S. HRG. 107–450

CLOSING THE GAPS IN HATCH-WAXMAN: ASSURING GREATER ACCESS TO AFFORDABLE PHARMACEUTICALS

HEARING

BEFORE THE

COMMITTEE ON HEALTH, EDUCATION, LABOR, AND PENSIONS UNITED STATES SENATE

ONE HUNDRED SEVENTH CONGRESS

SECOND SESSION

ON

EXAMINING CERTAIN PROVISIONS OF THE 1984 DRUG PRICE COMPETITION AND PATENT TERM RESTORATION ACT, KNOWN AS THE HATCH-WAXMAN ACT, ASSURING GREATER ACCESS TO AFFORDABLE PHARMACEUTICALS

MAY 8, 2002

Printed for the use of the Committee on Health, Education, Labor, and Pensions

U.S. GOVERNMENT PRINTING OFFICE
79–636 PDF WASHINGTON : 2002

For sale by the Superintendent of Documents, U.S. Government Printing Office
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C O N T E N T S

STATEMENTS

WEDNESDAY, MAY 8, 2002

ADDITIONAL MATERIAL

CLOSING THE GAPS IN HATCH-WAXMAN: ASSURING GREATER ACCESS TO AFFORDABLE PHARMACEUTICALS

WEDNESDAY, MAY 8, 2002

U.S. SENATE,
COMMITTEE ON HEALTH, EDUCATION, LABOR AND PENSIONS,
Washington, DC.

The committee met, pursuant to notice, at 2:31 p.m., in room SD–430, Dirksen Senate Office Building, Senator Kennedy (chairman of the committee) presiding.

Present: Senators Kennedy, Wellstone, Murray, Edwards, Clinton, Gregg, Frist, Hutchinson, and Collins.

OPENING STATEMENT OF SENATOR KENNEDY

The CHAIRMAN. If we could have your attention, please, today's hearing focuses on a rising tide of anti-competitive abuses, misleading patent filings, and sham litigation which is driving up the cost of prescription drugs. Each and every day, pharmaceutical companies exploit loopholes in the law to maintain their monopoly over their drugs and keep more affordable generic drugs off the market. America's consumers are paying the price.

This chart over here is an indication of the difference between the increase in the cost of drugs and also what drugs cost versus the CPI for 1996 through the year 2000.

Although it has been a tremendous success in promoting competition and innovation, there are clearly weaknesses in the Hatch-Waxman Act, and today, of the top 15 best-selling drugs potentially subject to generic competition, the basic patents on at least five of them have long expired. Their exclusive rights to market their drugs have long expired. Yet there is no generic competition. Clearly, the system needs to be repaired.

Prescription drugs are spiraling out of reach of the elderly and uninsured. They are draining the health care budgets of State Governments, employers, and labor unions—and all because brand-name drug companies can exploit loopholes in the law to pocket the windfall profits.

Generic drugs are clearly part of the answer. Simply put, a 1 percent increase in generic use can decrease the Nation's yearly bill for drugs by $1 billion. And ensuring the timely approval of generic drugs could save the consumers over $71 billion over the next 10 years. This chart indicates what the savings could be if we had the timely approval of generic drugs in terms of the consumers.

Prozac is clearly an example. This anti-depressant clearly went off-patent after generic companies challenged and defeated a Prozac patent. Today, you can buy 30 generic Prozac tablets for nearly a third of what the brand-name Prozac will cost. These charts indicate the difference, obviously, between the generic and the brand name.

But somehow the pharmaceutical companies game the system by listing spurious patents with FDA—patents on unapproved uses, unapproved compounds, or formulations that they don't even market. Then they get automatic 30-month stays delaying approval of generic drugs.

One company blocked general competition with the 30-month stay triggered by a patent for simply adding a water molecule to its basic drug. That is months of delay in which the company enjoyed huge profits while preventing affordable generic versions from reaching the market. This single water molecule will cost consumers at least $1.4 billion in savings for their prescription drugs, and we still don't know when a generic will come to market.

Senator McCain and Senator Schumer propose eliminating these 30-month stays and would require the drug industry to defend its patents the same way any other industry does.

A second tactic used by the drug companies is to collude with a generic drug manufacturer to block other generic versions of the drug from getting to consumers. Under the Hatch-Waxman Act, the first generic drug company which gets to market has that exclusive right for 6 months before any generic can compete. In some cases, brand drug companies have agreed with such a generic drug company not to exercise its 6-month right, thereby blocking other generic versions of the drug.

The McCain-Schumer bill closes this loophole and ensures open generic challenges to invalid patents, a provision which will save consumers nearly $10 billion on high-priced blockbuster drugs.

The Hatch-Waxman Act has been a tremendous success in stimulating both competition and innovation, but there are weaknesses in this law which are being exploited to delay competition and shore up the bottom lines of the drug companies with empty pipelines. Drug companies are entitled to fair profits on their research and innovation. But when the patents expire, these companies must innovate to succeed and help patients, not block competition to their old drugs.

We must restore the balance of the original Hatch-Waxman Act, end the abuses which block competition, and close the gaps in the Hatch-Waxman Act. This is an important task and will be a matter of continuing inquiry by this committee.

[The prepared statement of Senator Kennedy follows:]

PREPARED STATEMENT OF SENATOR KENNEDY

Today's hearing focuses on a rising tide of anti-competitive abuses, misleading patent filings, and sham litigation which is driving up the cost of prescription drugs. Each and every day, pharmaceutical companies exploit loopholes in the law to maintain their monopoly over their drugs, and to keep more affordable generic drugs off the market. And America's consumers are paying the price.

Although it has been a tremendous success in promoting competition and innovation, there are clearly weaknesses in the Hatch-Waxman Act. Today, of the top fifteen best-selling drugs potentially subject to generic competition. the basic patents on at least five of them have long expired. Their exclusive rights to market their drugs have long expired. Yet there is no generic competition. Clearly, the system needs to be repaired.

Prescription drug costs are spiraling out of reach of the elderly and uninsured. They are draining the health care budgets of State governments, employers and labor unions. And ail because brand-name drug companies can exploit loopholes in the law to pocket windfall profits.

Drug spending rose almost 25 percent annually between 1996 and 1999, and experts expect the growth in prescription drug spending to continue to outpace the growth in health care spending. To be sure, some of this increase is due to increased use of drugs. But experts agree that spiraling drug prices have accounted for almost two-thirds of growth in drug spending—especially the higher prices of new, aggressively promoted drugs.

Generic drugs are clearly part of the answer. Simply put, a one percent increase in generic use can decrease the Nation's yearly bill for drugs by a billion dollars. And ensuring the timely approval of generic drugs could save consumers over $71 billion over the next 10 years.

These savings are easy to understand. For patients and health plans alike, the costs for a brand drug are 4 times higher than for a generic equivalent That difference is even higher for the elderly and uninsured, who must often pay hill price for their medicines. On average, a month's supply of a generic drug costs a patient $4 and the health plan $16; the costs for a brand drug are 4 times higher: $16 for the patient, $64 for the plan. For the uninsured, and seniors who lack prescription drug coverage, the hull costs are either $20 for the generic or $20 for the brand drug.

Prozac is a clear example. This anti-depressant recently went off-patent after generic companies challenged and defeated a Prozac patent. Today, you can buy 30 generic Prozac tablets for less than $30—less than a third of what brand-name Prozac will cost you.

But some pharmaceutical companies game the system by listing spurious patents with the FDA—patents on unapproved uses, unapproved compounds, or formulations that they don't even market. Then they get automatic 30 month stays delaying approval of generic drugs.

For example, Neurontin is a drug approved by FDA to treat epilepsy. In 2001, Neurontin sales exceeded $1.1 billion. The basic patent on the drug compound expired in 1994, and the patent on the approved method of use expired in 2000. But the company had listed two additional patents on the drug that the generic companies had to certify were invalid or not infringed. These two patents were on an unapproved compound—just the addition of a water molecule to the basic compound—and on an Unapproved use, the treatment of neurogenerative disease.

The first 30 month stay needlessly delayed generic competition for half a year. But before that stay was up. Neurontin's manufacturer listed a third formulation patent with FDA. The generic ap-

plicant had to certify to that patent as well and another 30 month stay will delay generic approval until December 2002. In total, a generic version of this drug will be delayed 30 months, at a cost to consumers of $1.4 billion.

In effect, Neurontin's manufacturer blocked generic competition by simply adding a water molecule to its basic drug. That's months of delay in which that company enjoys huge profits while preventing affordable generic versions from reaching the market. This single water molecule will cost consumers at least $1.4 billion in savings for their prescription drugs—and we still don't know when a generic will get to market.

Senator McCain and Senator Schumer propose eliminating these 30 months stays and would require the drug industry to defend its patents the same way any other industry does.

A second tactic used by the drug companies is to collude with a generic drug manufacturer to block other generic versions of the drug from getting to consumers. Under the Hatch-Waxman Act, the first generic drug company which gets to market has that exclusive right for 6 months before any other generic can compete. In some cases, brand drug companies have agreed with such a generic drug company not to exercise its sit month right, thereby blocking other generic versions of the drug.

For example, Cardizem is used to treat high blood pressure and chest pain. Consumers used nearly $900 million dollars of the drug in 1999. A generic was supposed to have gotten to market in July 1998, but Hoechst Marion Roussel reached a sweetheart deal with a generic company, Andrx, to keep Andrx's generic Cardizem off the market. That in turn blocked other generics from getting to market for almost a year. Hoechst Marion Roussel paid Andrix nearly $90 million under the agreement. The Federal District Court in Michigan held that the agreement was per se illegal under antitrust laws. That ruling is on appeal. The result has been consumers paying hundreds of millions more than they should have because generic competition was delayed.

The McCain-Schumer bill closes this loophole and ensures open generic challenges to invalid patents—a provision will save consumers nearly $10 billion on high-priced blockbuster drugs.

The Hatch-Waxman Act has been a tremendous success in stimulating both competition and innovation. But there are weaknesses in this law which are being exploited to delay competition and shore up the bottom lines of drug companies with empty pipelines. Drug companies are entitled to fair profits on their research and innovation. But when patents expire, those companies must innovate to succeed and help patients—not block competition to their old drugs.

We must restore the balance of the original Hatch-Waxman Act, end the abuses which block competition and close the gaps in the Hatch-Waxman Act.

This is an important task, and will be a matter of continuing inquiry by this Committee.

I welcome our witnesses and look forward to their testimony.

The CHAIRMAN. I recognize my friend and colleague, the Senator from New Hampshire, Senator Gregg.

OPENING STATEMENT OF SENATOR GREGG

Senator GREGG. Thank you, Mr. Chairman. I appreciate your holding this hearing, and I think it is a topic which needs to be visited, and I obviously appreciate Senator Hatch, who is the author of the original bill, being here and Senator Schumer and Senator McCain and Senator Johnson, all of whom have strong opinions, and in Senator Schumer's and Senator McCain's case, a piece of legislation which has some very redeeming qualities to it on this issue.

The issue, as I see it, is how do we make Hatch-Waxman continue to fulfill its original goals. Obviously, Senator Hatch can maybe express those better than I can, but as I understand them, they were essentially twofold: number one, to make generics more readily available to the American public and, thus, reduce the cost of drugs; but at the same time not undermine the fundamental incentive that the primary drug company has in actually putting the dollars necessary to develop those drugs initially.

We all know that the cost of bringing a new drug online is extremely high. It is estimated between $300 and $500 million, with a period of 7 to 12 years involved. And we recognize that if people are going to be willing to make those investments, they have to have a reasonable right to use the product that they have produced.

At the same time, we recognize that after a certain period of time, a generic drug which is identical to the one that has been put forward by the initial drug company, when brought to the market, can dramatically reduce the price to the consumer. And that is appropriate in the context of reducing price, but also in the context of recovery—when it is done in the context that gives reasonable recovery to the initial inventor of the drug.

And so this is the balancing act which we have to pursue and which Hatch-Waxman has done an extraordinary job of pursuing. It is, in fact, a tremendous success story. We have seen a dramatic expansion in the activity of generics since it was put in place, with a huge increase in the amount of generics on the market, and at the same time, we are continuing to see a very significant expansion in the investment into the production of new drugs. So those being the two goals, obviously it is successful.

As the chairman has alluded to, there are some areas, however, where the initial bill is being gamed, it appears. The 180-day rule and also the 30-month stay are two examples of that. The best way to address those two issues is still to be determined, and that is obviously what this hearing is about, or part of what this hearing is about.

So I look forward to moving forward as we try to tweak the Hatch-Waxman bill. I don't think we need to radically change it, but to tweak it to make sure that it continues to produce the strong results which it has produced so far.

The CHAIRMAN. Thank you very much.

We had the hearing on McCain-Schumer, and so in this situation, I know Senator McCain has an appointment, so we would recognize him, then Senator Schumer, then Senator Hatch.

Senator HATCH. Recognize Senator Schumer next.

The CHAIRMAN. Generally we recognize by seniority, but since this hearing is focused on their legislation, I will proceed in that way, if that is agreeable.

STATEMENT OF SENATOR McCAIN, A U.S. SENATOR FROM THE STATE OF ARIZONA

Senator MCCAIN. I thank you, Mr. Chairman, and since I was here, unlike my three colleagues, to hear your entire statement, I will make mine brief because I wouldn't want to—I think you laid out the situation very well, so I would just like to make a couple of additional remarks.

As you said, Mr. Chairman, the cost of prescription drugs is skyrocketing. Just last month, the Nation's largest provider of health care, CalPERS—California Public Employee Retirement System—announced it would have to increase its members' premiums by 25 percent next year. According to CalPERS' assistant executive officer for health benefits, Allen Feezor, and I quote, "In two of the past 3 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 1 year to the next."

CalPERS, the largest provider of health care, announced a 25 percent increase in their premiums, said that the major cause of that was the increasing cost of pharmaceutical drugs.

The other point I would like to make, sir, is that none of us here want to weaken Hatch-Waxman. It is a wonderful piece of legislation. Thanks to Senator Hatch and Congressman Waxman, it has done wonderful things. But obviously people have "gamed the system."

I have a letter that I would ask be made part of the record with unanimous consent, Mr. Chairman, from Mr. Timothy Muris, who is the chairman of the Federal Trade Commission, and in his letter he says, "The Hatch-Waxman amendments have also been abused with the effect of preventing American consumers from obtaining low-cost generic drugs. Although many drug manufacturers, including both branded and generics, have acted in good faith, some have attempted to game the system, securing greater profits for themselves without providing corresponding benefits to consumers."

[The letter referred to was not received by press time.]

Senator MCCAIN. The Chairman of the FTC has it exactly right, Mr. Chairman, that the large majority of pharmaceutical companies in America are doing a fine job. There are some pharmaceutical companies and generic companies that are gaming the system at great cost to the consumer, and it is that simple. And we think we have some pretty simple and elementary fixes.

I want to thank you, Mr. Chairman. I want to thank you for having this hearing. I know how heavy your schedule is and how busy we are, particularly this time of year. But I believe that all Americans, particularly seniors, need immediate relief, and they need to be able to procure a prescription drug at the least cost. And they are not doing that today. We think we have got a fix, and there is hardly anybody in America outside of the drug companies them-

selves who don't believe this isn't a good fix. And we would welcome improvements so that we can make this more effective.

I thank you, Mr. Chairman, and thank you for allowing me to appear before you today.

The CHAIRMAN. Well, I want to thank both Senator McCain and Senator Schumer for the work you have done in this area, your longstanding commitment in terms of not just accessibility, but accessibility and affordability. And I think you are to be commended for the thoughtfulness of the recommendations that you make.

I know that you have got other responsibilities. We are very grateful to you for being here personally and speaking on this issue, and we will look forward to working with you as we move the process along.

Senator MCCAIN. Thank you, Mr. Chairman.

The CHAIRMAN. Thank you very much for being here.

Senator Schumer, we are glad to have you here, and we know how strongly you feel about this legislation. You have spoken to me I think just about every day, morning, afternoon, evening, weekends, on planes, on trains. We know you wanted this hearing, and we welcome the chance to hear from you on this. We thank you for being here.

STATEMENT OF SENATOR SCHUMER, A U.S. SENATOR FROM THE STATE OF NEW YORK

Senator SCHUMER. Thank you, Chairman Kennedy and Ranking Member Gregg. I really thank both of you, and I particularly do want to thank you, Chairman, for listening to my long, heart-felt pleas about why it would be a good idea to have such a hearing.

More importantly, I want to thank you for your leadership on this issue. You have been leading the fight to add a meaningful prescription drug benefit to Medicare, and as you know, our proposal, the proposal of Senator McCain and I, would make it a little easier to do that because it would reduce the cost to Medicare. And your willingness to hold a hearing on this issue and kicking off this committee's consideration of our GAAP Act is really important.

