 812 would not close loopholes, it would undermine the Act's few, critical protections for innovator intellectual property rights. Without these protections, there will be less innovation, fewer new drugs for generics to copy and, more importantly, fewer new drugs to enhance treatment for patients.

This concludes my written testimony. I would be pleased to answer any questions or to supply any additional materials requested by Members or Committee staff on these or any other Issues.

Senator DORGAN. Dr. Glover, thank you very much.

Next we will hear from Ms. Kathleen Jaeger—I hope I'm pronouncing that correctly—president and chief executive officer of Generic Pharmaceutical Association. Ms. Jaeger, why don't you proceed?

STATEMENT OF KATHLEEN JAEGER, R.PH., J.D., PRESIDENT AND CHIEF EXECUTIVE OFFICER, GENERIC PHARMACEUTICAL ASSOCIATION; KAREN WALKER, COUNSEL, GENERIC PHARMACEUTICAL ASSOCIATION

Ms. JAEGER. Thank you. Mr. Chairman, distinguished Members of the Committee, thank you for your leadership in calling for this hearing and for the opportunity to testify. My name is Kathleen Jaeger, and I'm the president and CEO of the Generic Pharmaceutical Association. Also with me today is Karen Walker, counsel to the organization. She will be available to answer any FTC-related questions the Committee member may have.

While I represent the interests of the industry, I'm also speaking to you as a mother of three young children, as a pharmacist who grew up in a family owned pharmacy, and as an attorney. We are here today, not to debate the brand-versus-generic issue, but rather the issue of how we can better restore the balance between fostering innovation and increasing competition. There is an extraordinary and growing momentum for change. A coalition of leading consumers and aging advocacy groups, businesses, unions, insurers, pharmacists, and Governors are all raising concerns about the lack of accessible, affordable medicine. The time for action is now.

One solution is clear: the use of affordable generic alternatives. Generics already save this nation billions of dollars a year. As Senator Rockefeller noted previously, nearly one in every two prescriptions was filled with generic, but only about 8 percent of all dollars spent on drugs was spent on generics. Conversely, brand-name drugs represent 55 percent of all prescriptions dispensed, but consume approximately 92 percent of all prescription costs. Generics could save more. One percent increase in the usage of generic drugs would yield an additional billion dollars in prescription drug savings.

Congress can encourage this by supporting education and by creating insurance benefits for public programs. But Congress and should do more. Congress can guarantee countless billions of dollars of additional savings by restoring the balance and intent of the Hatch-Waxman Act. Signed into law in 1984, Hatch-Waxman may be one of the most important pro-consumer, pro-competitive legislation ever passed. But most recently, brand companies have exploited loopholes that delay or block generic competition.

Under the bipartisan leadership of Senator Schumer and Senator McCain in the Senate, and Representatives Brown and Emerson in the House, thoughtful legislation has been drafted that would, one, eliminate the enormous financial windfall that flows from the automatic stay of the 30-months provision; two, preserve the incentives to challenge questionable patents; and, three, provide other measures that enhance competition.

We believe reforming Hatch-Waxman could encourage the brand industry to refocus its efforts on true product innovation while also increasing access to affordable medicines. Those who argue against restoring the balance under Hatch-Waxman are, unlike most purchasers of prescription drugs, quite comfortable with the status quo. The brand industry certainly will not acknowledge that long overdue reform of Hatch-Waxman will actually refocus the brand industry on true R&D innovation and away from legal loophole innovation.

At most legislation could stop abuses and restore the balance between innovation, competition, and access that Hatch-Waxman was designed to address. Strengthening the Hatch-Waxman in ways that restore the intended balance and closing unintended loopholes is one way. Increasing utilization of affordable generic medicines is another.

I would like to thank you for the opportunity to speak for the generic industry and the consumers we serve. Again, we thank Chairman Hollings and Senator Dorgan, for holding this hearing, as well as Senator McCain and Senator Schumer for their leadership on

this issue. I'd be remiss if I didn't mention the work of Senator Rockefeller, Senator Edwards, and Senator Carnahan and others to address the lack of affordable medicines, one of the greatest social problems of our time.

I'd be happy to take any questions.

[The prepared statement of Ms. Jaeger follows:]

PREPARED STATEMENT OF KATHLEEN JAEGER, R.PH., J.D., PRESIDENT AND CHIEF EXECUTIVE OFFICER, GENERIC PHARMACEUTICAL ASSOCIATION; KAREN WALKER, COUNSEL, GENERIC PHARMACEUTICAL ASSOCIATION

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 percent 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 percent 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 percent of all dollars spent on drugs were spent on generic medicines. Brand name prescription drugs, conversely, represented 55 percent of all prescrip-

tions but consumed approximately 92 percent 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 percent.

Expressed another way, brand name prescription drugs represent about 22 percent more prescriptions than generic drugs yet consume almost 500 percent 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 percent of the labor force by 2009 (up from 23 percent 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 percent did not purchase at least one prescription issued by their doctor in the previous year because of cost. Additionally, 14 percent of patients reported taking a drug in smaller doses than prescribed and 16 percent 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 5 "reasonable." We should not be drawn into the false argument that it is necessary for the pharma-

ceutical 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) 6 months of pediatric exclusivity for the study, and (2) 3 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 it's 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 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 con-

verting 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 2½ 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 Plantinol® 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 believes that the patent challenge provisions of Hatch-Waxman, with their180-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 ge-

neric medicines. Thank you. I would be happy to respond to any questions you may have.

Senator DORGAN. Ms. Jaeger, thank you very much.

Next we will hear from Mr. Steven Martin, who is the president and chief executive officer of Nebraska BlueCross BlueShield. Mr. Martin, you may proceed.

STATEMENT OF STEVEN MARTIN, PRESIDENT AND CHIEF EXECUTIVE OFFICER, BLUE CROSS AND BLUE SHIELD OF NEBRASKA

Mr. MARTIN. Thank you, Mr. Chairman and Members of the Committee.

I currently serve as president and chief executive officer of Blue Cross and Blue Shield of Nebraska. Previously I was president and chief executive officer of Prime Therapeutics, Inc., administrator of pharmacy benefits in the States of Minnesota, North Dakota, Nebraska, Kansas, and Wyoming, which is the largest administrator of benefits in those states and a national administrator of benefits. It was also founded by those respective BlueCross plans to begin to understand the problems of pharmacy cost escalation and some of the potential solutions.

I thank you for the opportunity to testify on behalf of the Blue Cross and Blue Shield Association on this important issue of consumer access to generic drugs. Blue Cross/ Blue Shield Association represents 43 independent Blue Cross/ Blue Shield plans through the nation that together provide health coverage for 83 million, one in four, Americans.

Because pharmaceuticals are a key component in preventing and treating disease, Blue Cross/Blue Shield plans offer drug benefits to their members. Americans want a robust pharmaceutical industry with strong research and development, but they also want affordable prescription drugs. Our constant challenge is to provide a meaningful level of coverage for prescription drugs while keeping premiums as affordable as possible.

However, the cost of drug benefits is high and is accelerating at up to 20 percent per annum in our respective plans. As a result, drugs today account for a growing share of BlueCross/BlueShield plans total medical costs and our members premiums. BlueCross BlueShield plans employ a range of techniques to keep drug coverage affordable. Several of these methods are outlined in my written testimony.

In spite of our efforts, however, employers are telling us it's not enough. In fact, I just returned from touring the State of Nebraska, where I met with most of our employers, our large groups and associations. And without exception, every major employer, group, and association I met with is working on reexamining their prescription drug coverage.

Unfortunately, those employers, groups, and associations are looking to increase the copayments and cost contributions of our members as a way to control the ever-rising costs of coverage so that they can continue to offer a broad-based coverage to the members in their respective groups. This reality and its impact on healthcare coverage availability and affordability is exactly why today's hearing is so important.

We want to assure that health plans and employers have enough resources to pay for future breakthroughs in drugs and medical technology, so we are looking beyond benefit design to other ways to address these skyrocketing drug costs. We believe the most obvious way is to ensure that lower cost, safe and equally effective generic drugs get to market when they should.

A generic drug typically enters the market priced about 30 percent below its brand counterpart. Within 2 years, the average price of the generic drops, until it's about 75 percent less than the brand competitors. According to the Congressional Budget Office, the use of generics in place of brand names could save consumers between $8 billion and $10 billion each year. BlueCross BlueShield plans believe the best way to lower prescription drug costs is to encourage appropriate and vigorous competition in the marketplace by improving access to generics.

We urge Congress to pass the Greater Access to Affordable Pharmaceuticals Act. This legislation, sponsored by Senators John McCain and Charles Schumer, and in the House, by Representatives Sherrod Brown and Jo Ann Emerson, would improve access to generic drugs in several ways. Most significantly, it would eliminate barriers to market entry, including the automatic 30-month stay of FDA review where generic application which is triggered as soon as the brand manufacturer files suit. By passing legislation that promotes vigorous competition in the prescription drug market by improving access to generic drugs, Congress will ensure that healthcare coverage remains available and affordable to consumers.

Thank you again for the opportunity to testify today. I'll be happy to address any questions.

[The prepared statement of Mr. Martin follows:]

PREPARED STATEMENT OF STEVEN MARTIN, PRESIDENT AND CHIEF EXECUTIVE OFFICER, BLUE CROSS AND BLUE SHIELD OF NEBRASKA

Mr. Chairman and Members of the Committee, I am Steve Martin, President and Chief Executive Officer of Blue Cross and Blue Shield of Nebraska. BCBS Nebraska provides health care coverage to more than 640,000 (one in three) Nebraskans.

Prior to joining Blue Cross and Blue Shield of Nebraska last month, I was President, and CEO for Prime Therapeutics, Inc. of Eagan, Minnesota. Prime Therapeutics, Inc. is a pharmacy benefits management company (PBM) owned by five Midwestern Blue Cross Blue Shield plans.

Today, I am testifying on behalf of the Blue Cross and Blue Shield Association (BCBSA). CBSA represents the 43 independent Blue Cross and Blue Shield Plans throughout the nation that together provide health coverage to 83 million—one in four—Americans. I appreciate the opportunity to testify on the important issue of consumer access to generic drugs.

Blue Cross and Blue Shield Plans have extensive experience in providing prescription drug coverage to both working and retired Americans.

- BCBS Plans offer health coverage to working and retired Americans through a variety of managed care and indemnity products, including health maintenance organizations (HMOs), preferred provider organizations (PPOs) and point of service (POS) plans. Nearly all of these plans provide prescription drug benefits to their members.
- Collectively, BCBS Plans provide Medicare HMO options to more than one million Medicare beneficiaries, making them collectively the largest Medicare+Choice (M+C) contractor in the country. Most of BCBS M+C plans provide some coverage for outpatient prescription drug to their M+C members, although continuation of this coverage is a challenge given overall problems with continued funding of this program.

- Blue Cross and Blue Shield Plans underwrite and deliver the government-wide Service Benefit Plan under the Federal Employee Health Benefits Program (FEHBP). It covers over two million contracts and more than four million lives. The Service Benefit Plan provides outpatient prescription drug benefits to its members, many of whom are retired.

Our constant challenge is to provide a meaningful level of coverage for prescription drugs while keeping premiums as affordable as possible.

In my testimony today, I will address three areas:

- Background on the skyrocketing costs of prescription drugs;
- The critical role of generic drugs in keeping health care coverage available and affordable and how BCBS Plans promote appropriate generic drug usage; and
- Legislative changes needed to promote vigorous competition in the prescription drug market.

I. Background on Prescription Drug Cost Trends

Prescription drugs have significantly increased Americans' life span and contributed to their improved health status in the 20th century. Because pharmaceuticals are a key component in preventing and treating disease, BCBS Plans offer pharmacy benefits to their members. However, the cost of drug benefits is high and accounts for a growing share of BCBS Plans' total medical costs and our members' premium dollars. Our Plans are experiencing up to 20 percent increases in prescription drug costs each year. BCBSA expects these costs to continue to grow rapidly.

Factors Contributing to Increased Prescription Drug Spending

While BCBS Plans use a range of strategies to manage growing prescription drug costs on behalf of their subscribers, spending is being propelled by a number of market and structural forces over which private insurers have little control. Some of the most significant forces are the following:

Demographic Trends

As the U.S. population ages, the number of people at risk for chronic and disabling diseases is rising dramatically. The single largest market for prescription drugs is the aging baby boom generation. According to U.S. Census data, the 54–to–64 age group will expand by 59 percent between 1998 and 2010. The drugs used by the middle aged and elderly tend to be expensive and often treat chronic conditions, such as hypertension, high cholesterol, diabetes and arthritis, which require a steady regimen throughout the patient's remaining life.

Rapid Flow of New Drugs to Market

Over the past decade, many new prescription drugs have come to market. One of the most robust measures of the flow of pharmaceutical technology is the annual number of new molecular entities (NMEs) approved by the FDA. NMEs are compounds that have never before been marketed in this country. Over the course of a generation—from the early 1960s to the mid 1990s—the annual number of new molecular entities (NMEs) receiving FDA approval nearly doubled. From an average of 13.7 in the 1960s, annual NME approvals rose to 25.6 in the first half of the 1990s and to 36.8 by the end of the decade.

Some of these new drugs are "breakthrough" products, which treat diseases and conditions that previously lacked effective therapies. Others are differentiated from older drugs only by having slightly less prevalent side effects, or different dosing forms. Physicians tend to adopt such new drugs rapidly, and direct-to-consumer advertising also increases their rate of market penetration. While these new products often provide important clinical benefits, they also increase health insurance premiums. Blues Plans have a longstanding commitment to provide coverage for clinically sound, effective services while finding ways to keep premiums affordable.

The National Institute for Health Care Management (NIHCM) recently released a report on trends in pharmacy spending for 2001. This report—subtitled "Another Year of Escalating Costs"—examines the growth of retail prescription drug sales. The report found that:

- Spending on outpatient prescription drugs dispensed through U.S. retail stores and pharmacies grew 17.1 percent from 2000 to 2001, from $131.9 billion to $154.5 billion. This represents the fourth straight year that spending on prescription medicines escalated 17 percent or more.
- Price increases were a more substantial component of the rise in drug spending in 2001 than in the previous year, accounting for 37 percent of the spending.

The average price of a prescription bought at a retail pharmacy rose 10 percent from 2000 to 2001, to $49.84 from $45.27.

- A shift to prescribing more expensive medicines was responsible for 24 percent of the rise in drug spending in 2001.

We expect the flow of new drug technology to continue. Over the past two decades, the pharmaceutical industry and the federal government, through the National Institutes of Health, have made massive investments in research and development. For example, the Pharmaceutical Research and Manufacturers of America (PhRMA) has estimated that the pharmaceutical industry spent $30.3 billion in R&D in 2001. This represents more than three times the amount, $8.4 billion, that private industry invested in pharmaceutical R&D in 1990, and is a 16.6 percent increase over the 2000 level.

Therefore, we want to assure that health plans and employers have enough resources to pay for all of the new breakthroughs in drugs and medical technology expected over the next several years.

Direct-to-Consumer Advertising of Prescription Drugs

Over the past decade, direct-to-consumer (DTC) advertising has revolutionized the marketing of prescription drugs. Traditionally, such advertising was limited to medical journals and trade publications aimed at physicians. Since 1985, when the FDA lifted its moratorium on promotion directed to consumers, this form of advertising has exploded, and since the agency relaxed its regulation of broadcast advertising in 1997, TV ads for prescription drugs have proliferated. In 1991, pharmaceutical companies spent $55.3 million to promote prescription products directly to consumers. According to NIHCM, outlays on DTC advertising in 2000 were $2.5 billion, more than double what was spent in 1997.

DTC advertising can promote the public health by encouraging patients with undiagnosed and untreated conditions to see their doctor. However, this consumer demand also contributes to health benefits costs. Surveys of both consumers and physicians show that DTC ads for prescription drugs are effective in stimulating demand for branded products.

For example, preliminary results of a new survey by the FDA indicate that patients who ask their physicians for a specific brand-name drug usually get a prescription for that medication. The survey found that nearly 25 percent of survey respondents asked their doctor for a specific brand-name drug, and 69 percent of those patients ultimately received a prescription for that drug. By comparison, 41 percent of respondents who asked their doctors about any drug were given medication by their doctor. The full FDA survey is expected to be released later this month.

II. Generic Drugs Play a Critical Role in Keeping Health Care Coverage Available and Affordable

Generic drugs are subject to rigorous review by the FDA to ensure that they are as safe and effective as their brand-name counterparts. Once approved for marketing, generic drugs offer consumers, employers and insurers significant savings compared to brand drugs. Generic drugs play a critical role in keeping health care coverage available and affordable.

Generic Drug Safety

The first phase of new drug development—preclinical research—involves laboratory and animal testing of the compound and is primarily aimed at establishing safety. If successful, the brand manufacturer can then file an Investigational New Drug Application with the FDA. At the successful completion of lengthy human clinical trials, the brand manufacturer files a New Drug Application submission with the FDA seeking to bring the new compound to market. This rigorous process also is the basis for the generic drug application.

The generic manufacturer relies on the underlying safety and efficacy data supplied by the brand manufacturer when it submits its application to the FDA for approval. The generic manufacturer must demonstrate in its application that the generic drug is equivalent to the branded product based on bioavailability and/or bioequivalence studies. When compared to brand-name drugs, FDA-approved generic drugs must have the:

- *same* active ingredients,
- *same* dosage form,
- *same* standards for purity and quality,
- *same* standards for manufacturing,

- *same* amount of drug absorbed over the same time, and
- *same* clinical effect.

The only significant difference between generic drugs and their brand name counterparts is price.

Generic Drugs Create Billions of Dollars in Savings

Every day, the choice of generic products creates substantial savings for consumers. Typically, a generic drug enters the market priced 30 percent less than its brand counterpart. Within two years, as more generics enter the market, the average price of the generic version of a drug drops until it is 75 percent less than the brand. According to the Congressional Budget Office estimates, the use of generics in place of brand names could save consumers between $8 billion and $10 billion each year.

As the Administration and Congress continues to work to develop a new Medicare prescription drug benefit, a new study finds that if such a program is enacted, it potentially would save $14 billion in 2003 and $250 billion during the next 10 years by increasing the rate of generic drug usage. The study, "Greater Use of Generics: A Prescription for Drug Cost Savings," was sponsored by the Generic Pharmaceutical Association and conducted by researchers from Brandeis University. It concludes that Medicare could achieve these savings by using generic pharmaceutical incentive techniques currently used in the private sector.

Generic Drug Market Penetration

Although generic drugs have the same safety and effectiveness profile as their brand counterparts and can produce significant cost savings for consumers, they have a low rate of market penetration.

According to NIHCM, only five generic drugs were among the 50 best-selling drugs in 2001. Data from the Generic Pharmaceuticals Association indicate that generic drugs made up approximately 42 percent of all prescriptions dispensed at the retail level but accounted for only approximately 8 percent of the $141 billion spent on prescription drugs in 2000. Stated another way, brand name drugs, representing 58 percent of all prescriptions, accounted for 92 percent of the total retail cost of prescription drugs in 2000.

Using Benefit Design to Encourage Appropriate Use of Generic Drugs

BCBS Plans have experienced a rapid acceleration in prescription drug costs over the past few years. BCBSA expects pharmacy costs to continue to rise, propelled by the medical needs of an aging population, the flow of new technology, and strong consumer demand. As this occurs, health insurers will need to manage prescription drug benefits as effectively as possible in order to keep premiums affordable. Some of pharmaceutical benefit management tools our Plans use to promote the use of generics and control costs include:

Tiered Copayment Plans

Blue Cross and Blue Shield Plans design their pharmacy benefits to ensure consumers have access to appropriate medications. One approach to achieving this objective is the tiered copayment plan. Now popular among nearly all health plans, tiered benefit designs provide financial incentives to encourage members to make cost effective drug purchases. Under these programs, plan members have more choices available to them than they would under more traditional benefit designs, but they pay a higher share of the cost of expensive drugs that have safe and effective, but less costly, alternatives. The intent is to encourage members to use drugs that are both clinically efficacious and cost effective.

Three-tiered structures, which classify drugs into three categories with differing levels of copayment (or coinsurance), are often structured as follows: Tier 1 consists of generic drugs, and has the lowest copayment/coinsurance. Tier 2 contains branded drugs that are clinically effective, cost effective, and meet the needs of most patients; these drugs require a moderate copayment/coinsurance. Tier 3 drugs, with the highest copayment/coinsurance, generally include branded drugs with a generic equivalent or branded therapeutic equivalent in Tier 2.

Step Therapy Programs

Another approach to ensuring cost-effective appropriate drug coverage is the use of step therapy programs. Thanks to continued innovation on the part of the pharmaceutical industry, multiple drug therapies now exist to treat many health conditions. Step therapy is a type of protocol that specifies a sequence of different therapies, including prescription drugs, for a given medical condition. Hypertension, for example, can be treated with dozens of different drugs, some of which have generic

counterparts, some of which do not. Under step therapy, a patient with hypertension would be treated first with medications (generics, where available) known to be safe and effective for this condition. The patient would remain on those medications if they prove effective in managing the hypertension. If not, more innovative treatments would be tried.

Physician Education

Health plans must work hand-in-hand with physicians to make these programs a success. For example, to support step therapy programs, a number of health plans share data with their participating physicians that compare their prescribing patterns to those of their peers. In regular meetings with network physicians, health plans can review these data and encourage physicians to adopt a step therapy approach where appropriate.

BCBS Plans' experiences confirm the savings derived from improved generic access. One Plan reported that just a one percent increase in generic drug utilization for the 760,000 people covered results in a $3 million savings in drug costs per year.

As such, BCBS Plans strive to promote appropriate generic utilization through innovative programs. For example, Blue Cross Blue Shield of Michigan is launching a $1 million public awareness marketing campaign using the slogan "generic drugs: the unadvertised brand, " to increase consumer awareness of the quality and value of generic drugs.

As a result of this campaign and other initiatives to support appropriate use of generic drugs, Michigan Plan members saved about $13 million on an annualized basis. In addition, the initiative is believed to have generated annualized savings of as much as $25 million statewide.

Despite the implementation of a range of benefit management tools and innovative consumer education campaigns about the safety and value of generic drugs, BCBS Plans continue to experience unsustainable prescription drug costs. In fact, I just returned from touring the state of Nebraska and every major employer, group and association has been re-examining their coverage. Employers are having to increase out-of-pocket costs for drugs and employees will be expected to pay more. This reality, and its impact on health care coverage availability and affordability, is exactly why today's hearing is so important.