He had to go, but I want to thank Senator McCain for his leadership on this issue and for being a great partner as we try to reduce the costs of drugs for everybody in a free market way. And I want to also thank our House colleagues, Congressman Brown of Ohio, Democrat of Ohio, Congresswoman Emerson, Republican of Missouri, for their leadership as well in helping us focus attention.

Now, Mr. Chairman, we have heard time and time again from the big pharmaceutical companies that patent protection is the key to innovating new drugs. I have said numerous times—and I heard you just say it as well, and I couldn't agree more—when drug companies innovate new drugs which benefit the patient, they are indeed preventing disease and saving lives. And they should be rewarded for doing so with a period of time to exclusively market the drug, and that is how the system is supposed to work.

But over the 20 years since Hatch-Waxman was passed—and I want to praise my colleague. I have said this to him privately and I have said it publicly. I think that the proposal that he and Congressman Waxman put together, which was keenly and exquisitely balanced, has done more for people—it is one of those quiet things

that passes and just does a world of good. There are literally, I think, tens of thousands, if not more, people alive today because of Hatch-Waxman, because drugs are within their reach, and they are not avoiding drugs that they need. And I thank him for that. And the balance that that bill had was just fine and had broad bipartisan support.

The trouble is the balance is out of whack, and that is what we are seeking to restore, Senator McCain and I. And today I would like to just debunk some of the myths that the drug companies are perpetuating about the way they are using patent laws and how the bill that Senator McCain and I have introduced will impact innovation.

Now, PhRMA has been circulating a list of claims it has been calling a reality check. If a bank tried to cash that check, it would bounce.

Today I want to shine light on some of the PhRMA claims and ensure that the public knows the truth about what is going on in the drug industry. The reality is that drug companies are not spending enough time innovating new drugs, and they are spending too much time innovating new patents. The whole purpose of the law is getting new, wonderful, miracle drugs on the market, not spend all your time rearranging the chairs and saying if we can get a new patent on the same old drug. But that is what has been happening, and that is how they spend too much of their time and energy.

I would like to say to the pharmaceutical industry they have done great things and they have saved so many lives, and I don't begrudge them their success or their profits. But, you know, it goes in cycles, and there is a whole huge bunch of wonderful drugs that have been under patent for a long time. And they are going to come off the market, and the pharmaceutical industry ought to accept that and go back and design new drugs. And if it means they have a few years of lower profitability for the public good, then they will have the higher profitability when the new drugs come out.

Instead, what they are spending too much of their time doing is figuring out how to extend the patents on the existing drugs way out of the spirit, in my judgment, of the Hatch-Waxman Act.

So our bill is not about robbing pharmaceutical companies of legitimate patent protection. It is not about theft of innovation. It is not about taking steps to enact laws that are not in the best interest of consumers. It is about the opposite. It is about examining competition in today's marketplace and revisiting a compromise, an exquisite compromise, as I mentioned, that was struck 18 years ago.

In recent years, as the profits and stakes have become higher, drug industry lawyers have picked the Hatch-Waxman law clean. Companies are aggressively pursuing extended monopolies through filing weak or invalid patents and engaging in deals which the FTC is increasingly scrutinizing for anti-competitive motives. They are going to kill the goose that laid the golden egg as they push this too far. So we are trying to save them despite themselves, and we want to put an end to these abuses.

The GAAP Act does not intend to cut innovators off at the knees, and it isn't a freebie for the generic drug industry. As Senator

McCain mentioned, we come down on the generic drug companies that engage in collusive practices as well.

Let me tell you what the bill would do. It would eliminate the automatic 30-month stay handed to brand companies who file suit against a generic challenger. I know of no person, no objective observer, who thinks there is a justification for an automatic 30-month stay. We would instead require these companies to allow a court to decide whether the case merits a stay.

It would prevent abuses like we are discussing, reducing incentives to list patents that are not truly innovative, but instead are intended to solely extend monopolies. The GAAP Act reforms the so-called 180-day rule by closing the loophole that enables a brand-name company to pay a generic manufacturer to stay off the market, putting a kibosh on competition.

Now, PhRMA will tell you the law is not broken. They will tell you that the generic share of the prescription market has increased from 18 percent in 1984 to 45 percent today. That is true. What they won't tell you is that generics have been stuck around 45 percent for the last 8 years, and it should keep going up as new drugs come off patent and come on the market.

PhRMA will tell you patents on new products never delay generic versions of old ones, and if we are talking about patents on new drugs, that would be a true statement. But that is not what we are talking about, and please listen to this. What we are talking about here is new patents on old drugs. That is what they are doing: new patents, old drugs, not new drugs, not new innovation, not new people's lives saved.

The drug companies are coming up with different formulations or dosage forms or other unapproved uses for old drugs whose patents have either expired or are about to expire in order to keep the low-cost generic competitor off the market.

Since the generic has to show that it doesn't infringe on these new patents before it can enter the market, the drug companies buy extra time and extend their market exclusivity. The changes Senator McCain and I have proposed protect the brand companies from having their patents infringed upon, but they also prevent the brand companies from abusing their patents and keeping generics off the market.

Our bill would require a name-brand drug company to first prove to a judge that a case has merit before the delay is triggered. Now, let's look at some of the innovations, so-called innovations, that the brand companies are listing in the FDA's Orange Book. It is these kinds of patents which can automatically delay competition.

For Ultram, the first one on the chart, the brand company has come up with a new dosing schedule. Because it is a strong medication, they suggest you could take the pill, take a quarter of the pill at a time and slowly build up to taking the whole pill. That is a dosing method which doctors and pharmacists have used on many drugs in many instances, yet somehow J&J got a patent on it. In other words, they just say take a quarter of a pill at a time, build up to the new use, new patent. That is not what Hatch-Waxman was intended to do.

How about the next one on the chart, Fosamax? It is a drug for osteoporosis. It is a very fine drug. Well, here the company has

come up with a kit inside which the pills are arranged. They are rearranging the pills. This may be a great little kit, but its patent shouldn't be listed in the Orange Book where it can delay generic competition.

The next one is Pulmicort, an asthma medication. The company has a patent on the container the drug is in, and that patent is listed in the Orange Book where, again, you get another 30-months against the generic.

On Thalomid, a cancer drug, the company has come up with not one but two computer programs that pharmacists can use when doling out prescriptions. Same drug, new computer program. That is what we are talking about here to get a new patent. Not a new drug, a new computer program.

Give me a break.

Finally, Cyclessa. This is similar to Fosamax. there is a patent on it, on the kit which reminds you how to take the medication. Generics can make their own kit, I assure you. A new piece of plastic shouldn't keep an old pill off the market.

These patents are real. They may be on things that are novel, but they have nothing to do with the drug substance that is helping the patient. They are put in the Orange Book for the sole purpose of extending a company's monopoly.

PhRMA says the automatic 30-month stay never extends a patent. Well, it may not extend the amount of time a company can exclusively sell its particular container, but it certainly extends the amount of time that the brand can keep its competition away from the customers.

And brand companies are getting better and better at timing the filing of their patent applications so that their new patents are issued just as the original patents are expiring. This practice causes a delay in generic competition, which is nothing less than de facto extension of the original patent.

What has happened with these drugs is that the drug companies saw the original patents about to expire and created new ones simply to maintain the control over the market, and these practices, Mr. Chairman, which should raise everyone's eyebrows, have become the norm. Companies figure out new ways to keep the dollars rolling in, stooping to new lows every day to maintain their exclusivity rights.

So I will ask that the rest of my statement be read into the record, Mr. Chairman, but I want to thank you for holding this hearing. I think you all get the point. What our bill tries to do is go back to the good old days. You make a new drug, you get a new patent. And God bless you, you deserve it. You deserve the money for the innovation. You deserve the money for saving lives. But not this kind of stuff. This doesn't belong, and the bill that Senator McCain and I have introduced will restore the balance.

And I thank you, Mr. Chairman, for the—I know I have taken a bit of time. I get kind of excited about this subject. [Laughter.]

The CHAIRMAN. We thank you. Thank you very much, Senator Schumer.

We will hear from an old friend, Senator Hatch, former chairman of this committee.

STATEMENT OF SENATOR HATCH, A U.S. SENATOR FROM THE STATE OF UTAH

Senator HATCH. Well, thank you, Mr. Chairman.

The CHAIRMAN. We look forward to having you back.

Senator HATCH. Thank you, sir.

The CHAIRMAN. Wish you hadn't left.

Senator HATCH. Well, I kind of wish I hadn't left, too, when I see what you guys are doing around here. [Laughter.]

Senator HATCH. I think you are doing a great job, and I want to thank you, Mr. Chairman, Senator Gregg, Senator Hutchinson, and other members of the committee.

I am pleased today to give you my perspective on the operation of the Drug Price Competition and Patent Term Restoration Act of 1984. This carefully crafted balance promotes the development of tomorrow's innovative therapies and allows today's off-patent drug products to be sold by generic manufacturers at the most competitive prices to patients very concerned about the ever rising costs of health care.

No law with the complexity of the 1984 Act is so perfect that it cannot be improved as it faces the test of time and changing conditions. In my view, there have been several unintended and unanticipated consequences of the 1984 law and other changes in the pharmaceutical sector that bear attention by Congress. Today I wish to share my perspective on how the 1984 Act has worked, how the science of drug discovery and the pharmaceutical marketplace have changed, and to comment upon the process and some proposals for changing the law.

When we adopted the 1984 law, we were in an era of small-molecule medicine and large-patient-population blockbuster drugs. We are now rapidly entering an era of large-molecule medicine and small patient populations, or should I say small-patient-population drugs. In fact, we may be entering an age of literally single-patient, person-specific drugs.

Over the next decade or two, a great deal of inventive energy will be concentrated on developing biological products. The future of the drug industry may 1 day be dominated by biological products. As we enter this new era of drug discovery, certain policy questions should be considered by Congress. Are our pharmaceutical intellectual property laws adequate to promote the large-molecule, small-patient-population medicines? Does Hatch-Waxman as a general matter of policy adequately value pharmaceutical intellectual property relative to other fields of discovery? Is the current lack of Waxman-Hatch authorization of generic biologicals sound policy? How can Congress enact and sustain over time a Medicare drug benefit unless we seriously explore what steps must be taken to end an FDA regulatory system that acts like a secondary patient for biological products?

The last overarching question I will raise for the benefit of my colleagues is whether we need to think about ways to increase the strength of America's research-based industry. I have made it clear that my vision and preference on how to approach Waxman-Hatch reform is to help facilitate a dialogue among interested parties on a comprehensive range of innovator generic drug issues, including the matters that I have just outlined.

I recognize that the members of this great committee and other Senators may have your own views on the proper scope of inquiry. Proponents of the McCain-Schumer bill, S. 812, have a somewhat narrower but, nevertheless, extremely important agenda. There is no question that pharmaceutical prices are an issue of concern to each of us and our constituents, especially to many seniors, but we must proceed in a thoughtful fashion.

Many of us would be very interested in the results of the extensive FTC survey of the drug industry that will examine many key aspects of the 1984 law. Let's get the facts before we change the law.

Now, I would like to refer to S. 812, the GAAP Act. let me make a few comments about this McCain-Schumer bill.

First, I want to commend the efforts of my colleagues, Senators Schumer and McCain. To make drugs more affordable is their goal to those many citizens who have had a hard time paying for their medications. They have done an impressive job of building support for this legislation. Unfortunately, in its current form, I cannot support the GAAP Act. In fact, with all due respect to its cosponsors, both of whom I admire and both of whom are friends, I oppose adoption of this bill. In the interest of time, I will concentrate my remarks today on two central features of the bill: the 180-day marketing exclusivity rule and the 30-month stay.

Perhaps no single provision of the 1984 law has caused so much controversy as the 180-day marketing exclusivity rule. The statute contains this incentive: to encourage challenges that test the validity of pioneer drug patents and to encourage the development of nonpatent-infringing ways to produce generic drugs.

The Judiciary Committee held a hearing on this issue last year and reported Chairman Leahy's bill, S. 754, which I supported. The FTC has settled several antitrust cases and is investigating other possible violations pertaining to pioneer generic 180-day rule settlements.

The McCain-Schumer bill addresses the 180-day situation by adopting a so-called rolling exclusive policy. If the first filer does not go to market within a specified time period, the 180-day exclusivity rolls to the next filer. I do not favor rolling exclusivity.

As Mr. Gary Buehler, then Acting Director of FDA's Office of Generic Drugs, testified before the Judiciary Committee last year, "We believe that rolling exclusivity would actually be an impediment to generic competition."

In 1999, FDA proposed a rule which embraced a "use it or lose it" policy whereby if the first eligible ANDA—abbreviated new drug application or applicant—did not promptly go to market, all other approved applicants could commence sales. If our goal is to maximize consumer savings after a patent has been defeated, it is difficult to see how rolling exclusivity achieves this goal.

Now I certainly prefer FDA's "use it or lose it" policy over the McCain-Schumer brand of rolling exclusivity. I would also note that there are those who have suggested that the 180-day exclusivity may not even be necessary given the incentive to attack pioneer drug patents. One of FDA's top legal experts, Liz Dickinson, has asked, "I suggest we look at whether 180-day exclusivity is even necessary."

I think it appropriate for Congress to consider whether there is a need to retain any marketing exclusivity reward for successful patent challenges, or at least to ask whether the reward should continue in the present 180-day form.

We need to examine further if identical rewards should be granted for successful invalidity and noninfringement claims. At present, I am of the mind to preserve at least some sort of financial incentive to encourage vigorous patent challenges by generic drug firms. While I think changes to the current system may be in order, I am opposed to McCain-Schumer rolling exclusivity.

Now, with regard to the 30-month stay, my preliminary view at this point is that the provisions of the McCain-Schumer bill related to the 30-month stay may overcorrect a problem that may, in fact, be somewhat overstated in the first place. We just need to find out more about the facts, and we should wait until these facts are brought forward, because they are under study and they are going to be brought forward.

As I understand S. 812, the current statutory 30-month stay would be eliminated in favor of a system of case-by-case application for injunctive relief. Now, I hope that this hearing and the forthcoming FTC study shed some light on the facts of the matter concerning improper and consecutive 30-month stays.

I also want to see what the FDA concludes with respect to the scope of the alleged consecutive stay problem and what its recommendations are to address this situation.

What is often left unsaid by advocates of changing the law is that the Hatch-Waxman bill created a unique provision in the patent code that essentially allowed generic drug firms to infringe pioneer firm patents. This was a huge change. I don't think people realize who aren't familiar with this bill and this area what a huge change that was in the last, a change that no other industries enjoy.

That is a point I cannot overemphasize. As a general rule, Title 35 provides that no one can make, use, or sell a product while it is under patent. There is one exception to this general rule against patent infringement. This provision, the so-called Bolar amendment of the Hatch-Waxman bill, is codified at 35 U.S.C. 271(e). Here is what it says. Do we have the chart there? OK.

"It shall not be an active infringement to make or use a patented invention solely for uses reasonably related to the development and submission of information under a Federal law which regulates the manufacture, use, or sale of drugs or veterinary biological products."

What this means is that the generic drug firms and only generic drug firms among all other generic product industries gets statutory protection from activities that would otherwise constitute blatant acts of patent infringement. This is the only case, and it is Hatch-Waxman that gave that right.

Anyone involved in the negotiations will tell you that the Bolar provision was a significant factor in striking the final balance that led to the passage of Hatch-Waxman. In my mind, the Bolar amendment is directly related to the 30-month stay which allowed what was thought of as a reasonable time for courts to act responsibly on patent changes initiated by generics.

The reason why no one would simply buy the argument that the changes in the 30-month rule proposed by S. 812 only leveled the playing field on patent challenges is because generic drug firms enjoy the unique and unprecedented protection of Section 271(e)(1) and get a head start that no other type of patent challenger is afforded.

Now, I am concerned that simply throwing the matter of injunctive relief to Federal district courts absent a period to allow the court to sufficiently familiar itself with the issues at hand not only disrupts a justified internal check and balance of Hatch-Waxman, but also sort of creates something of a crap shoot in the district courts with respect to these injunctions.

While I can see how some enterprising generic firms and their attorneys might be able to turn this new, potentially unpredictable environment into leverage for settling patent challenges, I am not sure that this instability is either fair to pioneer drug firms or in the long run to the interests of the American public. It seems to me that one of the most beneficial steps that this committee as well as the Judiciary and Commerce Committees can play is to get the facts of the matter on how many times and under what circumstances the 30-month stay provision has been used in an abusive fashion. And we don't have those facts right now. We have the allegations, but we don't have the facts.