III. Legislative Changes Are Needed to Promote Vigorous Competition in the Prescription Drug Market

BCBS Plans believe the best way to lower prescription drug costs is to encourage vigorous competition in the marketplace by improving access to generics. BCBSA urges Congress to pass the Greater Access to Affordable Pharmaceuticals Act (GAAP). This legislation, sponsored by Senators John McCain and Charles Schumer and in the House by Representatives Sherrod Brown and Jo Ann Emerson, would:

- Improve access to generic drugs by eliminating barriers to market entry, including the automatic 30-month stay of FDA review of a generic application which is triggered as soon as a brand manufacturer files suit;
- Accelerate generic drug competition by transferring the market exclusivity granted to the first eligible generic applicant to other applicants if the former does not go to market; and
- Strengthen the citizen petition process by curbing abuses that delay competition in the marketplace.

Eliminate Barriers to Generic Drugs: 30-Month Stay

Several provisions of current law have the unintended consequence of delaying market entry of generic drugs. First, consumer access to generics is often delayed for 30 months because the law requires the FDA to automatically defer approval of a generic application if the brand manufacturer sues for patent infringement, costing consumers billions. The GAAP bill would eliminate the automatic 30-month stay, and brand manufacturers would retain the ability to seek a preliminary injunction from the courts to protect their interests.

A second barrier to generic market entry is created when brand manufacturers list patents with the FDA as late as a year or more after a generic application has been filed—which triggers a 45-day window during which a lawsuit to resolve the patent status can be filed. Brand manufacturers can and do use this strategy to delay generic competition because they currently are not required to list all patents with the FDA. The GAAP bill would remove this barrier by requiring brand manufacturers to list all patents for which an infringement claim could reasonably be asserted and to certify to the FDA that the listing is complete and accurate, to prevent unforeseen infringement suits.

A third barrier to market entry for generic drugs is the aforementioned 45-day period allowed for a brand manufacturer prior to suing a generic company for patent infringement. During the waiting period, a generic company's right to market its product is unprotected, discouraging market entry. The GAAP bill would allow generic manufacturers to seek a declaratory judgment that their product will not violate any patent listed with the FDA, expediting consumer access to affordable medicines if the challenge is successful.

In addition, under the GAAP legislation, if a patent is listed a year or more after a generic application is submitted, generic manufacturers could bypass the 45-day waiting period and immediately seek a declaratory judgment of invalidity or noninfringement for any patent listed with the FDA.

Accelerate Generic Drug Competition: 180-Day Exclusivity

Current law grants a 180-day period of market exclusivity to the first generic applicant who certifies that the patents on the brand product it intends to copy are either invalid or will not be infringed by the manufacturing and marketing of a generic version of the drug. However, the 180-day period does not begin until the first applicant goes to market or litigation surrounding the certification is resolved. In the interim, all other generic applicants are kept out of the market. For this reason, brand name drug manufacturers have an incentive to pay the first generic applicant to stay out of the market, preventing competition among generic companies and delaying consumer access to generics for an extended period.

The GAAP bill allows the 180-day market exclusivity rights to become available to the next-to-file generic applicant if the previous applicant meets one of several conditions, including reaching a financial settlement with the brand name drug manufacturer to stay out of the market until the patents have expired.

Strengthen the Citizen Petitions Process

The citizen petition process is an important vehicle for public concerns regarding a drug's approval, but it is subject to abuse by those seeking to delay competition in the marketplace.

The GAAP bill would require the FDA to instruct the Federal Trade Commission to investigate any citizen petitions submitted to the FDA that are suspected of being filed for anticompetitive purposes. The bill also would require petitioners to notify the FDA whether the petitioner has received, or will receive, consideration for filing the petition and to identify the party furnishing consideration.

BCBSA Strongly Supports the GAAP Bill

BCBS Plans strongly support the GAAP bill because its provisions would encourage vigorous competition in the prescription drug marketplace. BCBSA has endorsed the bill and has organized a Coalition to focus solely on moving this bill forward. The Coalition includes representatives from large businesses, unions, consumer groups, the insurance industry, and generic drug manufacturers.

In addition, BCBSA is sponsoring research to highlight the costs to consumers of delayed access to generic drugs.

IV. Conclusion

Health plans have developed a number of strategies for addressing the rising cost of prescription drugs, with some success. However, as drug costs continue to skyrocket, Congress must re-examine current laws that contribute to rising costs. Legislation such as GAAP that promotes vigorous competition in the prescription drug market by improving access to generic drugs will assure that health care coverage remains available and affordable for consumers.

Thank you again for the opportunity to testify today.

Senator DORGAN. Mr. Martin, thank you very much.

Finally, we will hear from Ms. Shelbie Oppenheimer, from the ALS Association. Ms. Oppenheimer, you may proceed.

STATEMENT OF SHELBIE OPPENHEIMER, ALS ASSOCIATION

Ms. OPPENHEIMER. Thank you, Mr. Chairman and distinguished Committee Members. My name is Shelbie Oppenheimer, and I'm grateful to have been invited here to share with you what I think is an important perspective on generic versus innovative drugs.

To me, this debate is more important than policy, law, and politics. It's about the reality of life and health and death. I have a disease that cannot be cured today, Amyotrophic Lateral Sclerosis, ALS, also known as Lou Gehrig's Disease. It's a progressive disorder that causes my motor nerve cells to die. And as a result, I am steadily losing muscle control. Without a treatment or cure, I will eventually become paralyzed and die. This happens to most patients within two to 5 years after diagnosis.

Research, drug development, and innovation are the answer for people like me with ALS. At any given time, there are about 30,000 people living with ALS, so drugs for my condition would not be a so-called blockbuster. A pharmaceutical research and development project directed to finding new drug treatments for ALS is viewed as costly and difficult and a very high risk for a company. The market will never be huge, so the chance of a big return on investment is a question mark. As I see it, a patent on new drugs is the one thing a company can count on to justify its investment.

Mr. Chairman, I'm a realistic person. I know that innovation in medicine comes down to a business decision. The size of the patient population, the ultimate potential profit, and patent protection are key components in that decision. I want, perhaps I should say I need, ALS drug development to be competitive in a business environment. I want innovative companies to have the desire to apply their skills to ALS drug development, and I want their business considerations to be protected so ALS drugs can be worthwhile to bring to market. They'll certainly be worthwhile to me and to my family.

Legislation that lessens the incentives for innovation and research is a death sentence for too many Americans. I'm not an expert in the legislative process. I come before you as a mother, a wife, a daughter, and a person living and dying with ALS.

Although I devote my days to caring for, loving, and nurturing my daughter Isabel, and not wasting days consumed by what may be, I can't help but worry which muscle will fail me next and how will that affect my ability to care for her. When will my physical limitations become too big to hide for her? When will she need to feed me as I once fed her?

Without research, I'm destined to fade away physically while being completely aware of it mentally. Other Americans with other diseases face similarly horrific fates. There must be a better way to make prescription drugs more affordable than to steal the hope of research breakthroughs from the fractionalized suffers of an array of fatal diseases.

Thank you for listening, and I and my colleague, Steve Gibson, would be happy to answer any questions. Thank you.

[The prepared statement of Ms. Oppenheimer follows:]

PREPARED STATEMENT OF SHELBIE OPPENHEIMER, ALS ASSOCIATION

Thank you, Mr. Chairman and distinguished Committee members. My name is Shelbie Oppenheimer. I am grateful to have been invited here today to share what I think is an important perspective on the issue of generic drugs versus innovative drugs. To me, this debate is more important than policy, law and politics. To me, this is very personal. To me, drug development is less about the science of chemistry or biology or the complex economics involved or the enormous financial stakes. It's about the reality of life and health. Let me be very straightforward. I have a disease

that cannot be cured today. I have Amyotrophic Lateral Sclerosis—ALS, also known as Lou Gehrig's Disease. It is a progressive disorder that occurs when motor nerve cells in the nervous system cease functioning and die. Muscle control becomes completely lost, resulting in paralysis.

The life expectancy of an ALS patient averages about two to five years from the time of diagnosis and there is no known cause, prevention or cure. ALS can strike anyone. There is just one drug available that may extend life expectancy for some ALS patients for a few months, but that drug—as significant as it is—is not the answer for my condition. While I recognize the critical importance of the basic scientific research being done by the National Institutes of Health and The ALS Association, hope for me . . . and for others dealing with ALS . . . today is the discovery or development of better therapies and, perhaps, one day soon, even a cure.

Research, drug development and innovation are the answer for people with ALS. Like many other neurological disorders, ALS is a difficult disease to understand. It's causes and mechanisms are complex and therefore treatment is a maddening, multilayered puzzle. ALS is not a disease that affects millions of people. At any given time there are about 30,000 people with ALS. So, a drug for my condition will not be a so-called "blockbuster" on the marketplace. A pharmaceutical research and development project directed to finding new drug treatments for ALS is viewed as costly and difficult, and a very high risk for a company. The market will never be huge. So, the chance of a big return on investment is a question mark. As I see it, a patent on a new drug is one thing a company can count on to justify its investment.

Mr. Chairman, I am a realistic person. I know that innovation in medicines is not only an intellectual exercise. It is also a business decision. I know that if a project to develop a drug for high blood pressure is weighed against the choice of developing a drug for ALS, I will lose. The size of the patient population, the ultimate potential profit, and patent protection are key components in that decision. I want, perhaps I should say I need, ALS drug development to be competitive in a business environment. I want innovative companies to have the desire to apply their skills to ALS drug development and I want their business considerations to be protected so ALS drugs can be worthwhile to bring to market. They'll certainly be worthwhile to me . . . to my family.

Unfortunately, drug innovation is not a walk in the park. As an ALS patient who has seen many potential products fail, I want to stress and repeat what many before me have said, "there are very few initial drug candidates that ever reach patients." There are multiple reasons for this, but one of them is just simply that drug research and development is a risky expensive business. Sometimes, a company with very good intentions simply can't afford to go out on a limb to develop a "maybe" product that may help very few people. I am interested in any legislation that affects pharmaceutical research and development. I don't want to see legislation that would put people like me at risk of facing a future without incentives for innovation.

Companies that develop brand-name drugs are good at research. Companies manufacturing generic drugs essentially don't do research. They both make positive contributions to health care and are essential factors in economic considerations on many levels. I am simply asking you to be sure any legislation being considered is about patients- all patients, including those who have diseases that are relatively rare and those who are disabled, not just those whose conditions are treated by huge best seller drugs. Today, I am asking you to be careful and fair. There are some tempting headlines and sound bites here. But I urge your thoughtful consideration because vote-driven legislation in this case can hurt patients like me.

I am asking you please not to go for what may seem like an easy answer. Instead, think of the effect changes will have on my future. The drugs that will combat ALS, that will treat very rare cancers, which will truly change our world may only be dreams or vague ideas or they may be right around the corner. We don't know. We do know that people and companies must desire to pursue them and make them a reality. Incentives for companies to develop these drugs must be preserved and must be part of policy. I am not an expert in the legislative process; I come before you as a person living with ALS. Please don't do anything, however well-intended, that will discourage the pursuit of a treatment and eventually a cure for my horrific disease.

Although I devote myself every day to caring for, loving, and nurturing my daughter Isabel, and not wasting days consumed by what may be, sometimes I can't help but worry . . . which muscle will fail me next and how will that effect my ability to take care of her? When will my physical limitations become too big to hide from her? Will she need to feed me as I once fed her? Instead of thinking about a career, weekend plans, what to serve for dinner, and which school for my daughter to attend, I can't help but be angry that I must think about slowly fading away phys-

ically and being completely aware of it mentally. I cry at the thought of losing my ability to speak and not being able to tell my daughter and my husband Jeff that I love them. I weep at the thought of not knowing if I will be able to dance at my daughter's wedding. This is my future. This future can change if the right drug is available for me.