Now, once we have the relevant facts, Congress may well decide to make some appropriate adjustments in the 30-month stay. It could be that the potential for abuse under the current statement may justify some statutory refinement. But based on what we know today, I think that S. 812 goes too far by eliminating the 30-month stay and upsets the carefully balanced dynamic with the Bolar provision.

Now, I lived through this for 18 days day and night, 18-hour days, with both the pioneer firms and the generic industry. And it was no fun, I will tell you. In fact, at one time I had a root canal right in the middle of it, and I threatened to kill them if they didn't get this thing done the next day. And they did, by the way. So maybe my threats make some sense every once in a while.

In closing, let me commend you, Chairman Kennedy. I have great respect for you, as you know. Senator Gregg, I have great respect for you. You are doing a great job on this committee. And the committee, you other members, I am really pleased with you for holding its first hearing on this very important subject.

I commend Senators McCain and Schumer for helping to raise some important issues, even though I do not agree with how their legislation resolves these matters at this time. I maintain my longstanding interest in this law and intend to continue to work with all Members of Congress and other parties who are interested in this legislation, including my esteemed colleague, Henry Waxman. And although I no longer have the power of the gavel, I urge those who wield that power to engender a broad and thoughtful discussion of how Congress can achieve consensus in how to revise our pharmaceutical laws to best assist in ushering in this new era of molecular medicine.

It will be vitally important that we legislate in a manner that is driven by the facts rather than from the emotion of an election

year. Our goals remain the same as in 1984. How can we help bring the American people the best medicine in the world but do so in a fashion that makes their prescriptions as affordable as possible? This bill has saved consumers between $8 and $10 billion every year since 1984, and the reason it has is because of the delicate balance that encourages the pharmaceutical pioneer firms to spend up to $800 million for every blockbuster drugs and go through as much as a 15-year safety and efficacy process, while at the same time bringing those patented drugs off patent in the most efficient, quick way we can possibly do it so that the generic firms can bring the prices down. That should be our goal. That was the goal of Hatch-Waxman. We accomplished it. If there are faults with the bill—and I suspect there may be—we should at least get the facts before we go off half-cocked and lean everything toward the generics or everything toward the pioneers.

Now, nobody is arguing to lean the things toward the pioneers, but I tell you this: If the pioneers don't have the incentives to go through this safety and efficacy process that is a lengthy and costly process that costs up to $800 million per drug, then there won't be any generics in the future. We want to get that delicate balance so it works, and I intend to work with both Senators McCain and Schumer and all of you on this committee and all on the Judiciary Committee to see that we do it right. But I think we are a little premature until we get all the facts.

Sorry I took so long, Mr. Chairman, but I felt like I needed to cover that subject.

The CHAIRMAN. Well, thank you very much, Senator Hatch, for your comments on it. Obviously as an author, we take your experience very—pay a great deal of attention to what you have said on this. We thank you very much.

Senator HATCH. Well, I appreciate it. If there are any flaws, Mr. Chairman, then, of course, they have to be Henry's fault, not mine. [Laughter.]

Senator HATCH. I am only kidding. I better make that clear. Henry did it.

The CHAIRMAN. Since you brought up Henry, I will include his statement of support for McCain-Schumer in the record. [Laughter.]

You gave me that opening on that. I wasn't going to——

Senator HATCH. I understand. That is only fair.

Senator SCHUMER. Mr. Chairman, don't worry. I was.

The CHAIRMAN. Oh, you were. Good. Fine. But thank you very much.

Senator Johnson is here. We would welcome him. I know you have spoken eloquently about the cost of prescription drugs and the potential for generics, and I know it has some particular relevancy in terms of your State, so we would welcome any comments you would like to make.

STATEMENT OF SENATOR JOHNSON, A U.S. SENATOR FROM THE STATE OF SOUTH DAKOTA

Senator JOHNSON. Well, thank you, Mr. Chairman and members of the committee. I will be very brief this morning, but thank you for allowing me an opportunity to appear before the committee

today, in part to introduce Governor Bill Janklow from my home State of South Dakota. On behalf of Senator Daschle and myself, it gives us great pleasure to have the Governor of South Dakota appear before your committee providing testimony on behalf of our citizens on an issue of enormous importance to every one of us here.

I also want to thank the committee for its leadership on the prescription drug debate and for bringing issues of reforming the 1984 Hatch-Waxman Act to the forefront by holding today's hearing. While I regret that I have got to depart almost immediately in order to president on the Senate floor, I believe Governor Janklow's testimony will provide the committee with very valuable insight as to the direct financial impact that delays in being able to access generic alternatives which are prompted by pharmaceutical manufacturers' tactics have on State Medicaid programs and consumers alike.

Efforts to increase utilization of general drugs as a cost containment method for consumer and other drug purchasers could only be strengthened by addressing some of the concerns raised with existing loopholes in the Hatch-Waxman Act. We all know that using lower-priced generic drugs when possible helps reduce overall drug costs. However, it does little good if our current laws further promote the ability of drug manufacturers to use methods to keep the lower-priced competition from entering the market in the first place.

Along with Governor Janklow, I have supported legislative efforts such as the bill introduced by Senators Schumer and McCain that seeks to address generic drug reform issues. I want to commend Governor Janklow for his efforts that he has undertaken in the State of South Dakota to increase utilization of generic drugs which have mirrored some of the efforts that Senator Daschle and I have promoted at the Federal level. Governor Janklow has been implementing creative programs at the State level designed to maximize the savings associated with increased generic drug use.

Together, these types of initiatives at the Federal and the State level along with closing the gaps in the Hatch-Waxman Act can help us turn an important corner as we strive to enhance the quality of life for all Americans.

Again, I thank the chairman and members of the committee for allowing me the opportunity to present this statement and the introduction of Governor Janklow. Thank you, Mr. Chairman.

The CHAIRMAN. Thank you very much. We are glad you are all here. Appreciate it. We will move ahead with our panel.

Senator GREGG. Could I ask Senator Schumer a question?

The CHAIRMAN. Yes.

Senator GREGG. First off, I was very interested in what Senator Hatch said about your bill, and I am obviously interested in your language. I do think there is an issue here with regard to the 180 day exclusivity period and the 30 month stay, but another area which your bill raises a question on, and that I am trying to get clarified in my own mind, is this issue of bioequivalency. And it appears that your bill creates a new standard for approval. You seem to have added a new test for establishing generic bioequivalency, which is, as I understand it, therapeutic equivalency.

That is a new standard, and it implies, to me at least, that rather than requiring that the drug be basically identical with a 20 percent variable on either ends, it is no longer necessary for the drug to be identical; it just has to have a therapeutic equivalency, which means only the end has to be the same.

This is a huge issue because I think it gets into the public health question of whether a generic drug is safe. So I was wondering if you could just address that.

Senator SCHUMER. No, we don't intend to change the standard of bioequivalency. What we are trying to do is sort of meet the opposition in a certain sense—well, that chart isn't up there anymore—and deal with situations where you have the same drug in terms of bioequivalency and they just sort of say, well, it is a different drug because of nonbioequivalent changes. That is the bottom line.

Senator GREGG. So this therapeutic equivalency, you are not trying to set a new standard for generic——

Senator SCHUMER. No. Even if it were a totally different drug chemically——

Senator GREGG. —that gives them a new——

Senator SCHUMER. Yes, if it were a different drug chemically and did the same thing, but, you know, all the hydrogen and oxygen and carbon atoms and all these others were rearranged totally differently, it would not qualify under our bill.

Senator GREGG. Thank you. I think that is an issue, and I hope we can work on that language.

The CHAIRMAN. Could the Senator yield? As I understand, the ones that have been changing it have been the drug companies. What you are trying to do is put it in statutory form.

Senator SCHUMER. That is exactly right.

The CHAIRMAN. You are the one that is trying to regularize the process based upon—the companies have been the ones that are—as I understand.

Senator SCHUMER. While the Senator was out of the room, I pointed—if we could put that other little chart up there. These are the new patents. They don't change the bioequivalency. They don't change the drug. They change the dosing schedule, the kit, the container. They put a new piece of plastic in the kit, and they say, "We want a whole new patent."

Well, I can't believe—and I know Congressman Waxman agrees with me, and I am going to ask Senator Hatch about it, you know, when I get to see him next. I can't believe that that was ever the intent of Hatch-Waxman that you change the kit or change the dosage and you get a brand-new patent. And yet that is what is happening now, and that is what is getting people so frustrated.

We have a huge coalition. We have General Motors and the UAW on the same side on this issue. We have all of the HMOs, or many of them and their organizations, and the hospitals and the doctors, all of whom have seen that the law is being eroded. And we are just trying to restore the balance.

You know, I respect Senator Hatch enormously and, as he said, we are good friends, but he says the 180 days would inhibit generic competition. Then why is the generic drug industry for it? I mean, I don't think they want to inhibit generic competition.

And on the 30 months, his argument was, well, it was good back then, let's keep it the same way, that the drug companies made a deal and we have got to stick by it. Well, the drug companies are doing fabulously under the present law.

Senator GREGG. My point didn't go to those two issues.

Senator SCHUMER. Oh, I know.

Senator GREGG. Your language says "any other methodology that demonstrates that no significant difference in the therapeutic effects of an active ingredient are expected."

Currently, there is no comparable FDA regulation which allows approval of a generic drug based on therapeutic equivalency—that is a whole new standard for the FDA. I guess my question is: What is your intent there?

Senator SCHUMER. That is presently—the therapeutic clause that you mention, as I said, does interfere with bioequivalency. In fact, it is part of FDA regulations right now. We are just codifying it. Because what has happened, as Senator Kennedy said, the drug companies are trying to get rid of it as a way of expanding patents even further beyond any dimension that Hatch-Waxman had asked for. But that is not new. That would not change the present situation at all because it is in existing FDA regulations.

Senator GREGG. No, it is not. But we can talk about that.

Senator SCHUMER. I think it is, but we will.

Senator FRIST. Mr. Chairman, I do share Senator Greggs concern. As I look through the bill, this is one of the more egregious things to me because it looks to me, based on page 10 of the bill that Senator Gregg commented on, it looks like to me that we are giving FDA a blank check to do whatever they want to, and that may not be the intent, but to me that is the interpretation.

Senator SCHUMER. I would say this to you, Senator, and to Senator Gregg: That is not the intent. As I said, we are codifying existing regulation. The intent is to not get—to keep the bioequivalency standard, to stick with it, to not end up with all of these kinds of things. But what I would say to you is I would be happy to work with—I mean, if you have some sympathy for the 180-days problem and the 30-months problem, I would be delighted to work with you to make sure, because that is what the focus—those are the two major focuses of this proposal. There is not an intent to change the bioequivalent standard. It is to keep it where it is now.

Senator FRIST. The reading to me is that you are giving the FDA more discretion—and I don't think there is any evidence that we need to give the FDA more discretion, allowing more variations in bioequivalence for generic drugs by concentrating just on the therapeutic effect. That to me is potentially very dangerous.

Again, we don't need to piecemeal the bill now, but since the issue was brought up——

Senator SCHUMER. But what happens now, because there is a discrepancy between the regulatory standards and the statutory standard, it opens it up to more lawsuits, more 30-month situations, more delay. And so we wanted to harmonize the regulations with the statute in a way that restores the old balance. That is the intent of this proposal.

Senator GREGG. Well, there is sympathy for——

The CHAIRMAN. Well, as I understand, the bioequivalence has been established, but there are—under Hatch-Waxman it defines the bioequivalence. And the definition is, as I understand, inadequate for certain drugs, topical drugs that are applied to skin, inhaled drugs. And the FDA has defined bioequivalence further in regulations, but the drug industry sues when FDA applies these regulations. And FDA, as I understand, has never lost. What you are attempting to do is codify the regulations so that it will no longer be able to be used as a sham. That is what, as I understand, you were intending to do on this.

Senator SCHUMER. That is the purpose. But if somebody has come up with an interpretation——

The CHAIRMAN. If there is a better way of doing it——

Senator SCHUMER. You bet. I am willing to look at that.

The CHAIRMAN. That is what your point is. That is what your intention is, which is completely consistent with the rest of your testimony about trying to reduce these kinds of loopholes.

Senator SCHUMER. Litigation.

The CHAIRMAN. And litigation.

Thank you very much.

Senator SCHUMER. Thank you, Mr. Chairman. I thank the members of the committee for their attention, and particularly, I noticed in the corner there when I came in, my colleague Senator Clinton.

Senator CLINTON. Some moral support.

Senator SCHUMER. Thank you.

The CHAIRMAN. Good. Thank you for being here.

I am privileged to welcome Governor Bill Janklow of South Dakota and Bruce Bradley of General Motors to share their views on abuses of Hatch-Waxman and the impact on health care costs. We are delighted to have the Governor here, who has given this great attention and focus and study, and Mr. Bradley currently serves as director of Health Plan Strategy and Public Policy, General Motors health care initiatives, founding member and Chair of the Leapfrog Group Steering Committee, and a board member of the National Forum on Health Care Quality Measurement and Reporting.

So we will start with the Governor.

STATEMENTS OF HON. BILL JANKLOW, GOVERNOR OF SOUTH DAKOTA, AND CO-CHAIRMAN, BUSINESS FOR AFFORDABLE MEDICINE COALITION; AND BRUCE E. BRADLEY, DIRECTOR, HEALTH PLAN STRATEGY AND PUBLIC POLICY, GENERAL MOTORS CORPORATION

Governor JANKLOW. Thank you very much, Senator Kennedy and members of the committee, and I would request permission to take my written testimony and make it a part of the record, and that way I won't have to read through it all.

The CHAIRMAN. That is fine.

Governor JANKLOW. If I could, I would like to make the statement that I am here today to represent a group called Business for Affordable Medicine, which includes 10 Governors of the United States, labor unions of the United States, and many private companies, including General Motors, Weyerhaeuser, Wal-Mart, Kmart, Kodak, Georgia Pacific, Motorola, Verizon, and a very significant number of large and small companies.

At the National Governors Association annual meeting earlier this year, the Governors unanimously adopted a resolution. All the Governors who voted voted in favor of a resolution asking the Congress to please look at Hatch-Waxman in order to try and fix the parts of it that are broken.

If I could, there is a chart missing. Unfortunately, I didn't bring one. But there is a chart missing. When PhRMA talks, they talk about the fact that over the course of the last 20 years, 20-some years, 18 years since Hatch-Waxman was passed, that utilization of generics has gone from 18 to 45 percent. But you really need to have two charts because the increase from 18 to 45 percent took place the first 9 years, and in the last 9 years, for all practice purposes, the line would be flat. Because of the loopholes that have been discovered by the pharmaceutical companies, they have been able to exploit the continuation of their patents.

The fact of the matter is today, on a serious drug, it is not a 17-year patent. It is a 19½-year patent. Just add the 30 months to it, because the 2½ years that you add to it is really what the patent protection is. So if we put up a chart today, we would have to put up two charts to address the question of the increase from 18 percent to 45 percent, which is what PhRMA tried to explain to me when they came to South Dakota to tell me why we should leave the legislation as it was.

In addition to that, they talk about 6 percent of all the drugs that are expiring are drugs that face delays. Again, that is throughout the history of the 18-year period before they figured out the loopholes. So what we really have to do is look at that 6 percent figure but ask what has gone on the last couple years.

Well, let's take the year 2000: 50 percent of all the brand drugs, if I can call them that, 50 percent of all the brand drugs that expired, that should have expired at their 17-year period in the year 2000, still have not been approved today. And with respect to 2001, 70 percent of the drugs that were set to expire in 2001 have still not expired today. That is an incredible—that is just an incredible opportunity or indictment, depending on one's perspective, as to how good-faith legislation passed by this Congress has been figured out how to be exploited.

You know, in athletics, when people figure out a loophole, generally after the season—they let it continue until the end of the season, and then afterwards the rules committee gets together and addresses those kinds of problems. This problem is costing the American people a fortune.

Today, I am here to speak on behalf of other Governors with respect to Medicaid expenditures, but let me tell you, my friends, that is the smallest part of the problem because Government pays for Medicaid by taking people's money, and then in a partnership between the Federal and State Governments, we fund Medicaid.

What about that poor soul out there that is making $10, $11 an hour and they don't have any coverage and they are not eligible for Medicaid and they are not getting a benefit through their employer because they are not able to be provided for one reason or another? That poor sucker is getting the shaft all the time. They are paying more money—the person that pays cash for their drugs pays more money than Medicaid, Medicare, the military, the tell drugs or the

one that are mail-order drug companies, the chain drug companies, and the sole proprietor pharmacy. The person that pays cash pays more than anybody, and that is just ludicrous with respect to allowing that kind of thing to happen.