Thank you for listening, Mr. Chairmen and Members of the Committee. I would be happy, along with my colleague, Steve Gibson from The ALS Association, to answer any questions you might have.

Senator DORGAN. Ms. Oppenheimer, thank you very much, and thanks for your courage to come, and, Ms. Wolff, thank you for your courage to be here, as well. And our thoughts and prayers are with you as you battle this disease, Ms. Oppenheimer.

Let me also say that the goal that many of us have had of doubling the amount of money available for the National Institutes of Health in 5 years is now going to be achieved this year. We've gone from $12 billion a year for the National Institutes of Health to nearly $24 billion a year. Why have we done that? Because that investment in research will provide enormous benefits, and that investment will open the doors to cures for a wide range of diseases, we believe. So doubling, from $12 billion to $24 billion, the research that's occurring at the National Institutes of Health and then is spread out all over this country in healthcare facilities, I think and hope is a source of great hope to you and many, many others.

Let me ask a question of Dr. Glover first. Dr. Glover, you've heard the testimony of the chairman of the Federal Trade Commission, and I have a list of a wide range of issues here of companies that have been involved in attempting to delay or prohibit or in other ways impede the opportunity for a generic to come to the market. Are you saying that there isn't a problem here, or the problem is a small problem? I think, as you contemplate that, if someone were to say to me, "Well, in drunk driving there's not a problem, because 90 percent of the people driving are sober, only 10 percent are drunk," I'd say, "Well, but drunk driving is a pretty serious problem." Is there, with respect to the behavior of some companies, according the FTC, is there a problem in some magnitude here? And if so, what is that? Or is it your position, "This thing's working just fine. There's no problem"?

Dr. GLOVER. It is our position that the problem is small. Even with the cases that are cited by Chairman Muris and the Federal Trade Commission, we're talking about fewer than ten cases out of more then 8,000. In that circumstance, nevertheless, these ten cases are circumstances where—if you even take the facts as presented by the Federal Trade Commission as being accurate, these are circumstances where it is not going to solve the problem to change the Hatch-Waxman Act, because those cases outline facts and presented facts that would have been violations of the antitrust laws and/or the patent laws whether the Hatch-Waxman Act existed or not.

It is our view, also, that while there may be issues that should be addressed for the benefit of the pioneers and for the benefits of the generics in the Hatch-Waxman Act, this is an immensely complicated statute, whereby what we have works so well that making certain changes will not really benefit either party in any circumstance.

The last thing to understand is that where you have a statute that was originally designed as a compromise of balancing two conflicting interests, that you cannot manipulate and tweak that statute in an environment where one of the parties is deemed to be a villain and the other party is deemed to be an angel. We know that neither of those is completely true. This is an issue of business and commerce and competition. So unless we can move the debate having accurate discussions about what the Hatch-Waxman Act really does, and what the alleged abuses really are and where the genuine issues are, and leave out some of the rhetoric, we cannot move to a position where you can manipulate the act and get a result that will remain and maintain the balance.

Senator DORGAN. Dr. Glover, prescription drug companies, pharmaceutical manufacturers, have every right to patent protection. That is the umbrella under which they make investments and expect to be able to recover those investments. I fully support that.

On the other hand, the questions of today's hearing are questions about the Hatch-Waxman Act and the potential misuse of it. And let me give you an example. You say that it is really not of great significance—that is, the attempts to block generics. Generics are delayed so often that of the drugs that should have expired in 2000, 50 percent were delayed to 2001 or still have no generic competition. The majority of the abuses have occurred to protect some of the most profitable blockbuster drugs; 67 percent of the top 30 worldwide selling drugs subject to Hatch-Waxman's legislation are involved now in litigation.

There is a whole set of information that would suggest what you are saying is not accurate. I mean, you're saying that there's really no problem, and yet there's a substantial amount of other information, including the testimony by the Federal Trade Commission today, that there is, in fact, a problem.

Dr. GLOVER. Well, first, with respect to the Federal Trade Commission, we cannot comment on allegations by the Federal Trade Commission about investigations that are not yet public. We know about, they have told us about five public investigations, and each of those, I will remind you, are investigations where, if the facts alleged by the Federal Trade Commission are taken to be accurate, each of those cases would have alleged facts that would have been in violation of the antitrust laws or the patent laws in the absence of the Hatch-Waxman Act. Therefore, changing the Hatch-Waxman Act is not going to affect that.

Second, the mere fact that cases are in litigation does not indicate that there is a problem. Remember that the Hatch-Waxman Act was designed with a fundamental premise that you should not get the generic drug on the market until the patent on the pioneer's product is expired. There is never a patent infringement suit unless the generic has taken the position that they want to market their product before the patent expires, and that's when you get a patent infringement suit.

Senator DORGAN. But, Dr. Glover, if I might just continue, Biovail amended its label in April 2000 to indicate that Tiazac may be sprinkled on applesauce.

Dr. GLOVER. I am not aware of that, and that's not——

Senator DORGAN. Well, let me make you aware of it just for a moment here.

Dr. GLOVER. Okay.

Senator DORGAN. Biovail amended its label in April 2000 and indicated that Tiazac may be sprinkled on applesauce. Ergo, generic manufacturers were then required to test their products with applesauce, further delaying FDA approval. What if this company said, "Well, now, you've tested it with applesauce. We believe it should also be sprinkled on pizza."

My question is, do you think this kind of thing probably goes somewhere near the crevice or corner of Hatch-Waxman in a way that was not intended?

Dr. GLOVER. If I assume that those facts are accurate, which I doubt, yes, that would go beyond the edge. But the problem with that is if, indeed, there were a new indication that indicated that Tiazac could be spread on applesauce, the generic has the opportunity to eliminate that indication from the label. They don't have to certify it to the patent, and they can go on the market with their generic product. So these allegations that come up with these spurious suggestions about things that have occurred that are keeping things off the market generally are not accurate.

Senator DORGAN. Well, I'll go through a series of them in a few moments, but what I'd like to do is ask Senator Wyden to inquire at this point.

Senator WYDEN. Thank you, Mr. Chairman. And, Ms. Wolff, we're glad you're here. Gray Panthers have a long history of being gutsy, but you have brought new meaning to the concept of putting your body on the line——

[Laughter.]

Senator WYDEN. And we thank you for being here and your testimony.

Dr. Glover, let me begin with you, if I might, because I was around for Hatch-Waxman. That legislation was about striking a balance. It seems to me there now is a good case for adjusting the balance, and adjusting the balance on both sides, making generics more available and promoting innovation, the kind of thing that you have been talking about.

And what I'd like to do is, first, have you described how you think the Schumer-McCain proposal is going to discourage innovation? Because right now, and I referred to it earlier, there was a remarkable story last week in *the New York Times*, for example, where people within the industry said there was a clear fall in productivity right now. So we ought to be looking at ways to encourage productivity and innovation. Let's start by having you flesh out the statement you made this morning about how you think the legislation we're looking at is going to discourage innovation.

Dr. GLOVER. Right, let's start and understand where we started out before Hatch-Waxman. Before Hatch-Waxman, the pharmaceutical industry, as every other industry in the United States, even today, had the ability to prevent a potential infringer from making, using, or selling a patented product. One of the things that occurred in the Hatch-Waxman Act is that that right, at least to prevent someone from making and using a patented product, was taken away from the pioneers.

In exchange for that—and this is the so-called Bolar Amendment—in exchange for that, the Hatch-Waxman Act enacted a series of litigation protection procedures for the intellectual property. Those include the Orange Book listings, the Paragraph IV certifications, the 30-month stay, et cetera. Those were necessary, because, unlike every other industry, we cannot stop, by a patent infringement suit, a generic applicant from making and using our product to compete with us. That is the attempt that they're making. And we're only allowed to do so as of the time that they file a generic drug application, which is earlier than we otherwise would be allowed to do so under the special provision that applies to pharmaceuticals, but later than we would be allowed to do so for the procedures that apply to every other industry in the United States.

Having done that, it is very important that we have a way to adjudicate, or at least start adjudicating, the actual issues related to the patent that covers the pioneer product before the generic product gets approved. Bear in mind that when you live in a world, which is the Hatch-Waxman Act, where the underlying premise is that the generic will not go to market until the pioneer's patent has expired, the assertion by the generic that they intend to go to the market early, and having the 30-month stay occur during the patent term, is not truly delaying the generic product. It is merely putting a delay on the generic product within the period where the delay was going to occur anyway. All 30-month stays occur during the patent term. There's only one 30-month stay per patent, and the 30-month stay never extends a patent.

Senator WYDEN. I want to get into some other areas, as well. I'd like you to flesh out in writing how you think this legislation would discourage innovation, because I don't think you all have made the case.

Tell me, if you would, why you think changes in the Orange Book would be detrimental to the consumer and to the public. I think, again, there's been a very strong argument made that there have been abuses in this area. And, of course, this is a book that, if you walk down the street, nobody would know what it's all about, but it's right at the heart of getting generics out there to the public. Are you saying that there shouldn't be any changes in the Orange Book, even with misleading information and delays coming to light?

Dr. GLOVER. First off, the delays that have come to light have been those two cases that are so-called second-generation cases that were mentioned by Mr. Muris and appear in his testimony. And in each of those cases, the Orange Book listing itself is not the provision that was creating the problem. The problem was created by alleged bad-faith behavior according to the facts that were described in Chairman Muris's testimony as well as in some of those consent decrees, so that the mere fact that you change the Orange Book listings may or may not take care of those problems, but certainly will eliminate the ability of other good-faith actors to list appropriate patents in the Orange Book.

Senator WYDEN. So you are for no changes with respect to the Orange Book.

Dr. GLOVER. First off, the S. 812 does not propose changes in the Orange Book, so please give me an example of the types of changes that you would be interested in.

Senator WYDEN. Well, I think what we have learned today is that this has been a tool. And I think we've gotten some information on the record today that suggests that it is another vehicle for keeping the public from getting information and learning about generics. And I wanted to give you the opportunity to say this was an area perhaps that Congress could look at, and could be part of a new balance between the brand-name concerns and the generic concerns.

Dr. GLOVER. We do not believe that you can possibly take away the Orange Book listing process in the entire Hatch-Waxman litigation procedures unless you also do something to put the Bolar situation back to where it was prior to the Hatch-Waxman Act. These are not independent matters. The reason that we have the procedures in the Hatch-Waxman Act to help protect our intellectual property is because so much of our intellectual property protection was taken away by the Bolar Amendment.

Senator WYDEN. One question for the generic folks. Mr. Muris indicated that he's concerned about collusion among generic companies. What are you all doing about that, and do you think it's a concern?

Ms. JAEGER. Well, Senator Wyden and Cchairman, if I may have Karen Walker here, our FTC counsel, answer that question for you.

Senator WYDEN. Sure.

Ms. WALKER. Thank you, Senator. I'm Karen Walker. I serve as counsel to the GPHA. And the issues that Chairman Muris was speaking to, I am familiar with.

The first thing is, there are antitrust guidelines and rules and laws when there is true collusion where there are violations of the Sherman Act that can be addressed. I think that what we saw from Chairman Muris's presentation, however, that's important is there are very few that they have challenged. With the vast array of different products that have been brought to market, the fact that they have only brought three of the particular kinds of cases that were—we've been discussing indicates a couple of things.

The issue is, why is that? And one of them may be that the question we should be addressing here is not just how many cases there are there, but how many generic products are not being brought to market at all because of the obstacles that were not intended by Congress that have come about because of the loopholes that are available under Hatch-Waxman?

And the other issue is that the lawful acts that companies may engage in may not be antitrust violations. The companies involved may be doing something that is not a violation of the Sherman Act, for example. It's a perfectly lawful act to have engaged in, but it's not good public policy, and it's not something that the Congress intended when it passed Hatch-Waxman. That's the reason that the GPHA believes that the reforms that Ms. Jaeger outlines in her testimony are very important.

Senator WYDEN. I would only wrap up by way of saying that the people at this table may have enough clout to keep us from moving forward and adjusting the balance. I think that would be unfortu-

nate, because I think a lot of time has passed since the original law, and I think there are opportunities to address concerns that industry has with respect to innovation and to clearly speed the access of generics to the public. But if you all can't get together, as you did close to 20 years ago, we're not going to be able to address either of those concerns.

That was a remarkable article, Dr. Glover, in *the New York Times*, where people from the industry are talking about a clear fall in productivity. We've got to address that. We've got to address that to speed cures to the public. And I think what the generic people and what Ms. Wolff are talking about with respect to people who are walking this economic tightrope not being able to afford medicine is an equally critical concern, and we ought to go back to the statute and look at ways to modernize the law and bring it in line with the times. And that's why this hearing has been particularly good, Mr. Chairman, and I thank you for having it.

Senator DORGAN. Senator Wyden, thank you very much. Senator Breaux?

Senator BREAUX. Thank you, Mr. Chairman. I want to thank the panel, and particularly Ms. Wolff and Ms. Oppenheimer for your courageous statements. And if you think about it, I mean, really what we're trying to do is to do better things, from a drug standpoint, for both of you. Both of you have slightly different approaches to the problem, but the bottom line is that what we're trying to do is to help create a system which helps both of you. And because your testimony today I think was very important, and we thank you very sincerely for it.

It would seem that some would make the case that the poor generic industry is not doing very well. The industry has increased their percentage of the sales from about 19 percent to almost 49 percent last year. It's a wonderful thing when you get into the Internet; you can find out all kind of things I know nothing about; but then after you find them, you sort of feel better educated. And I was looking through it on this issue of brand names versus generics, and I ran across—Ms. Jaeger, I'll ask you the question—a thing in the Internet called Barr's Generic Pharmaceutical Business. And Barr, as you probably know, is a manufacturer and markets more than 80 generic pharmaceutical products. Their Internet Web site was really interesting. It's got a whole thing on how to challenge patents, "The Patent Challenge Strategy," with blocks about where you start, how you finish, what you do.

But the thing that I want to ask you—I'll read it to you, and tell me where you differ from this, if at any place. It's about the future of generics, the market dynamics and generic opportunities as they say in their publication. And I'll read you the paragraph and see if you disagree with what they're saying, because I think it makes the case that they're doing very well. "Expiring patents over the next decade will drive the growth in the generic pharmaceutical industry. Financial analysts project that brand products accounting for more than $41 billion in annual sales will lose patent protection and be available for generic competition. Twenty blockbuster drugs with sales greater than a half a billion dollars are scheduled to lose patent or market exclusivity in the next 10 years. And half of these products will lose exclusivity in the next 24 months alone. A total

of 45 of the 100 most prescribed drugs will face competition from generics within the next 5 years. And, in addition, approximately $7 billion in brand name products are already off patent with no generic competition."

To me, that sounds like the generics are doing very well. In the paragraph I read, what in that paragraph would you disagree with, if anything?

Ms. JAEGER. Senator, well, the industry is doing well. I think that, with some modest reform, we could put more generics into the marketplace. And if we start to look at the statistics that you're citing to, of the products in 2000 that should have had generic competition, about 50 percent were either delayed or still blocked. And of the products that should have had generic competition in 2001, 70 percent of those products either have delayed competition or do not have competition. So the modest reforms that we are advocating are basically to accelerate those products into the marketplace.

One of the major reforms that we are advocating is to eliminate the 30-month stay provision and go to a merit-based system whereby the brand company would have to establish the likelihood of success with the merits. And that system, in and of itself, should be able to get more products into the marketplace sooner, again, increasing competition. It's good for the consumer, it's good for the industry, because it will foster more true R&D.

Senator BREAUX. Well, I appreciate that, but, I mean, the statement from one of the larger generic manufacturers pointing out that $7 billion in brand-name products that are already off patent with no generic competition, why would that be, if they're off patent?

Ms. JAEGER. Some products are—do not have patent protection, are actually protected by what we call market exclusivity. The 1984 law basically wanted to ensure that research and development was actually rewarded. And in the 1984 law, they created these market exclusivity provisions which are basically mutually exclusive from patent protection, and it provides for exclusivity, whether it be 5 years for a new product or 3 years for a variant or a change in an existing product. And these provisions also stop some of the generic competition from going to the marketplace.

Senator BREAUX. Is that a—I mean, don't you have a 180-day market exclusivity for generic after you've made your application against that brand name drug? Don't you get that same type of protection among other generics?

Ms. JAEGER. That is correct, Senator, that the law creates 180 days of a generic exclusivity. And what that is to do is that's to reward and to encourage companies to take on challenges, basically to break down patents that they believe to be questionable, either that are invalid or that will not be infringed by their product.

Senator BREAUX. I understand.

Ms. JAEGER. And, if successful, they will be 180 days to go into the marketplace and to recoup their litigation costs. And it's important to note, when they go into the marketplace, they're about 20 to 30 percent less than the brand product. And immediately after that 6-month expiration period, you'll see a number of products

going into the marketplace dropping the product price down to about 67 percent.

Senator BREAUX. Okay. I don't have a lot of time. Thank you very much.

And, Dr. Glover, one final question. The 30-day—excuse me, I keep saying 30 days—the 30-month stay that brand-name products can acquire when they challenge, does that ever extend the life of a patent, or does it have to be within the context of an existing patent? How does that work? I mean, I'm getting the impression that some are saying that somehow you're getting a 30-month extension of the patent merely by going to court.

Dr. GLOVER. Right, that is a frequent misstatement of what actually occurs. First off, there is only one 30-month stay permitted per patent. The 30-month stay occurs when the generic company asserts that it wants to market its product before patent expires, and the pioneer sues. It does not occur if the pioneer does not sue. When it occurs, it begins on the date that the generic has provided notice of the Paragraph IV certification to the pioneer. All the 30-month stay occurs during the term of the patent. If, for some reason, the generic applicant files the ANDA late in the term of the patent, and the patent expires before the otherwise end of the 30 months, there is a procedure whereby the generic recertifies to a Paragraph II and is immediately approved by FDA if they otherwise meet the approvable requirements that FDA has set out.

Senator BREAUX. Well, thank you very much. Thank all of you, particularly Ms. Wolff and Ms. Oppenheimer, for being with us.

Senator DORGAN. Senator Edwards?

Senator EDWARDS. Thank you, Mr. Chairman. Dr. Glover, I agree with something you said a few minutes ago. You said this was not a case of good guys versus bad guys. I agree with that completely. Ms. Oppenheimer, sitting next to you, gave such moving testimony about her own situation as a perfect example of that. I do think, though, that there's some clear evidence that abuses are occurring. And when drug companies abuse their patents, ordinary folks are the ones who pay the price, and that's what my concern is.

Let me ask you about, I've got here an article written by Terry Mann in the Food and Drug Law Journal. And in this article, he's giving advice to drug company lawyers about what to do. And I just want you to comment on this, if you could. He says, and this is advice to, quoting, "maximize future earnings of their clients' drug patents." And I'm quoting now from his advice to drug company lawyers. This is published in the Food and Drug Law Journal.

He says, "Orange Book listing elevates every patent as a potential source of delay to generic competition. As both innovator and generic drug manufacturers have learned, the Orange Book can be a strategic weapon giving the patentee NDA holder almost automatic injunctive relief for even marginal infringement clients. Brand drug companies literally are encouraged by FDA rules to evergreen their drug patents. By filing and refiling improvement patents for the same basic drug product, they are able to create a minefield for generic applicants. Inactive ingredient and device-related claims that are drafted carefully can be bootstrapped into the Orange Book with little risk. Patent agents and attorneys acutely

aware of the advantages that accrue from Orange Book listing have learned to tip the Hatch-Waxman balance in favor of patentees."

I actually have spent a little time as a lawyer. And reading this—and this is advice, I understanding, being given in a reputable journal, about how to use the Orange Book—I guess my concern about it is, it seems to me, and I would like to know what your thoughts are about this, it seems to me there are two things that operate in deadly combination. One is the ease of getting a listing in the Orange Book. Basically, the drug company says, "Here it is. List it." The FDA lists it. And that, combined with the 30-day—excuse me, 30-month period of injunctive relief, as Mr. Mann is saying to drug company lawyers, tips the balance, the Hatch-Waxman balance, in favor of the patentee, the drug company that has the patent on the drug.

I wonder if you could respond to that.

Dr. GLOVER. Sure. As diplomatically as possible, I'm going to have to distance myself from Mr. Mann's statement. I believe that comment was actually made at a hearing in perhaps 1998 or 1999, and that what you're reading from, the Food and Drug Law Journal, is a summary of the individual panelists' statements from that hearing. Even before the Federal Trade Commission began its scrutiny of Orange Book listings and actions taken by pioneer companies under the Hatch-Waxman Act, I believe that there are—certainly most people in the industry that represent pharmaceutical companies would not have suggested that it would have been appropriate to use Orange Book listings in the way that were described there.

Now, with respect to the ease of listings and what happens when you make a listing, under current law, the only thing that happens when a listing is made by itself is that you have put the generic on notice of the patents that the pioneer intends to assert. The next step of the puzzle is a certification that comes from the generic. And the only thing that occurs under the current law when you make that certification is that the generic preserves for him or herself, if they are first, the 180 days of exclusivity, assuming they eventually get to market.

The next step that occurs requires an additional judgment by the pioneer company, the patent holder, and that judgment is whether you bring suit, based on the patent that is listed, against the generic company. And that decision is based on whether you have a good-faith basis to bring the suit, and you are subject to all of the other rules that prevent you from bringing frivolous suits, Rule 11 and other things of that nature. You're also subject to patent-misuse rules, which are very much an antitrust type of concept under the patent law, where you are pursuing a patent against a product where you know the patent does not appropriately cover the product or you have reason to believe that the patent is invalid.

And then there are separate, independent, true antitrust rules that prevent you from pursuing a patent that you have reason to believe does not appropriately apply to the product you're applying it to in bad faith against another party.

So all of those things go into play when a pioneer company makes a decision to sue a generic applicant. And those are particularly on the minds of companies as a result of the scrutiny that the

FDA has been placing. So as a result, I'm not really willing to admit at this point that the mere fact that the Orange Book listing process does not get intense scrutiny by FDA, and scrutiny in a way that FDA does not have the expertise or experience to provide, is going to create a problem. Because I believe, as Mr. Muris has described to us, their ability to sue companies for allegedly bad-faith Orange Book listings under his so-called second-generation cases will have a substantial effect in taking away any alleged abuses that occur by virtue of people trying to game that Orange Book listing process.