This 30-month loophole is almost unheard of. My good friend—and he is a friend of mine for many years—Senator Hatch, alluded to that one chart that talked about these unique protections that the generic drug companies have. As I understand that protection, what it really means is they can manufacture, they just can't sell it. It gives them a protection to manufacture it, but no protection to sell it. So they are unable to sell the drug.

Even Napster was able to—they figured out how to be able to deal with Napster through the normal judicial process. There is no legitimate reason in the world why anybody should be entitled to an automatic stay without any kind of judicial review.

My State just sued the Army Corps of Engineers, 2 weeks ago received a temporary restraining order. The last thing the judge determined before he had the hearing was what would be the bond that South Dakota has to post, and he has the discretion on whether or not to impose a bond. Why isn't there any discretion here? If these companies stretch their patent for 2½ years and then at the end of it it is determined that they shouldn't have been able to stretch it for 2½ years, people say, well, yes, the FDA will come in and make them refund the money. The people, the little guy out there on the street that paid the bill will never get their money back, ever. It will go to all the middlemen and -women, middle companies. But the little people on the street will never get their money back.

It is unheard of under the Federal Rules of Procedure, under State Rules of Procedure, that you can get a 30-month extension without having to show something other than your word that you are entitled to a continuation.

So I realize my time is up. I would just like to close by saying that this is—I don't have an opinion on the whole bill because, frankly, I don't know it. I do know this 30-month provision is costing billions of dollars to the people of America and the world, because that patent protection that they are entitled to here carries with it the intellectual property rights throughout the world. And so it is—they have discovered a way to legitimately extend a patent, not what was ever intended by you folks and your predecessors. You need to now as a rules committee come together and change it back to what the original intent of the Congress and the American people was. Every Senator—I have got to believe every Governor in America is calling ever one of you to tell you Medicaid is breaking them. Let's bring the playing field back to what was intended to make sure that these companies have marvelous patent protection, but that they have it for the 17-year period of time, and anything over that takes some kind of showing to somebody, whether it is the FDA, the courts, or someone.

And I close by saying this: If there is one other thing that is preventing States from moving forward to do something about the cost of drugs, every time a State attempts to do anything, there is a lawsuit filed against that State by PhRMA—the drug industry, I

should say. And they say that the States are violating interstate commerce, which is left exclusively to the Congress to regulate.

My friends, if you are going to give them the continued 30-month period, then pass a law that says the States are entitled to pursue their own approaches. As Justice Brandeis envisioned almost 100 years ago, he said the States are laboratories of democracy. Allow the States to do creative practices and run the risk of confrontation with these companies, but not let us have our statutes thrown out because they say it violates the Commerce Clause.

Senator Kennedy and members of the committee, you have been very generous with your time, and I appreciate it. Thank you.

The CHAIRMAN. Very compelling testimony.

[The prepared statement of Governor Janklow may be found in additional material.]

The CHAIRMAN. Mr. Bradley?

Dr. BRADLEY. Thank you, Senator. Mr. Chairman, Ranking Member Gregg, and distinguished committee members, I am Bruce Bradley, director of Health Plan Strategy and Public Policy at General Motors. Today I am testifying on behalf of RxHealth Value, a coalition of more than 20 organizations representing consumers, employers, unions, health plans, and providers. Our broad, diverse membership includes numerous prominent consumers and purchasers of pharmaceuticals such as AARP, Families USA, the Midwest Business Group on Health, Ford, Daimler-Chrysler, the United Auto Workers, the AFL-CIO, Kaiser Permanente, the Alliance of Community Health Plans, and Blue Cross and Blue Shield Association.

It is an honor to appear before your committee to share our experience regarding prescription drug cost increases and to underscore our belief that Federal policy reforms are necessary to restore the balance between pharmaceutical competition, consumer choice, and innovation.

Consumers, businesses, unions, the Federal Government, and health plans throughout the Nation are aggressively, and most unsuccessfully, attempting to manage soaring prescription drug costs. These expenditures are increasing at annual rates of up to 20 percent and are unsustainable. That is why GM is working with three coalitions—RxHealth Value, Business for Affordable Medicine, and the Coalition for a Competitive Pharmaceutical Market—to highlight this issue and advocate for Federal policy changes.

These broad-based, diverse, and respected organizations all represent purchasers who are growing increasingly concerned that the Hatch-Waxman law contains loopholes that allow the pharmaceutical industry to delay more competition and choice of high-quality, cost-effective generic drugs.

Collectively, RxHealth Value's members represent over 100 million Americans. These consumers spend billions of dollars each year on prescription drugs. The business and insurer purchasers that comprise RxHealth Value are reporting prescription drug cost growth trends of as much as 20 percent per year.

At GM, we insure 1.2 million workers, retirees, and their families and are the largest private provider of health care coverage in the Nation. We spend over $1.3 billion a year on prescription drugs alone. Our pharmaceutical bill continues to grow at the rate of 15

to 20 percent per year, more than quadrupling the general inflation rate. Such drug cost increases are driven by a host of factors, including higher utilization, direct-to-consumer advertising, price increases of existing pharmaceutical products, and the delay of generic competition.

Today's hearing appropriately focuses on barriers to generic entry into the marketplace. From our perspective, this problem has grown worse in recent years and, if not addressed, will almost certainly force companies and all other purchasers, public and private, to make extraordinary and painful benefit and cost-shifting decisions. Global companies and their suppliers—small businesses—simply will be unable to effectively compete in the world marketplace without relief from rising prescription drug costs.

Mr. Chairman, in the last several years, as the patents of prescription drugs have expired, purchasers have planned and budgeted for generic drug competition to reduce costs and increase enrollee choice. Such competition is critical to effective pharmaceutical benefit management programs as generic competition reduces costs by 50 to 60 percent or more. Time and again, however, purchasers have underestimated their liability as many pharmaceutical companies effectively extend their market exclusivity through inappropriate Orange Book patent listing, triggering the automatic and repeated use of the 30-month market exclusivity stay.

Since the enactment of Hatch-Waxman, the average number of patent extensions filed for blockbuster drugs has increased by five-fold—from two to ten patents filed. This trend has a very real and all too frequently devastating financial impact on GM and the other members of RxHealth Value.

Our concerns about inappropriate practices in the marketplace are not limited to the brand-name industry. We are troubled by and strongly opposed to brand-to-brand and brand-to-generic settlements that are designed to delay market entry of generic competition.

There have been cases when generic companies who initially filed to challenge a brand-name patent and thus were eligible for the no-generic-competition 180-day exclusive period have reached an agreement with the brand-name company to not enter the marketplace. Such agreements, which benefit both brand name and generic companies, are costly for purchasers and especially consumers of prescription drugs.

Within the last several years, RxHealth Value members have literally had to increase our budgets for pharmaceuticals by hundreds of millions of dollars a year. For example, without new legislation, we now estimate that if five blockbuster medications whose original compound patents should have already expired continue to avoid competition, GM will see increases in our prescription drug bill well in excess of $200 million during the projected period of delay of generic market entry.

Mr. Chairman, when access to lower-cost generics is inappropriately delayed, consumers and other purchasers have no remedy or recourse. We have no way to recoup the excess costs paid for pharmaceuticals. We are appearing before you today to highlight the tremendous challenge confronting us and to seek legislative relief.

We believe that this is the time for Congress to intervene and pass legislation that will restore the balance between competition and innovation that was initially intended by the Congress in the Hatch-Waxman Patent Restoration Act of 1984. For this reason, GM, as well as members of our RxHealth Value, support the Greater Access to Affordable Pharmaceuticals Act and other legislation designed to eliminate these barriers to generic drug entry into the marketplace.

We greatly appreciate the bipartisan leadership of Senator Schumer and Senator McCain in raising this issue and in developing thoughtful legislation. We hope this will serve as a critical foundation for constructive legislation to be reported out of this committee and passed in a bipartisan fashion by the Congress.

I do want to make clear, however, that GM, the auto industry, and the coalitions we have partnered with, including RxHealth Value, are strongly committed to and supportive of pharmaceutical research and development. We believe that innovative products should be strongly protected by patent law. We fear, however, that certain practices currently employed in the industry have effectively misdirected its attention away from true innovation and new product development and toward the preservation of old innovations.

Finally, notwithstanding our concerns about pharmaceutical cost increases, we regard coverage of prescription drugs as a basic, necessary benefit for all Americans. Prescription drugs used wisely are frequently the most clinically appropriate and cost-effective treatment. We strongly support bipartisan legislation that will enhance competition and choice while also encouraging meaningful innovation.

Mr. Chairman, we appreciate your leadership in holding this hearing. We look forward to working with you and providing any assistance possible in developing legislation in this area. I would be happy to answer any questions you may have.

Thank you.

[The prepared statement of Mr. Bradley may be found in additional material.]

The CHAIRMAN. OK. We will have 6-minute rounds. I will ask the staff to remind the Senators.

Mr. Bradley and Governor, how do you respond to the point that, well, this was a balance? You have pointed out at least some of the concerns you have about different provisions, but this is a balance between the generics and the drug companies, and you are just highlighting some of the provisions in here that appear to work to the disadvantage of generics to the consumers. If you start tampering with this, we are going to unravel something that was very important in terms of the development of the generic industry.

Just quickly, how do you answer that?

Dr. BRADLEY. Senator, we believe that the balance was very carefully crafted, and it was mentioned earlier that there were changes in circumstances and unanticipated interpretations of the law and actions from the law that were not part of that carefully crafted balance. And our belief is that we just need to go back to that very, very carefully crafted balance, which we believe is very, very important. We need new drugs. We need the great innovations. They

have done wonderful things for our people. But we also need at the end of the patents the legitimate patent life to make cost-effective drugs available to consumers and our employees. The cost issue here is very, very large.

The CHAIRMAN. Governor?

Governor JANKLOW. Thank you very much. Senator, you hit it right on the head. There was a carefully crafted balance, and somebody figured out how to find a loophole in it. Nobody envisioned that loophole. I bet you could back and check every single word of congressional testimony that ever took place by the witnesses and by the Members of the Senate and the House, and you won't find anybody that envisioned that it would be used like it is being used now.

And so an opportunity was found, and what you have to do is level the playing field back. The chart that Senator Hatch put up I think speaks for—that is what he emphasized, the good Senator did, with respect to the balance, the one that talks about how you can't be charged with infringement and the other one that gives you the protection.

And I think Senator Hatch hit it right on the head. They are given that protection, but they can't sell the drug. All they are allowed to do is manufacture it and warehouse it. So that just means that if and when the 30-month period expires or the litigation ends or the FDA decides to deal with it and the courts are then done with it, then they can sell out of the warehouse. But who is going to run that kind of risk? That is not what was intended, so you have got to fix the rules.

The CHAIRMAN. Governor, I have the survey about Medicaid, the State Medicaid survey, expenditures in 2001 $1,231,000,000. As I understand you, Mr. Bradley, the coalition asked each agency in the States to report in 2001 the expenditures for 17 prescription drugs that face patent expiration in 2002, 2003, and 2004. Forty-six States responded. Forty-six Medicaid agencies paid $1.2 billion for drugs. Nearly half the expenditures, $520 million, were for drugs that face patent expiration this year. States should be able to anticipate savings for the drugs up to 60 percent. This means that States should save up to $600 million with generic alternatives to the 17 drugs.

Governor, why in the world aren't they doing this?

Governor JANKLOW. Because the States aren't allowed to, Senator. We can only live or die under Hatch-Waxman. We are prohibited because we can't interfere with interstate commerce.

But, Senator, the point you make is eloquent, and let me tell you why. Medicaid drug costs are the lowest, so this number that you have just used, the $1.229 billion, and then you talk about what it would be less for those coming off patent, that is a drop in the bucket compared to the real costs out there for the General Motors of this world and, you know, Roy's Blacksmith Shop and everything in between or some individual retired person that is paying for their own on Social Security or a working person.

The point is they all pay more. General Motors pays more than any State in the Union does for Medicaid. You will pay more than any State in the Union. Medicaid is the lowest.

The CHAIRMAN. Not under the Senate health insurance.

Governor JANKLOW. Pardon me?

The CHAIRMAN. Not under the Senate health insurance bill.

Governor JANKLOW. OK.

The CHAIRMAN. That every Member of the Senate checks in. Not one of them refuses it. Not a single Member, not a Republican nor Democrat refuse it.

Governor JANKLOW. Good point.

The CHAIRMAN. Mr. Bradley, would you respond to what the Governor said? If this is understating it, what is your sense or can you tell us factually what you think are closer to the figures that could be saved?

Dr. BRADLEY. Well, we have taken a look at just our current costs, the current situation, and let me just give you an example of going forward where the potential savings are.

We believe that we can save over $200 million—and that is a conservative estimate—if five drugs—we did an analysis of them: Neurontin, Wellbutrin and its sister product Zyban, Paxil, and Prilosec—and pardon me for mispronouncing some of these drugs—which are right now being marketed without generic competition. We did a projection essentially that examined the impact based on our estimate and a conservative estimate of the difference between what we are projecting to pay for these drugs and what we would actually pay should the generic become available. And we see easily $200 million.

The CHAIRMAN. Well, this is the company—the fact is, with this legislation passed, we would be saving billions of dollars a year. And there is the issue of cost. There is the issue of access. We have to address both in this Congress. But we know—and you have given us very, very important information about what is happening out there in the real world in terms of the States. And we should find ways to be able to achieve it.

Senator Hutchinson?

Senator HUTCHINSON. Thank you, Mr. Chairman. I appreciate your calling this hearing today on a very important subject, the Hatch-Waxman law. As important as this is, achieving access to affordable pharmaceuticals by providing a Medicare prescription drug benefit for our seniors is even more critical for Congress to act upon this year. With that in mind, I have written Chairman Baucus asking him to schedule a markup of Medicare prescription drug legislation before we leave for the July 4th recess. At the same time, it is important that we also move ahead with hearings and examination of the Hatch-Waxman law.

Governor, thank you for your testimony and thank you for your passionate statement. It is obvious that you feel very strongly about this. A couple things came to my mind. You mentioned, as did Senator Schumer, the growth in the percentage of the market attributable to generics since the enactment of Hatch-Waxman. Over a period of 18 years, the generic market-share has grown from 18 percent to 45 percent. Both you and Senator Schumer also made the point that the problem is not that there has been this dramatic increase, but that the growth all happened in the first 9 years and has leveled off because drug companies have discovered loopholes in the law.

We have heard the Hatch-Waxman Act described as finely balanced legislation. We have seen a dramatic increase in the percent of the market that has gone to generics. How high should it go? And when drug companies, pharmaceutical companies are spending $800 million to develop a new drug, at what point is their role in the marketplace so diluted that they can't, or they won't make those kinds of investments? Is it 70 percent or 75 percent? Where should the generic market-share be at what point have we reached the point that you think is a sufficient movement upward?

Governor JANKLOW. Senator, I don't know what the dollar figure is, but, Senator, let me explain something, if I can. What we need in life is a set of rules. That is what we do when we legislate: we make rules.

I have never heard of legislation that was passed 22 years ago and people would say, well, let's pass a constitutional amendment saying this one can never be changed. When circumstances change, legislation has to change. And I am a passionate free enterpriser. I will guarantee you I am the most conservative person in this room. But I believe that if the game——

The CHAIRMAN. Now, wait a minute. [Laughter.]

Senator HUTCHINSON. Senator Kennedy will question——

Governor JANKLOW. And Senator Frist is a friend of mine. I know Senator Frist. I am the most conservative person in the room.

But you have got to play by the rules, and that is what is not happening—they are playing by the rules. They are not cheating. I don't say they cheat. I am saying they found a loophole, and when you find a loophole, you have just got to close it. That is all.

Senator HUTCHINSON. Certainly I believe that the abuses you refer to are why we need to re-examine the Hatch-Waxman law. We may need to change the rules, and that is exactly the proper purpose of this hearing. My question is, though: If our objection is that this 45 percent market share leveled off, how high should it have gone? I mean, is that really evidence, is that clear evidence that the law is broken?

Governor JANKLOW. The clear evidence is the incredible change that has taken place, that it went from that smaller percentage to 48, and then in the last 9 years, I think actually what they have told me in preparation for testimony today, it has actually started to dip down a little bit. And so it has actually regressed ever so slightly, maybe.

But I am just willing to concede it has been flat, but for something to be flat for 9 years after a meteoric rise, we have to ask ourselves the question: What happened the second 9 years that didn't happen the first 9 years?

Senator HUTCHINSON. It could be that it reached the right balance, that it reached the level at which the market would dictate.