Senator EDWARDS. Now I remember that you're a lawyer in addition to a doctor.

[Laughter.]

Senator EDWARDS. Let me ask you this. What I understand Hatch-Waxman says is that if you listed in the Orange Book, if you decide that a lawsuit should be filed, you get an automatic 30-month stay. What McCain-Schumer is proposing—and that's a special deal. I mean, that doesn't normally exist in the law, as you well know. What McCain-Schumer is saying, as I understand it, is that we're going to treat drug companies who bring such a lawsuit like anybody else who's trying to stop this kind of behavior by a generic company. And we're going to say you're got to go to court, and you've got to get a preliminary injunction instead of an automatic protection.

I gather that from the answer you just gave me, that you don't want the drug companies to be treated like everybody else.

Dr. GLOVER. Actually, if you're willing to treat us like anyone else, we'll take that deal. The everyone-else deal, though, is that we can sue at the beginning of the point that the generic begins to make and use our drug for commercial purposes. We're not able to do that right now. So the thought that we're being treated special is because the Hatch-Waxman Act puts us in a special position to begin with. And so while we would like to——

Senator EDWARDS. What is—excuse me for interrupting—what is your objection to having to show, through a preliminary injunction proceeding, the same thing that most folks would have to show in order to stop the generic, show cause?

Dr. GLOVER. Because you're not letting us do it earlier enough. You're only letting us do it at the time the generic has already done the studies to submit information to FDA, which, by virtue of statistics that FDA has published, they're only about 18 months from getting approval at that point. If you would let us do it when they started making and using our drug for commercial purposes, i.e. the development to do the bioequivalent studies and things, that——

Senator EDWARDS. Before they even go to market with it?

Dr. GLOVER. Exactly, which is the way that you can do it in every other industry. In every other industry, you are allowed to stop someone from manipulating, making, and using your product before they market it, if their intent is to use it in a commercial process.

Senator EDWARDS. Even though the patent is expiring.

Dr. GLOVER. The patent has not expired in any of these circumstances that you're talking about. None.

Senator EDWARDS. Well, I'm talking about a situation where the patent is expiring and youve filed a new—under what we've just been talking about, you file one of these new patent applications, and you're asking to be listed in the Orange Book——

Dr. GLOVER. Okay.

Senator EDWARDS.—which would occur. And under those circumstances, you're resistant to the notion that you have to go to court, show that the patent is valid, the new patent is valid, in order to stop the generic from going forward. You don't agree with that, I gather.

Dr. GLOVER. I don't agree with that, but I just want to make sure that you understand that this 30-month stay that everyone has been talking about, that you are referring to as automatic, occurs for every patent. This is a patent that was listed as soon as we got the new drug approval as well as the patents that people have—are alleged to be late listed patents. Those patents are not truly late listed, they are late issued. They are listed timely under FDA rules.

But I do want to go forth and explain how the system works. The later-issued patent circumstance is a relatively rare circumstance. Even based on the information that is put out by the generics, it seems to be fewer than about ten circumstances out of 8,000 or so. And let me describe why it is so rare.

Senator DORGAN. But, Dr. Glover, with due respect, you're answering a question he hasn't asked. The question that Senator Edwards has asked is the one we'd like you to address, if you would.

Dr. GLOVER. Okay, I thought I was answering it, but go ahead.

Senator EDWARDS. Thank you, Mr. Chairman. The question I was trying to ask was, do you have an objection to the notion that, under the McCain-Schumer bill, in order for there to be a stop to the generics actually going to market with their product, that the people who are claiming they have patent protection, the drug company, have to actually go to court, show, in fact, that it's a valid patent, and get a preliminary injunction under the way the law applies to preliminary injunctions?

Dr. GLOVER. Right. I object to that if you don't treat us the same way you treat everyone else with respect to allowing us to bring the suit earlier.

Senator EDWARDS. Okay. Mr. Chairman, I wanted to ask one last question, if I could.

Senator DORGAN. Proceed. I just—if you'll yield on that point. Essentially what you're saying is if you don't allow us to block it earlier, you object to the remedy in the bill.

Dr. GLOVER. Well, that's——

Senator DORGAN. The whole purpose of——

Dr. GLOVER.—because they both go together.

Senator DORGAN. The whole——

Dr. GLOVER. Those were designed to go together.

Senator DORGAN. But the purpose of the——

Dr. GLOVER. The Bolar Amendment and the 30-month stay, by taking one away, you are, by definition, diminishing our intellectual property.

Senator DORGAN. Dr. Glover, the purpose of this hearing is to describe conditions under which generics would be able to be brought

to market and provide competition. And Senator Edwards was asking a question that presumed that the patent protection would have expired. The conditions then were under what circumstances would you act to block that competition. I think you're saying, "Well, we need to be able to block it earlier."

Dr. GLOVER. If there is no patent, there is no 30-month stay, if there is no patent certification, none of this applies. I am completely confused by the——

Senator DORGAN. Well, I understand that.

[Laughter.]

Dr. GLOVER.—circumstances you're trying to describe here——

Senator DORGAN. I understand that, Dr. Glover.

Dr. GLOVER.—where the patent has expired and you're still complaining about certifications, Orange Book listings, and 30-month stays. That circumstance never exists.

Senator DORGAN. Well, what I understand is you're saying we need to be able to block this competition earlier. That's what I—I've taken Senator Edwards' time. You wanted to ask one additional question.

Senator EDWARDS. Actually, my question was for Ms. Jaeger. Ms. Jaeger, did you want to respond to that, first of all?

Ms. JAEGER. Well, I just wanted to clarify. I think that, from the industry's perspective, what we're having really concerns with is these patents are actually listed in the Orange Book that do not cover the drug product that is marketed in the United States. So it's—basically these patents are blocking our products from getting in.

Case in point, there's a product called Durantin. The generic name is Gavopantin. Basically, there's two patents that are in the Orange Book that are for unapproved formulation and unapproved medical use, each of which it basically caused the generic company to certify to those patents and kicked in in the 30-month stay, because, of course, the brand company sued. So at this point, we're in litigation trying to knock out those patents, going into court, demonstrating to the court that yes, indeed, these products do not cover the generic product.

If, with the reform measure, going to preliminary injunction standard, we would be very hopeful that the court would let FDA approve the product and we'd be able to get this product to consumers a lot faster. And basically, at this point, it's costing consumers about $1.5 million a day.

Senator EDWARDS. I just had one last question for Mr. Jaeger, Mr. Chairman.

Senator DORGAN. Proceed.

Senator EDWARDS. Ms. Jaeger, this had not been talked about very much. I wonder if you would talk about the issue of the 3-year exclusivity for new uses and what effect that has on consumers?

Ms. JAEGER. The 3-year exclusivity provision was intended to reward innovation for important product changes. However, over the course of the last couple of years, the brand companies have been using this particular provision to obtain exclusivity for minor product variations. The industry has a very large concern with this. We think it's another major loophole that we're looking at, and we think that this issue should be fixed.

Dr. GLOVER. May I comment on that, please?

Senator DORGAN. Certainly.

Dr. GLOVER. First off, the spurious use of the word "loophole" is merely in the eyes of the beholder. One person's loophole is another person's statutory provision that it just don't like—somebody else doesn't like. Second, we have seen in Mr. Muris's testimony, as well as in his oral testimony, complaints that we have patents on formulations that will take a drug, for example, from being injectable to being oral, from taking a drug from being four times a day to being one times a day. And now we have heard Ms. Jaeger complain about 3-year market exclusivity for new-use indications.

The new uses that come out in the marketplace that require separate FDA approval, additional FDA data, and may be covered by additional patents, are appropriate products for additional exclusivity and additional patent protection. None of those new uses and none of the patents that cover the new uses prevent the generics from going on the market with the original form of the drug. And that's what the generics will not tell you, is that the reason that they are complaining is that the improvements that have been made that physicians and consumers have determined are commercially valuable because they provide a significant improvement to the public health, it is that that they can't go on the market with, but they can still go on the market with the original products.

Senator DORGAN. Dr. Glover, you are invaluable to the industry. You do a great job in testifying and reflecting their perspective. I would really like you and I to have an exchange of letters with respect to the use of applesauce.

Dr. GLOVER. Certainly.

Senator DORGAN. I know you dismiss that out of hand, but let's you and I decide to get to the bottom of that case. We'll do it after this hearing.

Dr. GLOVER. Absolutely.

Senator DORGAN. But that represents just one more sprinkling of how one wishes to retain patent protection well beyond the expiration.

Ms. Oppenheimer, you're here in support of strong patent protection in order that an industry may retain—or may experience the profits that are necessary to drive the research and development and investment, and I support that. You don't find detractors on this Committee with respect to patent protections for prescription drugs.

I mentioned there are several ways by which we see innovation in life-saving medicines in this country. One is private investment. The other is public investment. The commitment that I and others have had to public investment I demonstrated earlier by saying we are doubling the investment of the National Institutes of Health. And so I assume, having listened to all of this, however, you're not here testifying that it is irrelevant if there are companies trying to extend patent protection by knocking a generic off track using approaches as suggested by the Federal Trade Commission chairman? I think I've heard from your testimony you're here supporting patent protection because that's important to the development of new medicines. Is that correct?

Ms. OPPENHEIMER. That's correct.

Senator DORGAN. I think it's important to say that, while we are dramatically increasing funding at the NIH, doubling it, the pharmaceutical manufacturing industry, I believe, is the most profitable industry in this country I wish for them to succeed. But miracle medicine and life-saving medicine is of very little value to someone who cannot afford to have it or cannot get access to it. And so that's why price is very important.

And we're talking, Mr. Martin, in your testimony about what's happening with respect to your insurance premiums. You've sat patiently and listened to Dr. Glover. And what Dr. Glover has said, and I think in a very aggressive way on behalf of the industry he represents, Dr. Glover says, "This is much ado about nothing. There's not an issue here with respect to generics. The legislation by Senator Schumer and Senator McCain is not necessary. In fact, it would be counterproductive." Tell me again, is this an issue? Is Dr. Glover right that this is much ado about nothing? Tell me from your perspective.

Mr. MARTIN. Well, from our perspective, it's not much ado about nothing. Affordability is essential for Americans who purchase health coverage. The issue here that we see is having, in an industry that, as you mentioned, does very well, that in the one place we can open more competition, make sure—this is a very complex industry—that the complexities over time can stack on each other. And it's these things we'd like to have examined. We think this bill examines those things and opens the door for more competition, for Americans to have more choice in the drugs that they can select, not just in having more choice—not just in product, but price.

Senator DORGAN. Thank you, Mr. Martin. Dr. Glover, on March 19th, the Wall Street Journal had a fascinating article about, "Drug makers face battle to preserve patent extensions." I want to read you one paragraph. "Executives at three of the top ten manufacturers, Merck and Company, Pharmacia Corp., and Eli Lilly, have expressed concern about other companies' aggressive patent extension tactics. Worried that perceived abuses could lead to a broader dismantling of their patent protections, they privately suggest they could support a crackdown against some techniques to extend patents."

Merck, Eli Lilly and so on, are they part of the Pharmaceuticals Manufacturers group?

Dr. GLOVER. Yes, they are.

Senator DORGAN. How do you respond that? Here you've got a couple of very large members of your group saying that what you say isn't happening is, in fact, happening, and it worries them.

Dr. GLOVER. The statement that you read, I don't think is accurate on its face, which is that it suggests that they're concerned about companies' abilities to extend patents. The way in which you extend the patents are all provided by statute and there are really no games you can play on that.