But let me ask you also, Senator Hatch in his testimony—I think I quoted this correctly—said eliminating the 30-month stay overcorrects a problem that may be overstated. And if I recall his testimony, it was not that we don't need to change the rules or that we may not need to refine Hatch-Waxman, but that we don't have enough evidence yet to do that. He recommended that we take a look at the FTC report, which is expected this summer, lest we

overcorrect a problem when we don't know how great that problem is.

Could you respond to his contention as one of the authors of that original bill?

Governor JANKLOW. Sure. I think very seldom should people make legislation without good evidence. It is no different to me than a jury verdict. You need all the facts to make a sensible decision.

Now, having said that, Senator, I think what is really important in this whole thing is that there is no penalty in a practical way. In a legal way there is, but in a practical way there is no penalty if a company abuses the 30-month continuance that they are entitled to because of the difficulty in getting the FDA and all the Attorneys General or whoever files all this litigation to go after the horses are out of the corral and you have got to round them up and get them back.

One of the things you may want to consider, I am like where Senator Schumer was at. He said if his idea doesn't work, let's figure out another one. That is what I am saying. And one thing you may want to consider is let them have their 30-month continuance, but if it is later determined by a court of competent jurisdiction or the FDA or some combination, they have to pay all the money back a couple times over at their expense to get it all the way down to the last person who got the shaft and the 30-month deal.

Senator HUTCHINSON. I am very pleased that there is some openness as to what kind of remedies or what kind of refinements are made in the bill.

I think also in your written testimony, you recommended that Congress restore integrity to the FDA Orange Book so drug companies can only list patents for new drugs and new drug uses.

In your view, does the McCain-Schumer bill address that issue of restoring integrity to the FDA Orange Book?

Governor JANKLOW. I really don't know, sir, but I know it is abused now legally. When I used the word "abuse" in my testimony, we are letting them do it. We as Americans passed a law that lets them do what they are doing. We need to stop letting them do what they are doing in that small respect.

Senator HUTCHINSON. My understanding is that it is not really addressed in this legislation.

Governor JANKLOW. I don't know, sir.

Senator HUTCHINSON. I do think that is one of the very important issues that should be examined and addressed.

Thank you, Mr. Chairman.

The CHAIRMAN. Thank you very much.

Senator Murray?

Senator MURRAY. Well, thank you, Mr. Chairman, for having this hearing and for this really important discussion. I think the intent of the 1984 Hatch-Waxman legislation was to ensure a fair balance between protecting intellectual property rights and ensuring timely access to lower-cost generic drugs for consumers. And, overall, that 1984 law struck a good balance that overall has proven very successful.

Unfortunately, I think we have seen that there have been costly abuses by drug manufacturers that have jeopardized access to af-

fordable prescription drugs for all consumers, and those allegations trouble all of us, including me, a great deal.

However, Mr. Chairman, I think it is important to point I think it is important to point out that abuses or potential abuses of Hatch-Waxman are not the reason Congress hasn't acted on a prescription drug benefit within Medicare. Clearly, drug pricing is going to be an issue when we move to a prescription drug benefit, but the challenges to achieving a prescription drug benefit go well beyond simply the pricing issue.

I also think we have to be really clear on what has driven this increase in prescription drug costs. I think it is clear that today prescription drugs play a much greater role in the delivery of health care than they did 15 years ago when the Hatch-Waxman legislation was written. Prescription drugs to reduce blood pressure or cholesterol rates have replaced extensive hospitalization and acute-care costs. So the increasing use of prescription drugs in itself is not bad, and, in fact, many of today's innovative drugs have reduced health care costs in other areas and have dramatically improved the quality of life for many Americans, including our children.

I want to, as we work through this, again, find the balance between protecting and encouraging innovation while ensuring timely access to affordable prescription drugs for all consumers. And I think our question before this committee is whether S. 812, the Schumer-McCain bill, represents that kind of balance. So, Mr. Chairman, I hope we have additional hearings on this as well, as we try and work through those questions.

One of the concerns I think we are attempting or I am attempting to balance in closing loopholes in Hatch-Waxman is the issue of innovation. We don't want to discourage companies from bringing innovative new treatments to patients, and I recognize that some companies may be misusing the innovation incentives in the current law. Changing the color of a pill or the color of a package, I think we all recognize, is not innovation and shouldn't be rewarded with a 30-month patent extension. But I don't think we should trivialize real innovation. Creating a new formula of a large-molecule drug, allowing it to be dispensed in a liquid form, is a huge benefit for our children. Developing new techniques to allow for changes in dosage from perhaps four a day to one a day is especially beneficial for our children, for any of you who have tried to make your child take four pills a day.

So I believe that kind of innovation does need to be rewarded, and I would ask our panelists whether allowing a generic alternative for a larger pill or a four-times-a-day treatment would discourage companies from moving innovation along to improve how a drug is dispensed or how many times it must be taken each day.

Dr. BRADLEY. My response is that the carefully crafted Hatch-Waxman Act was designed very much to stimulate innovation at what I would call the front end, giving the patent period a longer period of time.

It is my belief that extending a patent at the back end is, if anything, counterproductive to innovation because the incentive for the pharmaceutical company would be to get working on new breakthrough, wonderful improvements rather than focusing its time, en-

ergy, and resources on extending the patent at the back end. And, in fact, expiration of the patent may be one of the most powerful incentives for the pharmaceutical companies to invest in new breakthrough improvements.

Governor JANKLOW. Senator, I would like to just pick up right where he leaves off. I think he makes an elegant point, and that is that, to the extent the company is spending their time and resources trying to figure out how to manipulate the current 30-month period, they are not spending it on innovation. And if there is a concern about what you address—and what you say is perfect. I mean, your comments are perfect. I think what you need to do is just write it into law. Just say that this shall not be deemed to not be in compliance. I mean, to the extent—let them come forward and tell you the list. I mean, they always talk about PhRMA. Then I find out that Eli Lilly, Merck, and Pharmacia don't even agree with PhRMA's position on this 30-month extension. They are three of the top ten drug companies, and they are not in agreement with what PhRMA says when they come before the Congress all the time on that issue.

But just let all the players come before you and explain all these little nuances, and then take the ones you like and put them into law, and that gives them a protection, instead of leaving it so general. Where you know it is general and a problem, the only way to solve it is to be specific. Otherwise, let it be general. What you found is by being general, people after 9 years figured out how to game it. So for 9 years it worked. The last 9 years it hasn't.

Senator MURRAY. I appreciate the comments, and I do have some questions for our second panel. I know we are going to have a vote, Mr. Chairman, so I would retain the balance of my time so I can ask those questions—the third panel, actually.

The CHAIRMAN. Senator Collins?

Senator COLLINS. Thank you, Mr. Chairman. I know both you and I need to be at the Armed Services Committee for a markup as well, and with the vote ending, this may cause me to rethink my opposition to human cloning. I think it would be very valuable today to have a clone. [Laughter.]

I want to, in all seriousness, thank you for holding this hearing. I think this is an incredibly important issue. Both of our witnesses before us have described very eloquently the cost implications of spiraling prescription drug costs on a large corporation and on a State's Medicaid budget. And I know that the Governor of Maine would second many of the comments of the Governor representing many other Governors here today.

I would also say that it seems to me that the Hatch-Waxman bill has been a success in encouraging innovation and striking a balance. Unfortunately, however, it appears, as Governor Janklow has said, that there are abuses of certain of the provisions in the Hatch-Waxman law. And, in particular, I really think we need to substantially tighten up or eliminate the automatic 30-month stay. I just think that the evidence is overwhelming that that has been abused. And it is not just the witnesses before us who have said that. The Chairman of Federal Trade Commission has testified about a number of examples where drug manufacturers have

gamed the system and attempted to restrict competition beyond what Hatch-Waxman intended.

I also think that the evidence calls out for taking a close look at the 180-day exclusivity period in cases where there is essentially a deal between the generic manufacturer and the brand-name manufacturer.

So those are issues that I think we need to take a close look at. But at the same time, there are important issues on the other side. We do want to make sure that we are continuing to promote innovation, and I do share the concerns that were raised by Senator Gregg about the bioequivalency issue in the bill. I think that is a real issue, and we have to be very careful how we proceed.

So I think this hearing is an excellent first step in taking a look at this. I do think we need to come up with legislation, but that we have to carefully balance it. And I thank the chairman for the opportunity to comment.

[The prepared statement of Senator Collins follows:]

PREPARED STATEMENT OF SENATOR COLLINS

Mr. Chairman, thank you for calling this afternoon's hearing to examine the landmark 1984 Hatch-Waxman Act and to determine whether legislation is needed to close any "loopholes" that might have reduced its effectiveness in bringing lower-cost generic drugs to market more quickly.

The last twenty years have witnessed dramatic pharmaceutical breakthroughs that have helped reduce deaths and disability from heart disease, cancer, diabetes, and many other diseases. As a consequence, millions of people around the world are leading longer, healthier, and more productive lives. These new medical miracles, however, often come with hefty price tags, raising vexing questions of how both patients and public and private health plans can continue to pay for them.

Prescription drug spending in the United States has increased by 92 percent over the past 5 years to almost $120 billion. These soaring costs are a particular burden for the millions of uninsured Americans as well as for those seniors on Medicare who lack prescription drug coverage. Many of these individuals are simply priced out of the market, or forced to choose between paying the bills or buying the prescription drugs that keep them healthy.

The 1984 Hatch-Waxman Act made significant changes in our patent laws that were intended to encourage pharmaceutical companies to make the investments necessary to develop new drug products, while simultaneously enabling their competitors to bring lower-cost generic alternatives to the market.

To that end, the legislation has succeeded to a large degree. Prior to Hatch-Waxman, it took three to 5 years for generics to enter the market after the brand-name patent expired. Today, lower-cost generics often enter the market immediately upon the expiration of the patent. As a consequence, consumers are saving anywhere from $8 to $10 billion a year by purchasing generic drugs. At the same time, the brand-name companies have increased their research and development spending from $3.6 billion in 1984 to more than $30 million this year.

Moreover, there are even greater potential savings on the horizon. Within the next 4 years, the patents on brand name drugs with combined sales of $20 billion are set to expire. If Hatch Waxman works as it was intended, consumers can expect to save an average of 50 percent on these drugs as lower-cost generic alternatives become available after these patents expire.

Despite its apparent success, concerns have been raised recently that the Hatch-Waxman Act has been subject to abuse. While many pharmaceutical companies have acted in good faith, there is increasing evidence that some brand and generic drug manufacturers have attempted to "game" the system in order to maximize their profits at the expense of consumers.

I read with some alarm a recent Washington Post article detailing how AstraZeneca, whose patent on the lucrative drug Prilosec was set to expire last Fall, used the automatic 30-month stay to keep a cheaper generic version of the drug off the market. In 2000, Prilosec was the bestselling drug in the world and generated an estimated $4.7 billion in U.S. sales. Moreover, according to the article, at least 12 other drug companies have used that strategy to extend the patents on lucrative drugs.

This has understandably prompted a huge backlash on the part of the Governors, insurers, businesses, organized labor and individual consumers who are footing the bill for these expensive drugs and whose costs for popular drugs like Prilosec could be cut in half if generic alternatives were available.

I was also disturbed by the testimony last month of the Chairman of the Federal Trade Commission, Timothy Muris, before the Commerce Committee. Mr. Muris' testimony cites a number of examples where branded and generic drug manufacturers have "gamed" the system and attempted to restrict competition beyond what the Hatch-Waxman Act intended.

One case cited in Mr. Muris' testimony involved the producer of the heart medication Cardizem CD which brought a lawsuit for patent and trademark infringement against the generic manufacturer Andrx in early 1996. Instead of asking the generic company to pay damages, however, the brand name manufacturer offered a settlement to pay the generic company more than $80 million in return for keeping the generic drug off the market. Meanwhile, users of Cardizem—which treats high blood pressure, chest pains and heart disease—were paying about $73 a month when the generic would have cost about $32 a month.

Mr. Chairman, the original Hatch-Waxman Act was a carefully constructed compromise that balanced an expedited FDA approval process to speed the entry of lower-cost generic drugs into the market with additional patent protections to ensure continuing innovation. If we find that there are loopholes in the current law that have allowed the brand-name and generic manufacturers to game the system to restrict competition and secure greater profits, it is Congress' responsibility to take the action that is necessary to restore the original intent of the law.

Once again, I thank you for your leadership in calling this hearing, and I look forward to working with my Senate colleagues to address this issue.

The CHAIRMAN. I want to thank both of you for your testimony and responses, very knowledgeable, very helpful, and very compelling. I thank you very much, Governor, Mr. Bradley, for appearing before the committee. And we will be talking with you as we consider this legislation. You are obviously experts and have thought through this, so we are very, very grateful for your insights.

Governor JANKLOW. Senator, thank you for the courtesy in letting me appear today. I appreciate it.

The CHAIRMAN. Thank you very much.

Dr. BRADLEY. Thank you very much for inviting me.

The CHAIRMAN. Our second distinguished panel, two notable experts to share their respective views on their respective industries on Hatch-Waxman. Gregory Glover is currently a partner at Ropes & Gray. He is here today on behalf of the Pharmaceutical Research and Manufacturers of America. I look forward to his testimony on the impact of Hatch-Waxman on the pharmaceuticals. And Kathleen Jaeger currently serves as the CEO of General Pharmaceutical Association, previously served as the national practice leader at Kirkpatrick & Lockhart, food and drug practice. Ms. Jaeger is intimately familiar with the pharmaceutical industry, and I look forward to her testimony.

Dr. Glover, we will recognize you. I ask my staff just to remove the tabs here as we are moving through, if you will be good enough.

STATEMENTS OF GREGORY J. GLOVER, M.D., ON BEHALF OF THE PHARMACEUTICAL RESEARCH AND MANUFACTURERS ASSOCIATION (PhRMA); AND KATHLEEN D. JAEGER, PRESIDENT AND CEO, GENERIC PHARMACEUTICAL ASSOCIATION (GPhA)

Dr. GLOVER. 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. 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.

As a result of the balance achieved in 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. Advocates of change have a heavy burden to show that revisions are needed and that such revisions would not upset the equilibrium of the existing statute.

S. 812 is not about closing loopholes. What is a loophole in the eyes of the generics is a fundamental procedure that protects the intellectual property rights of the innovators. The Hatch-Waxman Act left the pioneer pharmaceutical industry, the source of virtually all new drugs in the United States, with only limited incentives to innovate. Instead of the protections afforded to every other U.S. patent holder, Hatch-Waxman altered the rights of the pioneer pharmaceutical industry and took away two of the three principal elements of patent protection.

Normally, a patent holder can prevent others from making, using, or selling a patented invention. However, after Hatch-Wax-

man, the generic manufacturer can make and use our invention from the day the patent is issued. The only element of patent rights that remains for the pioneer under the Hatch-Waxman Act is the protection against a generic selling our product.

The litigation procedures of the Hatch-Waxman Act counterbalance the elimination of the patent rights by establishing litigation procedures that include the 30-month stay of FDA approval to allow the patent disputes to be resolved. One of the underlying principles of the Hatch-Waxman Act is that the generic drug should not be able to enter the market until the pioneer's patent has expired or until the patent has been determined to be invalid or not infringed.

The 30-month stay is a critical component of the procedures that satisfy this fundamental principle of the act. Advocates of change would have you believe the 30-month stay extends a patent. They are wrong. The 30-month stay must occur during the life of a patent, and if the patent expires before the 30-month stay is over, the stay of approval is terminated. We must remember that if there is a 30-month stay, it is because the generics have attempted to market a copy of the pioneer's product that is covered by a presumptively valid patent before that patent has expired.

Advocates of change would also have you believe that multiple 30-month stays are commonplace and that they provide evidence of needed change. However, there are fewer than ten circumstances of nonconcurrent 30-month stays. Even where there are multiple patents listed for a product, in the great majority of the cases the 30-month stays will run concurrently so that there will be a single 30-month period in which FDA cannot give final approval to the generic product.

The claim that eliminating the 30-month stay is closing a loophole is, in fact, disingenuous, dangerous, and damaging because it takes away our ability to defend our intellectual property rights. Although the number of patent disputes is small, the advocates of change complain that these disputes occur for top-selling drugs. A drug is a commercial success because it provides substantial benefits to consumers and to the public health. These are the only drugs the generics want to copy. These are the only drugs whose patents are challenged early in the patent life. Accordingly, there should be no surprise that the patent disputes initiated by the generic manufacturers focus on top-selling drugs.

Despite the complaints, 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 manufacturers to get their copies of innovative medicines to the market following patent expiration. In fact, analysts predict that generics will make up 57 percent of the market in 2005. And as we project generic market shares exceeding 50 percent, we should bear in mind that no one should want 100 percent of the market to be in products that are mere copies, because that would mean that there are no more innovations to medicines, no more benefits to consumers, and no more improvements to the public health.

In summary, the Hatch-Waxman is one of the most successful pieces of consumer legislation in history. The law works. The proposed changes 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 treatments for patients.

I would be pleased to answer any questions the committee may have.

[The prepared statement of Dr. Glover may be found in additional material.]

The CHAIRMAN. Ms. Jaeger?

Ms. JAEGER. Mr. Chairman, distinguished members of the committee, thank you for your leadership in holding this hearing, and thank you for the opportunity to testify. My name is Kathleen Jaeger. I am the president and CEO of Generic Pharmaceutical Association.

Today, I would like to present testimony that I believe clearly illustrates why Congress should close the gaps in Hatch-Waxman, assuring consumers greater access to affordable pharmaceuticals.

In the years immediately following the passage of Hatch-Waxman in 1984, competitive markets were formed and the system worked reasonably well. However, during the last 5 years, unintended loopholes in the system have been exploited to delay generic competition. Unfortunately, this trend has increased with each passing month. Consumers, Governors, employers, unions, pharmacists, and other interested parties are raising concerns about the lack of accessible, affordable pharmaceuticals.

These groups understand the need to expand access to generic medications, but they have all too frequently been blocked from the market, and these groups are now calling on Congress to act. Clearly, there is cause for concern.

Yet PhRMA charges the generic industry is overstating its case and argues that the current system works well. Clearly, they have not put this argument to a vote by consumers, businesses, or other purchasers. And as to PhRMA's definition of "works well," it flies in the face of the real-life experiences of too many Americans across this Nation.

PhRMA's argument ignores the older American who had to pay more for his medication, Desyrel, because there was a patent on Desyrel's tablet design, which had nothing to do with the drug's chemical make-up or its effect.

PhRMA's argument ignores the single mother of an asthmatic child requiring the drug Maxair, who can't get an affordable equivalent today because a patent is listed, not on Maxair but on the new container that houses Maxair.

PhRMA's argument also ignores the cancer patient who will have to pay the higher brand prices for years to come because the brand company listed two patents that define how the product information should be inserted into pharmacy computers.

And PhRMA's argument further ignores the recent views of the FTC Chairman Timothy Muris before the Senate Commerce Committee on April 23rd that the 30-month stay is a serious problem.

These and other misuses of the Hatch-Waxman would be addressed by Senate bill 812, introduced under the bipartisan leadership of Senator Schumer and Senator McCain, a bill designed to re-

store the intended balance between innovation, competition, and consumer access.

PhRMA advances countless arguments against the closing of the loopholes in the current system, and I would like to take this opportunity, if I may, to set the record straight with a few of these.

First, PhRMA claims that the 30-month stay provision never extends a patent. Yet this statement not only is completely irrelevant to the consumers and health care providers, it ignores the real question. The issue is: Should an automatic 30-month stay block generic competition when a new patent is listed that in no way covers the brand or the generic product? This is like saying a patent covering a red light bulb should be able to block other manufacturers from marketing white light bulbs to consumers.

Second, PhRMA argues that Senate bill 812 would severely impair, if not eliminate, effective remedies for patent infringement. PhRMA is wrong. The bill in no way alters the U.S. patent code. Simply put, the rights of the brand industry to commence patent litigation which could result in treble damages remain unchanged under the bill. Instead, the bill would merely eliminate the automatic stay, the current standard, and replace it with a merit-based system, a system used by every other industrial sector in the United States.

Third, PhRMA claims that since 1984, only a small number of applications involve patent challenges. But PhRMA conveniently ignores the fact that the average number of patents listed for a blockbuster product has increased from two in 1984 to ten today, and that generic competition has been delayed for at least one-third of the 15 leading worldwide brand products as a result of a system abuse. Without policy intervention, this trend will only get worse.

The brand industry refuses to acknowledge that long overdue refinements of Hatch-Waxman will actually refocus the brand industry on true innovation and away from legal loophole innovation. Legal loophole innovation is not true innovation and does little for this country in terms of overall health care. Legal loophole innovation certainly does little for the 83 million Americans who take prescription drugs each day. We urge this committee to take action and mark up Senate bill 812, and we look forward to working with you on a bipartisan basis to pass this legislation.

We thank you for the opportunity to speak on behalf of the generic industry and the consumers we serve, and, again, we thank Chairman Kennedy and Senator Gregg for holding this hearing. We would also like to extend our appreciation to Senator McCain, Senator Schumer, Senator Rockefeller, Senator Edwards, Senator Clinton, and others for their leadership in addressing the lack of affordable medicines, one of the great social problems of our time.

I would be happy to answer any questions.

[The prepared statement of Ms. Jaeger may be found in additional material.]

The CHAIRMAN. Thank you very much. We will have a 5-minute rule here.

Dr. Glover, you were here when Governor Janklow made his presentation. What do you make of his presentation about what is happening out there in the real world in terms of the Hatch-Wax-

man and the kind of costs and expenses that are taking place in the States?

Dr. GLOVER. Governor Janklow had many of the facts about the Hatch-Waxman incorrect, but that is not really the principal concern that he had. His principal concern was the cost of pharmaceutical health care that his State has to provide, and that is not an issue that one can address solely through the Hatch-Waxman Act. You have to address that through Medicare prescription drug benefits and other things of that nature.

With respect to his concerns about the specific issues of the Hatch-Waxman Act, he was wrong, among other things, that the 30-month stay provides an extension of a patent. That is not correct. He was incorrect also about the term of a patent. It is not 17 years. Since 1995 in the United States it has been 20 years from filing.

What he needs to be aware of is that, regardless of the concerns that he has about the cost, the supposed changes in the Hatch-Waxman Act that are embodied in S. 812 might provide some short-term benefits because you basically take the work that has been done by the pioneer companies and give it to the generics who will sell it cheaper; but in the long run, the health care costs for his State and every other State will increase because they will not longer have cost-effective new medicines to keep people out of hospitals, to keep them on their jobs, and to help them live healthier lives.

The CHAIRMAN. In terms of what he was talking about, he also made a very powerful point that these kinds of activities by many of the drug companies in terms of resubmitting these various patents had never been anticipated at the time of the passage of the legislation, and that this contributed to the companies' sort of gaming the system.

Given your sort of knowledge about what is happening out there in the industry, what kind of weight should we give that?

Dr. GLOVER. You should give that very little weight, but what you also want to do is make sure you understand the definition of terms. Some people view gaming the system as developing an improvement in a drug that will take it from an IV dosage to an oral dosage, from four times a day to one time a day, and removing side effects. Our view is that that is not gaming the system in any such way because each of those improvements, to the extent that they get to be labeled and marketed for those additional benefits, has to require additional approval by FDA. If there are additional patents associated with those, we believe those patents are appropriately listed, and it is appropriate that those new patents prevent the generics from marketing those new and improved drugs.

But what the generics will not tell you is that when there is an improvement in a product that takes it from four times a day to once a day or from IV to oral that there is nothing about the new patent that prevents them from making the original version of the product.

The CHAIRMAN. And you sat in here, and that is the theme that you thought the Governor was really talking about?

Dr. GLOVER. That is correct.

The CHAIRMAN. That is what your conclusion was.

Dr. GLOVER. Absolutely.

The CHAIRMAN. Well, I must say, I sat here and thought he was talking about an entirely different way that many of the drug companies were gaming the system.

Federal Trade Commission Chairman Timothy Muris testified 2 weeks ago that some drug companies have attempted to—he uses the words—"game the system, securing greater profits for themselves without providing corresponding benefit to consumers." Obviously, like us, the FTC is investigating and worried about the extraneous patent listings, multiple 30-month delays, and collusive agreements. That is what the Governor was talking about. That was his case that he made, I thought very powerfully, but that is what you have been rather dismissive of.

Dr. GLOVER. Absolutely. Let's go back to the Muris testimony.

The CHAIRMAN. OK. Well, you——

Dr. GLOVER. Commissioner Muris reported on five circumstances in which the Federal Trade Commission had investigated alleged anti-competitive behavior in the pharmaceutical industry. Three of those were pioneer generic settlements; one of those settlements, and perhaps more, the Federal Trade Commission stated in closing the case and announcing their settlement that there was no evidence that the activities of the pharmaceutical company had delayed for 1 day the introduction of a generic pharmaceutical product.

Of the remaining two issues, one was a circumstance in which the Federal Trade Commission filed an amicus brief in the context of a summary judgment motion, and their amicus brief was accepted in large part by the court. But as you will recall, a summary judgment motion is not a circumstance where all the issues get fully litigated.

The final circumstance is the case of Biovail, and Biovail is a member of the Generic Pharmaceutical Association masquerading as a pioneer patent holder, and in that case there was a settlement reached with the FTC regarding Biovail's abuse of the patent-listing procedure.

The CHAIRMAN. Well, I appreciate your response. I will put in the record, because I have limited time, his response to just the kind of cases that you have given and the rebuttal to your comments.

[The information referred to was not received by press time.]

The CHAIRMAN. A recent analysis by the University of Minnesota shows that drug companies list an average of 4.9 patents on their drugs with annual sales over $1 billion, which is twice the average number of patents listed on the smaller market of drugs. The analysis shows that considering all these patents, these blockbuster drugs can be expected to have at least 19.2 and probably more than 20 years of actual market exclusivity. By contrast, the smaller selling drugs average about 15 years.

The data show that drug companies list more patents on the blockbuster drugs and these extra patents extend their monopolies on their products. They draw the conclusion that the drug companies are gaming the system under Hatch-Waxman.

Dr. GLOVER. I would simply point out, Senator, that the mere fact that innovation continues after a drug is discovered and some of that innovation results in new patents and some of those new

patents get listed in the Orange Book does not in any way suggest that the system is being gamed.

The CHAIRMAN. All right. And how they are using those new drugs and the timing of those new drugs and the way that they are able to effectively keep the generics off the market, don't you think we ought to take that into consideration as well as the questions of innovation?

Dr. GLOVER. Absolutely not. If what you are suggesting is that there should be no innovation and that there should be no additional——

The CHAIRMAN. That isn't what I am suggesting.

Dr. GLOVER. But let's make sure I can answer your question. That is, it cannot be the case that we must be concerned about improvements to products that pharmaceutical companies make, and as long as those improvements to products do not prevent the generic from making a copy of the original version of the product, that is exactly what we want to happen in the system. And we cannot also take the view that certain types of innovation are "better" than other types of innovation. Sequential innovation is the nature of this industry, and sequential innovation is what allows us to make substantial improvements to benefit the public health, and over time we will make the substantial quantum leap in innovation that will make everyone happy.

The CHAIRMAN. You know, my time is up, but, Mr. Glover, you are representing the industry, and we are here to try and help people. I would have thought that as the spokesman for the industry and what is happening out there in real terms across America on this, that you would be forthcoming, give us some ideas, give us some recommendations rather than effectively denying every—that this is even a challenge or not.

Dr. GLOVER. Senator, I cannot——

The CHAIRMAN. Wait a minute now. Wait——

Dr. GLOVER. I cannot——

The CHAIRMAN. —just a minute. Wait a minute. I am going to let you give a response.

Dr. GLOVER. OK.

The CHAIRMAN. I am going to let you give a response on it. But I just want to express this Senator's—as we are finding, as you have heard from Republicans and Democrats, both access and cost, and we have heard very eloquent, thoughtful commentaries from a number of Republicans, Democrats, Senators on all sides about this particular kind of abuses in Hatch-Waxman, and not to recognize that there are these kinds of abuses or not to even come in here and make recommendations in ways that can be useful and helpful for not only our seniors but for people to have some way of getting some relief in terms of cost is disappointing.

That is my statement, and I would welcome any comment that you want to make on it.

Dr. GLOVER. Senator, I cannot accept your statement that the industry is not being forthcoming and that we do not help people. That is not correct.

Our concern is that where you start with a balanced act that everyone agrees was initially balanced, or at least the attempt was in 1984, you cannot in the environment that is exemplified by your

statement, where one party is deemed to be a villain and the other party is deemed to be an angel, come out of that process whereby you will continue to have a balanced statute. That is our position.

The CHAIRMAN. Senator Hutchinson?

Senator HUTCHINSON. Thank you, Mr. Chairman. Well, that is kind of my concern, that we start making villains and we say industry is because they are industry or they don't care about people. I don't think any reasonable person could look at the pharmaceutical industry and conclude that they aren't helping people, and that while this is, can be, if we have fair and honest hearings, can be a very productive process that will result in making the kind of refinements that are going to help more people and make pharmaceutical drugs more affordable, more accessible, if we go about this wrong, we can do a lot of damage, I think.

I have the utmost respect for Senator Hatch, who said that he didn't think we had enough information to pass the proposed legislation; that, in fact, we might overcorrect a problem that may be overstated. We don't even have the FTC reports yet. And patients diagnosed with Parkinson's and Alzheimer's and cancer and other diseases for which there are no cures today, they have got a pretty important stake in this debate.

Now, Dr. Glover, the figures that I have been presented from Med Ad News say that generic R&D expenditures in the year 2000 amounted to $613 million, that innovator R&D expenditures in the year 2000 amounted to $41 billion.

So I would like you to respond to the criticism or the concern that some have expressed about McCain-Schumer on its potential impact on research and development for new drugs. How would this kind of legislation impact the willingness of innovator companies, pioneer drug companies, to make the kinds of investments, $800 million on average, to bring a new drug to market? What kind of impact do you see this kind of legislation having when we are talking about the stake that patients with Parkinson's, Alzheimer's, cancer, and other very serious diseases have?

Dr. GLOVER. Senator, it would have a substantially negative impact in the following way: We first start with what the Hatch-Waxman Act actually does. It takes away the ability of patent holders, who are pioneer pharmaceutical companies in this case, to enforce their patents against generics who start making and using the pioneer's product before—during the term of the patent. Every other industry—if the generic starts making and using the pioneer's product, the pioneer can actually stop that as an act of infringement. So as a result of allowing the generics to do that, because in theory it is part of the system, you want them to do that so that as soon as the patent expires, they will have done all the things they need to do for FDA to be able to approve the product and they can get on the market. Those things include actually having to formulate the drug, prove to FDA that they can scale up on a commercial manufacturing scale, and other things that are necessary but are, nevertheless, acts of infringement.

In exchange for that, when the generic files their abbreviated new drug application and a paragraph IV certification is made and the pioneer brings suit, you get 30 months to try to resolve the patent issue before the generic drug is approved by FDA. But during

that 30 months, FDA continues to review the product. They can even issue a tentative approval. The 30-month stay does not delay anything going on at FDA other than the final approval.

And bear in mind that the underlying premise of the Hatch-Waxman Act is that the generics should not be able to get on the market until the pioneer's patent has expired. Even with the 30-month stay, FDA approves the product at the end of the 30 months regardless of the circumstance or status of the patent infringement suit.

So if you change the ability to have 30 months in which you can conduct discovery and at least move the case along so that it might become clear to the generic that the pioneer's case is quite good and they ought not go on the market, then you do not—you are not able to understand nor able to predict that you will have any meaningful protection to your intellectual property and, therefore, making that decision to put the $800-plus million into a drug has to be a much more cautious decision.

Senator HUTCHINSON. Thank you.

Ms. Jaeger?

Ms. JAEGER. Yes, I would like to just respond to some of the comments that Dr. Glover just mentioned.

What he is talking about is the fact that, yes, the generic industry is allowed to do the research and development during the patent time. And for some of those, that is called the Bolar amendment. But what he is failing to tell you is that the Bolar amendment also applies to other products that are regulated by the Food and Drug Administration. So medical devices that have to go through the premarket approval situation, they have a Bolar amendment, food additives, animal drugs, and the like. So it is not just unique to, I would say, the generic industry. This actually crosses over all segments with respect to health care products that are regulated by the Food and Drug Administration.

Second, when it comes to the 30-month stay, all the generic industry is saying is that we have no problem with respect to innovation. If the patent covers the drug product, the actual product, then the patent is properly lifted, and if we went to a merit-based system, which is what McCain-Schumer would do, then most likely the judge would issue an injunction against FDA actually approving that product. But what is happening today, as we have actually illustrated, I think, a number of different times, is that patents are being lifted in the Orange Book that do not cover the drug product. They may cover an unapproved use, an unapproved formulation, a computer program. I mean, what does a computer program have to do with a drug? Why is generic competition even delayed 1 day because a computer program is listed in the Orange Book?

And that is what we have concern about, and that is what consumers have concern about. And so what we are asking for is to basically restore the intended balance, pull back, go to a merit-based system, don't make it a free windfall which creates a perverse incentive to go out and innovate patents, as Senator Schumer said, so they can go list them in the Orange Book to delay generic competition. What we are saying and what we are proposing and why we support McCain-Schumer is go to a merit-based system.