If what they are suggesting is that the ways in which companies attempt to extend protections for a product that may be covered by multiple patents, then there's, of course, disagreement on that. But in each of those cases, where those companies have not been involved in the actual facts, I would submit that they are probably

reading the press accounts, which, in many circumstances, are inaccurate.

Now, if we go farther to say, however, that where there have been alleged abuses, and these abuses, I believe, we can say, in some circumstances, there have been facts elicited that show other activities, unrelated to the Hatch-Waxman Act, per se, that the companies should not have engaged in, I believe their issue is accurate in that circumstance.

That is, you don't want a circumstance where someone has obtained a patent in inappropriate circumstances or where someone has listed a patent that they knowingly should not have listed, to therefore, cast aspersions on the way the Hatch-Waxman Act is otherwise intended to work so that you start changing things systemically that have great benefit to the great majority of the industry for the benefit of trying to capture those fewer than ten cases our of 8,000.

Senator DORGAN. So you're saying that three of your member companies are not concerned—as the Wall Street Journal suggests—about these tactics? The story says that these companies—Merck, Lilly, and others—are worried that perceived abuses could lead to a broad dismantling and so on. You're saying that——

Dr. GLOVER. I think——

Senator DORGAN.—they're not concerned about that?

Dr. GLOVER. I think that is, on its face, accurate. That is, for the industry as a whole, perceived abuses are the reason that we're having this hearing, are the reason that the FTC is providing greater scrutiny. So everyone is going to be concerned about perceived abuses. The real question is, are the abuses accurate abuses? Are the descriptions accurate? Do they suggest that there need to be changes in the Hatch-Waxman Act, or do they suggest that we already have the legal and statutory authority to take care of these so-called abuses through the antitrust laws?

Senator DORGAN. But it says they've expressed concern about other companies' aggressive patent extension tactics. Have you been involved in discussions at which Merck and Lilly and others were around and they said, "Look, we've got some problems here if this behavior continues"? Have you been involved in any of those discussions in your industry?

Dr. GLOVER. I have not been involved in those discussions. However——

Senator DORGAN. Do you think the discussions have taken place and you're simply not there, or are these discussions that are not taking place and the reports are inaccurate?

Dr. GLOVER. My expectation is that those discussions did not take place in a collective group. And what has probably occurred is that the reporter individually interviewed the three executives and came up with a comment that suggests that they were all together.

Second, as I mentioned to you, it is not uncommon for anyone in the industry to say that they're concerned about the perceived abuses and the effect that the perceived abuses will have on the way that everybody does business. But that does not mean that we believe the changes that are required to prevent the perceived abuses require changes in the Hatch-Waxman Act.

Senator DORGAN. Let me make one additional comment. The chart that I showed at the start of this hearing shows that the cost of prescription drugs last year increased 17 percent. That follows, I think, four or five successive years of double-digit cost increases, partly due to utilization, partly to price inflation. That is unsustainable, in my judgment. We cannot, in this country, sustain double-digit after double-digit after double-digit year cost increases in prescription drugs. It'll just break the back of consumers. It'll break the back of people who are sick. It'll break the back of Medicare, break the back of state governments and the Medicaid system. It'll break the back of the Federal Government. We just can't do that. It is not sustainable. The question is, how do we respond to it?

Now, the point I made at the start of the hearing is that we don't have prescription drug controls in this country, with the exception of the fact that the pharmaceutical manufacturers themselves control the price. There are controls with respect to that, but we don't, like most other countries, have prescription drug price controls. I'm not suggesting that today. We will have a second hearing on the issue of reimporting prescription drugs, from Canada, especially, in which prices are more moderate on the same pill put in the same bottle made by the same company, FDA approved, I might add.

But let me, as I finish my questioning, say this about the industry. I want the pharmaceutical industry to do well, want them to succeed, but we have competing interests here, and we have to resolve them.

The pharmaceutical industry has announced in recent weeks programs for lower-income senior citizens, or senior citizens with up to 200 percent of average income, I believe. And, look, I think that the industry is recognizing a problem, and I applaud them for it. They're addressing that in that narrow area. But this is a broader problem and one that begs, it seems to me, for public policy discussion, and that's the purpose of this hearing.

This is the first hearing on the general area of prescription drug pricing, generic drug policy. We will have a second followup hearing on the issue of reimportation. Then we will have a third hearing, as well.

Dr. Glover, we will be inviting you back, as well as other members from the Pharmaceutical Manufacturers Association. This is not a search for a bad actor. This is a search for public policy that will advance the interests of everyone in this country. The interests of the pharmaceutical manufacturers is important. Ms. Oppenheimer, who suffers from an insidious disease, makes the case that we need research and development and life-saving discoveries in order to address the battle that she and so many others are fighting. I agree with that.

And so, as we balance all of these interests: the profitability of the industry, the needs of the patients, the ability for the insurance plans and the Federal Government, Medicare to deal with cost increases, we need to come to some conclusion. And my hope is that we can perhaps reach that conclusion this year.

Now, I'm going to ask Senator Wyden for his last round of questioning, and I must depart for the floor of the Senate while he does

that, so Senator Wyden will chair and adjourn the hearing following his last round of questioning. Senator Wyden?

Senator WYDEN. Thank you very much, Mr. Chairman.

Dr. Glover, I want to go back to this issue of the significant decline in productivity in the industry. And I was just struck last week, when Dr. Frank Douglas—he's the chief scientific officer of Aventis—was quoted in the paper as saying, "There's been a clear fall in productivity." Now, some would say, well, maybe this is due to the fact that pharmaceutical companies spend money on advertising that they should put into research and development. There may be some who say, well, the FDA holds everything up, that the fact that it takes so long to get through the FDA system is behind it. But I think it would be very helpful to have on the record the industry describing what they think is behind a very ominous, you know, development. Now, this is not somebody who's anti-industry. These are the words of people within the industry saying that there's been a clear fall in productivity. I think we all know that this ought to be a spectacular time with all the innovations and the genome and computers and the like.

Tell us, for the record, what you think is behind this fall in productivity.

Dr. GLOVER. Senator, of course we will supplement my comments with a more elaborate position, but I think there are several things to understand about research and development in the pharmaceutical industry. One is that it is not linear. It's not predictive. It is a high-risk proposition. As a general circumstance, you start off with about 5,000 or so drugs that you will use in the preclinical animal studies for every one that eventually gets to market. And of those products that get to market, only one out of ten recovers the research and development costs associated with it. So you can just see, by virtue of what we're doing as an industry, it is very, very risky, and the likelihood of success is very small.

The second thing to understand is where we have come and where we are in the series of trying to treat diseases, where some 30 or 40 years ago we really had very little success in doing so. We have over the years, by virtue of just the way science works, we have started with perhaps the easiest diseases to treat because they were the most obvious. We had the technology early on. You start by replacing molecules that are absent in the body, then you start by trying to manipulate certain disease systems through the immune functions and things of that nature. And as time goes on, we move toward more and more subtle and sophisticated diseases that we're trying to treat that require much longer clinical trials, require end result, by definition, and a much higher failure rate. These trials that are longer are also more expensive. So, therefore, the decisions that have to be made in the commercial process of when you decide to go forward in pursuing a drug or not pursuing a drug, critical important decisions are made earlier and earlier in the process because the dollar figures are so high.

I think that's just the beginning of what the—what our more elaborate and complete answer is going to be, but I believe that is really what we're facing right now.

Senator WYDEN. Well, I think, again, this is part of the area that ought to be addressed in trying to look at creating a new balance

in the statute, because patent protection was considered one tool—not the only tool, but one tool in promoting productivity and innovation among industry. Now we've got industry people saying we aren't being particularly productive. Certainly, supporters of the McCain proposal could say, well, if they're aren't making as many golden eggs, at least let consumers afford the ones that are out there.

So I think that you are going to have to give some very specific answers with respect to what needs to be done to address this productivity question. Otherwise I think, first, the country is going to suffer, because citizens want the new cures, and, second, I will tell you that any legislator who faces a group of citizens, they say, "Shoot, if they aren't making the new cures as fast as they said they would if they got patent protection, well, at least us be able to afford the medicines that are out there." And I think that is as compelling an argument as I know for getting this table back together to try to modernize this law, because that's really what we're talking about.

I mean, you've had the head of the Federal Trade Commission saying that there's a pattern of gaming the system, and he essentially outlined it. And starting with the examples that came from Ms. Wolff and, you know, other consumers, this is in line with what we hear from constituents at home. I've got to be sensitive to that as a legislator. And especially given my roots in the consumer movement, I want to make sure that there are answers to those arguments.

At the same time, I want to address concerns like those that were described in the paper about this, you know, fall in productivity. That would devastating to this country. You don't want that. Your association doesn't want that. But when people within the industry are talking about it—this article says that the industry is preoccupied with the fall in productivity—We're going to have to have some better answers, and I hope you can supply those.

One that I'll be asking about, so you'll be ready for it down the road, will be the effect of mergers, because I think that mergers have taken a toll with respect to productivity, as well. But I'd like to see us strike a new balance. I'd like us to address the arguments that Ms. Wolff and other consumers have made, and I'd like to do it in a way that addresses these productivity concerns.

And if any panel member would like to comment on this, you're welcome to do so. And otherwise, we'll adjourn.

Ms. WOLFF. Within 1 year, the price of Prilosec rose about $9.00, I think.

Senator WYDEN. Yeah. These price increases don't——

Ms. WOLFF. For a 90-day supply.

Senator WYDEN. Ms. Wolff, you've said it all. The price increases don't pass the smell test. There aren't that many new developments, you know, within a year. All of us in the Congress are hearing about it. There's got to be a better answer, and I want it done within the kind of framework that will address what the industry is basically describing as a productivity crisis.

Dr. GLOVER. Senator, I just want to point out that the industry, and even the executive of Aventis, would not suggest that the industry is not productive. I mean, the industry has, over the last

century, taken us from a society where people just didn't live very long to where the average expectancy is over 75 or 76 years or so. So we are productive. The real issue for us is that are we productive enough to continue to be able to put money into the research and development system, when we have competitive pressures that result from the appropriate entry of generics into the marketplace, that result from competition between pioneer companies and not just between generic companies, and, at the same time, when we know that every new drug we develop is likely to cost more than the last drug we developed.

And I certainly agree with you that we will address your question, but I do want to point out that I don't think that it's fair to say that we are not productive. We're just not as productive as perhaps the industry would like to be.

Senator WYDEN. Nobody is saying that there is absolutely no productivity whatsoever, but when you have the chief scientific officer of a major company, Aventis, saying—this is his quote, Dr. Glover, "There has been a clear fall in productivity," I think we've got to have some thoughtful answers to that. That was why I was trying to have you flesh out why you think that the McCain-Schumer legislation would discourage innovation. I'll look forward to your answer on that. I'd like to know what you think is behind the decline in productivity.

I'm asking these questions for a reason. I think it's time to strike a new balance in the law. I think the consumer groups have made a good argument. I happen to agree with a number of the points that the generics have made, as well. I want to make sure at the end of the day, when and if we can modernize this law, we've done the kinds of things that we thought we were doing in the original Hatch-Waxman law, which is to encourage innovation and new cures, as well.

What brought me to this hearing today is to get beyond the brawl between the brand names and the generics. I've watched that for years and years. I think there's an opportunity to do something that will speed generics and reasonably priced medicines to the public and also address what companies like Aventis are saying in terms of the decline in productivity.

That, from my standpoint, is about as good a challenge as I can issue to the folks at the table. You all have made a good case. And, with that, the Committee is adjourned.

[Whereupon, at 12:25 p.m., the hearing was adjourned.]

A P P E N D I X

PREPARED STATEMENT OF HON. SHERROD BROWN, U.S. REPRESENTATIVE, RANKING MEMBER, HOUSE ENERGY AND COMMERCE HEALTH SUBCOMMITTEE

Prescription drug costs are growing at an unprecedented and unsustainable rate in the United States. Spending on prescription drugs doubled in the 1990s, and drug prices in the U.S. today are as much as four times higher than in other industrialized nations. On average, health insurance premiums increased 11 percent last year alone, largely due to high prescription drug costs. State Medicaid budgets were in the red last year, largely because of rising prescription drug costs.

One in four Americans, 70 million, lack prescription drug coverage. Many are seniors on fixed-incomes. Prices for one-third of the drugs seniors use most increased by 10 percent or more last year, while Social Security checks increased only 3.5 percent. Brand-name drug prices are not just high, they are unjustifiably high. In the last 20 years, drug prices in the United States have risen over 300 percent.

In today's prescription drug market, the best way—actually, the only way—to achieve lower retail drug prices is to purchase generic drugs. Generic drugs are identical to their brand name counterparts—except for price. Generics are typically 40–80 percent less expensive than their brand-name counterparts. In some cases, the price differential is even greater than that. The anti-anxiety drug Vasotec sells for $180 per prescription. The generic version of Vasotec sells for $55.00 per prescription, a savings of $125.00.

Unfortunately, loopholes in federal law have enabled brand-name drug manufacturers to delay access to generic drugs. These delays, which allow drug companies to sustain grossly inflated drug prices, translate into billions of dollars in lost consumer savings. To close these loopholes, Representative Jo Ann Emerson and I joined Senators Charles Schumer and John McCain in introducing the *Greater Access to Affordable Pharmaceuticals Act* (GAAP).

The GAAP bill would get generic drugs to market faster in three key ways:

1. Under current law, brand name drug companies can earn 30 additional months of market exclusivity by filing additional patents on an existing drug, whether or not these new patents are legitimate. While the 30-month stay was part of a deal cut to win passage of the 1984 Waxman/Hatch Act, no one anticipated the extent to which this provision would be exploited to delay generic drug approvals. Brand-name drug companies have taken to filing frivolous patents right before a drug reaches the end of its patent life, which enables them to reap additional monopoly profits at the expense of American consumers. The GAAP bill eliminates the 30-month provision and the billions in lost savings it represents.
2. Under another provision of the Waxman/Hatch Act, the first generic drug company to challenge the legitimacy of a brand-name patent is rewarded with 180 days of market exclusivity. By encouraging generics to identify and challenge inappropriate patents, the law seek to open up an unjustifiably closed market to generic competition. Unfortunately, brand name drug companies have taken to cutting deals with their generic challengers to keep them off the market. This defeats the purpose of the law and costs consumers billions. Our bill restores the original intent of the law by rescinding market exclusivity from generics that cut such deals.
3. Our bill puts the force of law behind FDA's bioequivalency standards, preventing brand name drug companies from using endless court challenges to delay access to generics.

Last year the House of Representatives passed, by a 324–89 margin, an amendment I offered to the Agriculture spending bill which would allocate an additional $2.75 million to the Office of Generic Drugs. The dollars were to improve review times and raise public awareness of generic products.

The fact that this amendment won overwhelming bipartisan support is telling. Members on both sides of the aisle recognize that it is time to do something about

runaway prescription drug costs. Removing unjustifiable barriers to generic drug access is a logical first step.

PREPARED STATEMENT OF THE GRAY PANTHERS

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 Re*Ph*orma. 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 Re*Ph*orma 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 2½ 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

PREPARED STATEMENT OF JODY HUNTER, GEORGIA-PACIFIC CORPORATION, CO-CHAIRMAN, BUSINESS FOR AFFORDABLE MEDICINE

Mr. Chairman and Members of the Committee, it is a pleasure to provide testimony to the Senate Commerce Committee. My name is Jody Hunter and I am Director of Health & Welfare Benefits at Georgia-Pacific Corporation.

I serve as co-chairman of Business for Affordable Medicine (BAM), a growing national coalition of leading U.S. employers, governors, and labor organizations dedicated to improving pharmaceutical competition by closing loopholes in the federal Hatch-Waxman Act this year. I am here representing BAM's corporate membership, which includes companies such as the following:

- Verizon Communications
- Wal-Mart
- K-Mart
- Weyerhaeuser Corporation
- Eastman Kodak
- Albertson's
- General Motors
- Motorola

All prescription drug purchasers, including the corporations that belong to BAM, are frustrated by the rising cost of prescription drugs. Every year, the impact on our bottom lines gets bigger, forcing employers to either absorb these growing costs or pass them along to employees and retirees.

Now, let me cut to the chase because I want to set the record straight on exactly what our coalition is seeking to accomplish this year.

The Hatch-Waxman Act is broken and needs to be fixed. Unintended loopholes are providing drug manufacturers with opportunities to engage in anti-competitive practices that are designed to delay the introduction of lower-cost alternatives to branded pharmaceuticals.

Their tactics are costing drug purchasers billions of dollars every year in lost savings because generic drugs are not available when they should be—namely, as soon as brand drug patents expire.

Let me be very clear that BAM members do *not* seek to undermine the critical safeguards provided to intellectual property owners by the patent process. Most, if not all, of our corporate members hold numerous patents. None of us would advocate Hatch-Waxman reform if we felt the proposed changes would violate intellectual property rights.

Neither do BAM members begrudge brand drug manufacturers the profits they make on their products. In fact, our companies enjoy excellent working relationships with many of the manufacturers.

So why are we here asking Congress to reform the Hatch-Waxman Act this year? I can sum it up in one word: fairness.

What we are saying is this:

- Loopholes in the Hatch-Waxman Act allow drug manufacturers to unfairly delay competition.
- These delays cost U.S. purchasers billions of dollars annually.
- Congress must close these loopholes this year and restore the Act to its original intent.

Meanwhile, drug manufacturers are trying to convince Congress that all is well and nothing needs to be done to fix these problems. Here are some of the things they are saying:

- The Hatch-Waxman Act is working as intended, and there is no need to change it.
- Thousands of generic drugs have successfully reached the market over the past 18 years.
- Fewer than 6 percent of generic applications face any delay at all.
- Closing loopholes in the Act will result in inability of drug manufacturers to develop new medicines.
- Closing loopholes in the Act will undermine intellectual property rights.

You may even see colorful charts that illustrate these points, but the devil is in the details. Drug manufacturers, however, do not want to discuss the following points:

- First, of course the Act works well if you are the beneficiary of its loopholes, which effectively extend patents on blockbuster drugs beyond their expiration dates. If I were in the shoes of brand drug manufacturers, I would not want to change the law that allows me to delay competition with little effort.
- Second, the 6 percent of cases in which generic drug approvals have been delayed are for products that cost purchasers like Georgia-Pacific the most, such as Prilosec and Buspirone most recently—a small percentage in terms of total drug applications, but a huge percentage in terms of actual pharmaceutical profits.
- Third, patent expirations are the sole incentive for investment in development of new drugs. Brand industry investments in research and development have increased from 11.4 percent as a percentage of sales in 1970 to 18.5 percent in 2001, according to PhRMA. This increase coincides with the impending expiration of billions of dollars worth of patents.

Let me share some of the challenges we are facing at Georgia-Pacific, as well as those faced by the other corporate members of BAM.

At Georgia-Pacific we provide healthcare plans that include prescription drug coverage for approximately 70,000 active employees and their covered dependents. We also cover more than 26,000 retired employees and their dependents. Our prescription drug costs in 2001 exceeded $42 million (up 21 percent from 2000) for our self-funded plans, which cover approximately half of our employee base. Increased Rx costs also added significantly to HMO fully-insured premiums we pay for the remaining half. Our 2002 HMO premium increases ranged from 16 to 42 percent. Most of these increases were related to increasing Rx costs. Our total medical and prescription drug healthcare costs for 2001 exceeded $300 million.

The actions we are taking at Georgia-Pacific to control these unsustainable double digit cost increases are similar to actions taken by other corporations, including:

- Changing medical and prescription drug coverage plan designs.
- Sharing more cost with employees and retired employees.
- Reviewing and analyzing the need for customized prescription drug formularies.
- Using co-payment or coinsurance incentives to promote greater use of generic drugs.
- Reviewing the possibility of using alternative medical and prescription drug plans for our retired employees that may result in greater financial risk on their part in order to reduce their premium contributions.

Like the governors who are trying to identify healthcare cost savings at a time when budgets are extremely tight, corporate purchasers of prescription drugs are anxious to have full access to lower-cost generic alternatives as soon as brand patents expire.

Last year the corporate members of BAM spent more than $132 million to purchase the 17 brand name drugs that face patent expiration before 2004. Our collective cost for just the 5 drugs that face patent expiration this year was $58.4 million—almost half of the total spent for all 17 drugs.

What's more, BAM corporate members spent more than $188.5 million last year to purchase the 10 brand name drugs that face patent expiration in 2005.

In preparation for this testimony, we used data provided by all BAM member corporations to determine the annual cost to all S&P 500 corporations for these 17 drugs.

Using conservative estimates, we concluded that nearly $1.9 billion was spent by the Fortune 500 companies last year alone to purchase just these drugs. More importantly, we estimate that these companies will save over $950 million annually if Congress simply ensures that generics are allowed to enter the market on time, as intended by the 1984 Hatch-Waxman Act. This savings can only be assured if Congress acts this year to close the loopholes in the Act.

If Congress will act this year to close these loopholes, all drug purchasers—including 40 million uninsured Americans—could anticipate saving an average of 50 to 60 percent on prescription drugs once their patents expire and lower cost generic alternatives become available.

In our view, this could go a very long way in helping Congress and the Administration deliver on its promise in the last election to address the problem of escalating pharmaceutical costs.

Like all purchasers, we want access to lower-cost alternatives *on time* after brand name patents expire. Closing the loopholes in the Hatch-Waxman Act will restore *certainty* to the prescription drug market and help purchasers manage the cost of these expensive drugs.

Until that happens, the writing on the wall is quite clear—experience has taught us that delays are inevitable, especially for the blockbuster drugs that are driving our cost increases through the roof.

The reason some pharmaceutical manufacturers oppose closing the Hatch-Waxman Act loopholes is clear—continue to delay reform, at significant cost to all purchasers, while prolonging monopoly profits on blockbuster drugs.

Corporations like Georgia-Pacific joined BAM in order to convince this Committee and all of Congress that we cannot survive under the present system. We believe that enough is enough. All BAM members believe that the best interests of prescription drug purchasers—including consumers across America—far outweigh the arguments put forward by those drug manufacturers that engage in unfair, anti-competitive practices in order to extend their profits.

Mr. Chairman and Members of the Committee, if Congress is to make good on its promise to seniors to deliver a Medicare prescription drug benefit, the issue of pharmaceutical costs must first be addressed.

Prescription drug purchasers need the certainty that can only be provided by closing loopholes in the Hatch-Waxman Act. We encourage this Committee and all of Congress to act this year to stop the anti-competitive practices that result from loopholes in the Hatch-Waxman Act.

Thank you for the opportunity to provide this testimony.