So, indeed, if that patent covers the drug product, then most likely, again, the judge would issue an injunction. And, again, this is a standard that is used by every other industrial sector in the United States. So it would infuse some legal discipline and accountability into the current system.

Dr. GLOVER. Every other industrial sector in the United States allows the patent owner to bring suit against someone who makes and uses their patented invention for a commercial purpose.

Senator HUTCHINSON. That was the trade-off.

Dr. GLOVER. That was the trade-off.

Senator HUTCHINSON. Mr. Chairman, my time has expired, but thank you.

The CHAIRMAN. Do you want to say a final word?

Ms. JAEGER. Yes, Mr. Chairman. We actually would disagree with the trade-off. As Justice Scalia pointed out in the case of Eli Lilly v. Medtronic, there were two distortions in the marketplace going on at the same time: a distortion with respect to the value of the patent, the fact that the industry wasn't getting a full value because they had to do that research and development, and they had to go through a very lengthy approval process. And so Congress in its wisdom gave them 5 years of patent restoration time.

At the same time, Congress realized what they wanted to do, of course, was to give consumers access, immediate access upon the patent expiring. So, in turn, they allowed the companies to do the research and development during the time period. And as Justice Scalia stated in the case, those two were the offsets for one another and that the ANDA approval process and the 30-month stay was an independent function of that analysis.

Dr. GLOVER. Although Justice Scalia is not here, Senator Hatch has been here, and Senator Hatch agreed with our position, which is that the 30-month stay was a trade-off for the exemption for patent infringement under the Bolar amendment.

The CHAIRMAN. And Congressman Waxman differs with you as a cosponsor.

Dr. GLOVER. Moreover, we know that Justice Scalia——

The CHAIRMAN. Listen, I am glad to have you, Dr. Glover, but, I mean, we have got time here and I am going to recognize——

Dr. GLOVER. I was simply trying to answer the question.

The CHAIRMAN. They have answered it. I think you have answered it. If you want to give us further answer on it, you can file it, like every other witness does before our committee.

Senator Edwards?

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

Mr. Chairman, I have a couple of comments and then some questions for the witnesses, and I think we have about 9 minutes left on the vote, so we are going to be on a tight time here.

Reforming our drug patent system this year should be one of Congress' top priorities. The reason is simple: If we are going to have and be able to afford a prescription drug benefit, we need to get the costs of prescription drugs under control. And we need patent reform to do that.

I am going to be working very hard on this committee to make sure we get a reform bill this year. Drug companies, including drug companies that we are proud of located in the State of North Caro-

lina, have every right to profit from their breakthrough research, just as all Americans profit from it. But drug companies do not have the right to use legal loopholes and legal maneuvers to extend patents at the expense of patients, businesses, and taxpayers. We need to encourage innovation in the laboratory, but not in the patent process.

I was a lawyer for many years before I came to the Senate, and people often would ask me what I think of frivolous litigation. I think it is wrong. But what is happening today is that some drug companies have become powerful engines of frivolous litigation. It ought to stop.

I want to mention three reforms that I intend to work very hard for on this committee: first, to stop the abuse of these 30-month stays, and this is the issue addressed by the Schumer-McCain legislation. And I want to mention in this context a document that came, I believe from Pfizer, which addresses this whole issue of what has happened to patents and how patents have changed, and this came in 1998 from the Research Division of Pfizer. They say, first, the nature of patent protection around pharmaceutical products changed markedly over the past decade, which is roughly equivalent to the time since Hatch-Waxman has been in place. And they say, second, while the core patents still afford tremendous protection, newer claims can afford substantial market positions or, at a minimum, slow generic entry by a matter of years—talking specifically about the protection of market position and talking about preventing the entry of generics which would increase competition.

And then they have a comparison between pharmaceutical patents, the changing landscape, and in the 1980s, which is the time during which Hatch-Waxman came into play, there were five kinds of patents listed. And then the 1990s, there are 18 kinds of patents listed, including one for packaging.

Now, of course, the pharmaceutical companies knew in the 1980s about packaging and packaging being an issue. What changed as a result of Hatch-Waxman is using packaging to obtain new patents and market protection.

The second reform is to cut down on the mistaken issue of patents and listing of drugs in the Orange Book. We should beef up staffing at the Patent and Trademark Office and require more meaningful standards to get into the Orange Book. This is one way to stop patent litigation before it ever starts.

And, third, to make the 3-year market exclusivity for drug patents work the way it was supposed to work, so you can effectively get an extra 3 years on your patent when you make a real improvement that helps people, not when you add mint to gum, which is one thing that happened recently. Consumers should not lose access to cheap generics for 3 years because a company has added mint to gum.

Dr. Glover, if you are willing to work with us—as you know, the flow of breakthrough drugs has declined in recent years, and companies are increasingly varying their existing drugs. If we need to take real steps to encourage genuine breakthroughs in the context of real reform, we ought to look at that. At least I believe we should look at that.

The bottom line, though, is if we are going to get a real prescription drug benefit, we need to get real reform in the drug patent system. I am going to make it a priority to do that this year. And let me just say, Dr. Glover, I have a couple questions for you, specific examples, but it seems to me—I have been listening to your testimony. It is now the second time I have heard you testify. And I agree with those who have said up here, and you said it a few minutes ago, that there are no villains. I can tell you without any question that as between the pharmaceutical companies and the generics, I have no favorite in this. My only favorite are the people out there who are trying to pay for their medicine.

So I am just trying to find a way to try to get these prescription drug costs under control. It is just that simple from my perspective.

And I am sure that you are right, I am sure there are cases where, after many years of a product being on the market, that a genuine change occurs, a genuine innovation that has been discovered in the laboratory that makes the product significantly more beneficial, and as a result sometime before the patent expires a new patent is filed. I have no doubt that that occurs. But we also know in trying to be fair and reasonable about this, we also know that there are a number of examples of cases where abuse has occurred.

When somebody has a product on the market for many, many years, a pill, and then says they need a new patent because it needs to go in a brown bottle, I mean, it doesn't take a lot of common sense to figure out that most medicine, in fact, comes in brown bottles, and that is probably an abuse of the process. And, in fact, as you well know, the courts have found that, in fact, in that particular case that was an abuse of the process.

So my concern is we have some cases that are legitimate, no question about that, and then, on the other hand, we have cases where abuses are occurring. And when the abuses occur, it is not the pharmaceutical companies or the generics that pay the price. It is American consumers who pay the price. That is the problem we have here. And if it is an abuse, if, in fact, as we know, it has occurred in the past, it is an abuse of the patent system where someone files a new patent, they get listed in the Orange Book based on the color of the bottle or some other ridiculous basis, and then a lawsuit is filed. I mean, you are right. It is not an extension of the patent. It is a new patent. That is what it is. But sometimes these new patents are not legal, they are not legitimate.

And what happens is they get an automatic 30-month stay in a situation where the patent they have filed and that has gotten listed in the Orange Book was never real, never legitimate to start with. And when that occurs—and that is what our concern is. I hope you understand that. When that occurs, then it is not the pharmaceutical companies I am worried about, and it is certainly not the generic companies that I am worried about. I am worried about the people out there who, during that 30 months that the stay is in place, are stuck. They are stuck with the high price. We know that competition brings the prices down. And during that 30-month period, there is no competition. The patent is maintained, this new patent is maintained, and in some cases it is on the basis of the color of the bottle or being able to—I heard Senator McCain

talking about being able to sprinkle the product on oatmeal. I don't know about that particular case, but there are a series of these cases involving the drug Buspar, Platinol—I am not sure I am pronouncing these right—Wellbutrin. And you know about these cases where abuses have occurred.

The problem is we have to do something about those situations where, in fact, abuses are occurring. And that is the concern I have. I think it would be unfair and unreasonable to say that every time near the end of a patent period the drug companies come up with an innovation or a new patent that is bogus. That is not true. I don't think that is fair, and I don't think that is true. But there are occasions where that is clearly happening. And when it does happen, American consumers, people who have to go to the drug store and pay for their medicine and are having such a terrible time doing that, are having to pay the price.

So that is the concern I have, and I have now used up all my time talking. I wanted to ask you questions, but I am going to have to go vote. But I hope both of you understand that that is our perspective on this. Our perspective is not trying to advantage the generics or the pharmaceutical companies vis-a-vis each other. Our perspective is we want to provide protection during the time that there is a legitimate patent. We want to stop this abuse that is clearly occurring and the protections that are in place for abuse of illegitimate patents that, in fact, drive up costs for consumers. That is our concern about this whole process.

I have 30 seconds left to vote. I apologize. I would love to continue to talk to both of you about this issue. I think it is a legitimate issue. I don't think it should be good versus bad or that anybody in this fight is evil. But I do think that there are concerns here that need to be addressed.

Thank you all very much for being here.

The hearing is adjourned.

[Whereupon, at 4:41 p.m., the committee was adjourned.]

[Additional material follows.]

ADDITIONAL MATERIAL

PREPARED STATEMENT OF GOVERNOR WILLIAM JANKLOW

Good afternoon, Mr. Chairman and members of the committee. I am Bill Janklow, Governor of the State of South Dakota. I am honored to have the opportunity to offer testimony on the need to reform the 1984 Drug Price Competition and Patent Term Restoration Act, better known as the Hatch-Waxman Act.

INTRODUCTION

First, let me express my appreciation to you, Mr. Chairman, and to other members of this committee for taking time to explore ways in which we might improve the Hatch-Waxman Act. At our February meeting, the National Governors Association unanimously passed a resolution encouraging congressional review of the Act. We realize that you are making a great effort to respond to our concerns.

Second, let me also express appreciation to Senators Schumer and McCain for working hard over the past year to draft legislation that attempts to address many of the concerns we have regarding the Hatch-Waxman Act.

I appear before you today in two roles: representing South Dakota and representing 10 other Governors who are members of Business for Affordable Medicine. As Governor of South Dakota, I am concerned about the escalating cost of prescription drugs and the effect of these costs on consumers, seniors, taxpayers, hospitals, and employers in my State and on the State and Federal programs in South Dakota. We are doing everything we can think of to keep our prescription drug costs under control. A few examples are: 1) in the State Medicaid program paying for the least costly drug unless a physician specifies otherwise; 2) requiring Medicaid recipients to obtain prior authorization for specific high costs drugs; 3) providing incentives to pharmacists to obtain permission from physicians to prescribe a generic alternative in our State employee health plan; and 4) reducing co-payments for State employees purchasing less expensive but equally effective brand name drugs or generics. Unfortunately, the growing trend by pharmaceutical companies to prevent competition from lower-cost generic alternatives is defeating most of the gains we have made as a result of these initiatives.

BARRIERS TO GENERIC PRILOSEC ARE COSTING STATE MEDICAID PROGRAMS $135 MILLION ANNUALLY

For example, South Dakota's Medicaid program spent $1.4 million last year to purchase the ulcer medication Prilosec. The patent on Prilosec expired in October, which means South Dakota should save half that amount or $700,000 this year by purchasing generic alternatives. The problem is, the manufacturer of Prilosec has tied generic manufacturers up in litigation over secondary Prilosec patents in order to prevent competition. $700,000 in the State of South Dakota is a great deal of money, money that could be spent on other equally important health care issues.

As I indicated earlier, I am also appearing today on behalf of 10 other Governors who share my concerns about the ability under the Hatch-Waxman Act of pharmaceutical manufacturers to delay competition. Together, with several of the Nation's largest employers including General Motors who is with us today and a number of labor organizations, we have formed Business for Affordable Medicine, or BAM. BAM is committed to helping Congress close loopholes in the Hatch-Waxman Act so that all pharmaceutical purchasers can have certainty about their ability to save when brand patents expire. Let me give the committee a specific example from my State. In fiscal year2000, South Dakota's Medicaid program expenditures for Prozac were $817,990. In fiscal year2001 they were $878,946. Prozac went off patent this past August. As a result, our projected expenditures for fiscal year2002 for Prozac will decrease by $350,000. Expenditures will decrease even further as physicians become more comfortable with prescribing the generic alternatives.

Imagine this, Mr. Chairman: While every member of this committee is hearing from his or her Governor about the Medicaid funding crisis back home, states could be saving millions of dollars right now if generics for Prilosec, that should be available, were actually on the market. I have provided a list to the committee of the amount each State could be saving, but let me summarize: The Medicaid programs just in the states represented by members of this committee would save $135 million this year if timely competition would have been assured for just this one drug. All State Medicaid programs would have saved $332 million this year if they had access to generic Prilosec.

CLOSING HATCH-WAXMAN LOOPHOLES WILL SAVE STATE MEDICAID PROGRAMS $600 MILLION ANNUALLY

This is a huge concern for Governors because State Medicaid agencies spent $1.2 billion last year on 17 other drugs that face patent expiration in the next two and a half years. Under the original intent of the Hatch-Waxman Act, states should expect to save an average of 50 percent or $600 million on these drugs as lower-cost alternatives become available after patents expire.

Here is a question for you, Mr. Chairman, and for our friends from the brand pharmaceutical industry who are with us today: Will we get generic alternatives to these 17 drugs on time?

I suspect that the answer to that question is "no." In fact, the only certainty provided today under the Hatch-Waxman Act is that the manufacturers of these drugs have ways to delay competition from generic alternatives.

As a result, members of BAM encourage this committee to close the Hatch-Waxman Act loopholes.

END THE 30-MONTH STAY OF GENERIC APPROVALS

Specifically, we hope you will question the wisdom of providing automatic 30-month stays on generic drug applications whenever brand manufacturers sue for infringement. While this provision in the Act may have been sound in 1984, today it is routinely used to simply stifle competition. A more sound approach, as incorporated in the Schumer-McCain bill, would be to require drug patent holders to pursue the same injunctive relief process required of all other patent holders.

RESTORE CONGRESSIONAL INTENT TO THE "ORANGE BOOK"

In addition, drug companies should only be allowed to list patents for new drugs and new drug uses in the FDA " Orange Book." This was the intent of the authors of the Act in 1984, according to everyone except the brand pharmaceutical industry.

Whether it was the intent or not, it should have been and Congress should make it clear in the statute that the secondary patents used to unfairly prevent competition can no longer be listed.

Finally, let me be very clear about an important point: Neither I nor any other member of the BAM coalition seeks to undermine the critical safeguards that are provided to intellectual property owners. We support strong patent laws and do not propose that they be weakened in any way.

But that is not what our effort or today's hearing is about. Our focus is on improving pharmaceutical competition for the benefit of consumers and the pharmaceutical industry. We know that pharmaceutical innovation is driven by competition, and that incentives to innovate are lessened when competition is impeded. The Hatch-Waxman Act embraced this concept and led to a long period of robust competition and big increases in drug research and development. We encourage this committee to fine-tune the law so the competition intended by the Act is restored for the benefit of consumers and all other pharmaceutical purchasers.

CONGRESS SHOULD ENSURE CONSUMERS WILL HAVE TIMELY ACCESS TO GENERICS

Our friends in the brand drug industry have indicated that, because only six percent of generic drug applications since 1984 have faced approval delays, we should not think there are significant barriers to competition. In fact, while few generics faced approval delays in the early years, the majority face delays today. It is also a fact that brand manufacturers delay competition for virtually all blockbuster drugs. As a Governor who must figure out how to pay for these extra costs in our State programs, I hope the committee will focus on the brand drug industry's intentions for the 17 drugs that face patent expiration soon.

At the State and Federal level, we have struggled to find ways to reduce prescription drug costs for seniors. Although closing the loopholes in the Hatch-Waxman Act is not the only answer, it certainly would offer some relief to senior citizens who must take a prescription drug that should go off patent. I don't know a single senior citizen in South Dakota who wouldn't appreciate paying 50% less for one of their prescriptions and who couldn't use that savings elsewhere.

I truly want to thank you again, Mr. Chairman and the members of the committee for the opportunity to offer my views on behalf of the citizens of South Dakota and the members of the BAM coalition. I look forward to answering any questions you may have.

PREPARED STATEMENT OF BRUCE E. BRADLEY

Mr. Chairman, Ranking Member Gregg, and distinguished Committee members, I am Bruce Bradley, Director of Health Plan Strategy and Public Policy at General Motors.

I am testifying today on behalf of RxHealth Value, a coalition of more than 20 national organizations representing consumers, employers, unions, health plans and providers. Our membership is broad and diverse, and includes numerous prominent consumers and purchasers of pharmaceuticals, such as AARP, Families USA, the Midwest Business Group on Health, Ford, Daimler-Chrysler, the United Auto Workers, the AFL-CIO, Kaiser Permanente, the Alliance of Community Health Plans and BlueCross and BlueShield Association. It is an honor to appear before your Committee to share our experience regarding prescription drug cost increases and to underscore our belief that Federal policy reforms are necessary to restore the balance between pharmaceutical competition, consumer choice, and innovation.

As the Senate Committee with primary jurisdiction over many elements of this issue,prescription drug development, use, and marketing, we want to particularly thank you for your leadership in holding this hearing. It is our hope that today's hearing will foster a bipartisan effort to develop legislation that would bring relief to consumers, as well as public and private purchasers of prescription drugs.

PHARMACEUTICAL COST CHALLENGE

Consumers, businesses, unions, the Federal government and health plans throughout the Nation are aggressively, and mostly unsuccessfully, attempting to manage soaring prescription drug costs. These expenditures are increasing at annual rates of up to 20 percent, and are unsustainable.

That is why GM is working with three coalitions—RxHealth Value, Business for Affordable Medicine (BAM), and the Coalition for a Competitive Pharmaceutical Market (CCPM)—to highlight this issue and advocate for Federal policy changes. These broad-based, diverse and respected organizations all represent purchasers who are growing increasingly concerned that the Hatch-Waxman law contains loopholes that allow the pharmaceutical industry to delay more choice and competition and choice of high-quality, cost-effective generic drugs. We believe that inappropriate Orange Book patent listing and repeated use of the automatic 30-month market exclusivity provision granted to the pharmaceutical industry has led to exposure to unpredictable, unaffordable and unmanageable pharmaceutical costs.

Collectively, RxHealth Value's members represent over 100 million Americans. These consumers spend billions of dollars each year on prescription drug expenditures. The business and insurer purchasers in that comprise RxHealth Value are reporting prescription drug cost growth trends of as much as 20 percent per year.

At GM, we insure over 1.2 million workers, retirees, and their families, and are the largest private provider of health care coverage in the Nation. We spend over $1.3 billion a year on prescription drugs. Despite our use of State of the art management techniques that assure the most appropriate and cost effective use of prescription drugs, our pharmaceutical bill continues to grow at a rate of 15 to 20 percent a year-more than quadrupling the general inflation rate. Such drug cost increases are driven by a host of factors, including higher utilization, direct-to-consumer advertisements, price increases of pharmaceutical products currently on the market, and the delay of generic competition. The other members of the RxHealth Value have experienced the same disturbing and unsustainable cost increases.

BARRIERS TO GENERIC COMPETITION

Today's hearing appropriately focuses on barriers to generic entry into the marketplace. From our perspective, this problem has grown worse in recent years and, if not addressed, will almost certainly force companies and all other purchasers, whether public or private, to make extraordinary and painful benefit and cost shifting decisions. Global companies simply will be unable to effectively compete in the world marketplace without relief from rising prescription drug costs.

Mr. Chairman, in the last several years, as the patents of prescription drugs have expired, purchasers have planned and budgeted for generic drug competition to reduce costs and increase enrollee choice. Such competition is critical to effective pharmaceutical benefit management programs as generic competition reduces costs by between 50 to 60 percent. Time and again, however, purchasers have underestimated their liability, as many pharmaceutical companies effectively extend their market exclusivity through the automatic and repeated use of the 30-month market exclusivity stay, included in the Hatch-Waxman Act.

At this point, it is important to make clear that the extended market exclusivity or patent extensions utilized by the pharmaceutical industry occurs only after the underlying patent for the initial product has expired. In other words, by listing unapproved and unmarketed uses or altering nonactive ingredient components of the product in the Orange Book or through the U.S. Patent and Trademark Office, the industry has successfully protected their older products from generic competition.

For many of these product listings, however, independent experts have raised serious questions about whether such product changes really are true innovations meriting such protections. And when a pharmaceutical company contests a generic's challenge of a questionable patent or exclusivity claim, the pharmaceutical company routinely is granted a 30-month market exclusivity extension, regardless of the merits of the case.

We are aware of no other industry that has such an automatic protection against competition and we are virtually certain that Congress never intended that this provision to be repeatedly utilized. We believe that the expiration of patents after their intended statutory term creates a strong incentive for companies to develop innovative new products.

As a consequence of the practices of many in the pharmaceutical industry, GM and other members of RxHealth Value have seen our prescription drug costs skyrocket. Since the enactment of Hatch-Waxman, the average number of patent extensions filed for "blockbuster" drugs have increased by five-fold—from two to ten patents filed. And this trend has a very real and all-to-frequently devastating financial impact.

Our concerns about inappropriate practices in the marketplace are not limited to the brand-name industry. We are troubled by and strongly opposed to brand-to-brand and brand-to-generic settlements that are designed to delay market entry of generic competition.

There have been cases when generic companies who initially filed to challenge a brand-name patent and thus were eligible for the no generic competition 180-day exclusivity period have reached an agreement with the brand-name company to not enter the marketplace. Such agreements, which benefit both brand name and generic companies, do nothing for purchasers and consumers of prescription drugs.

COST IMPACT ON RXHEALTH VALUE MEMBERS

Within the last several years RxHealth Value members have literally had to increase our budgets for pharmaceuticals by hundreds of millions of dollars a year. At GM the so-called "evergreening" of the patents of five products designed to treat ulcers, cholesterol, diabetes, allergies and depression has increased GM's pharmaceutical costs for these five drugs alone by over $142 million.

Even more ominous is our fear that this trend will continue and likely grow worse. For example, without new legislation, we now estimate that, if just five pharmaceutical "blockbuster" product patents that are currently scheduled to expire are extended, GM will see increases in our prescription drug bill in excess of $204 million during the period of delay of generic market entry.

Mr. Chairman, when access to lower cost generics is inappropriately delayed, consumers and other purchasers have no remedy or recourse—no way to recoup the excessive costs paid for pharmaceuticals.

We are appearing before you to highlight the tremendous challenge confronting us and to seek legislative relief.

SUPPORT FOR BIPARTISAN HATCH-WAXMAN REFORMS

We believe that this is the time for Congress to intervene and pass legislation that will restore the balance between competition and innovation that was initially intended by the Congress in the Hatch-Waxman Patent Restoration Act of 1984.

We agree with the growing bipartisan consensus that it is time to Congress should eliminate the 30-month stay and transfer the 180-day generic exclusivity protection away from any generic company who has agreed to such a settlement and to the next generic competitor who will enter the marketplace. For this reason, GM, as well as members of RxHealth Value, support the Greater Access to Affordable Pharmaceuticals Act and other legislation designed to eliminate these barriers to generic drug entry into the marketplace.

We greatly appreciate the bipartisan leadership of Senator Schumer and Senator McCain, as well as Congressman Brown and Congresswoman Emerson, in raising this issue and developing thoughtful legislation. We hope this will serve as a critical foundation for constructive legislation to be reported out of this Committee and passed in a bipartisan fashion by the Congress.

I do want to make clear, however, that GM, the auto industry and the coalitions we have partnered with, including RxHealth Value, are strongly committed to and supportive of pharmaceutical research and development. We believe that innovative products should be strongly protected by patent law. We fear, however, that certain practices currently employed in the industry have effectively misdirected its attention away from true innovation and new product development and toward preservation of old innovations.

CONCLUSION

Mr. Chairman, pharmaceutical cost increases clearly cannot be sustained. Notwithstanding our concerns about these costs, we regard coverage of prescription drugs as a basic, necessary benefit for all Americans because prescription drugs, used wisely, are frequently the most clinically appropriate and cost-effective treatment.

Unfortunately, this Nation is not using prescription drugs wisely and is not even making them available to millions of Americans. We are not adequately encouraging either competition or true breakthrough innovation. We can and we must do better.

RxHealth Value believes that Hatch-Waxman reforms—such as the Greater Access to Affordable Pharmaceuticals Act—can enhance competition and choice while also encouraging meaningful innovation.

Mr. Chairman, we appreciate your leadership in holding this hearing. We look forward to working with you and providing any assistance possible in developing legislation in this area. I would be happy to answer any questions you may have.

PREPARED STATEMENT OF GREGORY J. GLOVER, M.D.

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 to 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 face a substantial challenge to show that change is needed and would not upset the careful balance achieved by Congress. The facts speak for themselves. The Hatch-Waxman Act works. It has promoted generic competition while affording sufficient protection to innovation, and the proposed changes would serve only to undermine this highly successful compromise.

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% of the Nation's economic output, is expected to reach 16% of output by 2010, and could exceed 20% by 2040.

Over the past 100 years, pharmaceutical research has helped transform health care, contributing substantially to an increase of nearly thirty 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 deaths per 1,000 individuals in 1920 to 0.8 deaths per 1,000 individuals in 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 thirty years, total GDP spent on drugs rose little from only

0.84% in 1965 to 0.86% in 1992. In 2000, drug costs accounted for 9% of overall healthcare costs, while hospital care accounted for 32% and physician care for 22%. Further, 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 . . .

The cumulative value of medical innovation is, in fact, in the trillions of dollars. Estimates by the Congressional Joint Economic Committee quoted by the National Institutes of Health show annual net gains of $2.4 trillion a year resulting from increased life expectancy alone. In particular, studies have shown that replacing older with newer medicines reduces illness, death, and total medical spending. Further, in a survey concluded in April, funded by PhRMA, of 400 physicians from throughout the country, over 90% considered the continuing development of new prescription drugs vital to patient care. In addition, 84% believed that prescription drugs have reduced the need for surgery, and 95% of these physicians thought that prescription drugs have shortened hospital stays.

The research-based pharmaceutical sector in the United States is 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.

New drug development is a lengthy process, and total drug development time has grown significantly. Average total drug development time has increased from approximately 8 years as of 1960, to over 14 years in the 1980s and 1990s. New drug development is also very risky. Most drugs do not survive the rigorous development process—only 20 in 5,000 compounds that are screened enter preclinical testing, and only 1 drug in 5 that reaches human clinical trials is approved by the FDA as being both safe and effective. Further, for those drugs that do reach human clinical trials, more and far larger trials are now typically performed. Accordingly, the average cost to develop a new drug has been estimated to now be approximately $800 million.

Enormous investments are needed to encourage further pharmaceutical innovations, investments as large or larger than those that have supported the extraordinary progress from which individual patients, the public health, and society as a whole now benefit.

PhRMA companies spend an estimated 17.7% 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 or 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% of the domestic sales of companies that conducted R&D in 1998, it accounted for 8.7% of all company-funded R&D, 18.7% of all company-funded basic research, and 4.8% of all research scientists and engineers. Contrary to some claims, PhRMA companies' research expenditures substantially exceed their marketing expenses, including direct-to-consumer advertising.

Research-based pharmaceutical companies allocate nearly 78.5% of their R&D expenditures to research and evaluation for new drug products. The remaining 21.5% 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. These repeated incremental innovation also lead to major breakthroughs in therapy. Sequential product innovation is an important feature of the innovative process for the pharmaceutical industry, expanding the variety of therapeutic choices available for consumers and their doctors to consider.

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% to almost 50%.

Before 1984, it took three 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% or more within weeks after generic copies enter the market.

Prior to 1984, only 35% 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, by restoring part of the patent life lost by pioneer medicines as a result of regulatory review by the Food and Drug Administration (FDA) and establishing 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 precisely 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, for the most part, 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 post1962 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 the bioequivalence of its copy to a pioneer product. 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. Upon such a showing of bioequivalence, FDA could rely on the pioneer's safety and efficacy data to approve the copy.

As a result of the Hatch-Waxman Act, generic manufacturers are able to avoid incurring 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 entity 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 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. During that 180-day period, the FDA cannot approve any other copies.

To attempt to balance the generic provisions, the Hatch-Waxman Act compromise also 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 before the patent expires.

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 the following 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 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 (no patent information has been filed) or the second certification (the patent has expired), approval can be made effective immediately. Under the third certification (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.

In short, although the Hatch-Waxman compromise stimulates competition and provides only limited incentives for the innovation upon which pioneer and generic pharmaceutical companies alike depend on innovation for new products to offer to consumers. Nevertheless, generic manufacturers, among others, are advocating major changes in the legislation. In view of the balanced nature of the law, any proponent of change faces a substantial challenge to show that change is necessary and would not upset the delicate compromise achieved in 1984. Adoption of changes advocated in current proposals is neither necessary nor wise. We strongly oppose 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.

In particular, S. 812 as it stands, reflects unfounded arguments in support of amendment of the Hatch-Waxman Act. We understand the intent of the bill to be to speed approval of generic drugs and enhance pharmaceutical competition. However, 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 likely delay most generic competition an additional 6 months or more.

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 noninfringement 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.

In only 5 patent disputes has the FTC reportedly challenged either the actions of the innovator or the settlement between the innovator and generic company-an infinitesimal percentage of the applications.

Ample means exist to assess any potentially inappropriate practices and to deter abuses. There is simply no reason to weaken or abandon a compromise that has worked so well. 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. As a result, a claim for patent infringement now 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, generic companies would continue to enjoy the benefits of the Hatch-Waxman Act that were created at the expense of innovator companies. Innovators, on the other hand, would no longer have appropriate, corresponding means to protect against patent infringement, made necessary by the unique exemption from patent infringement 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 requires the submission of 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, that the generic copy must be 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. This provision would officially sanction FDA's policy of approving generic drugs that are not duplicates of the innovator drug as contemplated by Hatch-Waxman.

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 scientific or other issues. 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 relevant 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 likely 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 generic drug companies that challenge an innovators patent to keep all other generic products off the market for 6 months.

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.

PREPARED STATEMENT OF KATHLEEN JAEGER

Mr. Chairman. Distinguished 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 more than 140 members, I want to thank you for convening this hearing to discuss pharmaceutical cost, the need for increased consumer access, and opportunities to close existing loopholes in the approval of more affordable prescription drugs.

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 manufacturers more than 90% of all generic drug doses dispensed in the United States. Our products are used in more than one billion prescriptions every year. 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.

Today, I want to discuss several issues that are critical to understanding the challenge of how to provide increased access to affordable medicines while simultaneously lowering costs and preserving the incentives that promote new product discovery and innovation. I will discuss the current landscape of the pharmaceutical industry both generic and brand, and debunk some myths that have arisen in the current debate.

Then, I want to turn my attention to how modest legislative reforms of the landmark Hatch-Waxman Act can restore the intended balance that served consumers well for more than a decade, but now is subject to manipulations that take money out of consumers' pockets. To accomplish this, I will describe the loopholes that are being exploited in the current law, and outline the ways that GPHA members believe that reforms could be made.

Signed into law in 1984, the Drug Price Competition and Patent Term Restoration Act, also known as Hatch/Waxman established the process that created the modern generic pharmaceutical industry.

Among all the pharmaceutical manufacturers, the generic pharmaceutical industry is unique. Every day, the use of our products saves millions of dollars for consumers and taxpayers. This daily savings amounts to more than $10 billion dollars in lower health care costs each year.

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 2001 was $172 billion, or approximately $601 per person. That represents an increase of 17% over the previous year. Of that total, approximately $13 billion, or approximately $48 per person, was spent on generic pharmaceuticals.

Last year, 47% of all prescriptions were filled with generic drugs. But while nearly one in every two prescriptions was filled with a generic drug, only approximately 8% of all dollars spent on drugs were spent on generic medicines. Brand name pre-

scription drugs, conversely, represented 53% of all prescriptions but consumed approximately 92% of all drug therapy dollars spent. The top ten brand pharmaceutical companies accounted for 61% of all pharmaceutical sales. These numbers reveal a stark reality: brand name prescription drugs exceed the cost of generics by almost ten-fold, and brand companies dominate the marketplace.

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

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

PhRMA is currently distributing a chart that purports to show the steady growth in generic substitution: from 19% in 1984 to 47% in 2000. Our brand colleagues would suggest that this demonstrates that Hatch-Waxman is working, that generics continue to prosper, and that Hatch-Waxman does not need to be reformed. But what PhRMA does not tell you is that while generic substitution increased from 43% to 47% over the past 5 years, the amount of money spent on generic prescriptions declined five percentage points, from 12% to 7.5% over that same period. So, consumers used more generics, and spent less on them, but at the same time the cost of prescription drugs continued to increase at double-digit rates.

Despite the indisputable savings to be gleaned from generics the Nation's prescription drug bill continues to show double-digit annual increases. And consumers, employers, insurers and government agencies are feeling the effects.

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

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

Major employers, such as GM, are feeling the profound effect of escalating pharmaceutical costs, and are actively encouraging generic drug utilization. Physicians are increasingly aware of the impact that rising drug prices are having on their patients. The AMA has a policy statement that "supports programs whose purpose is to contain the rising cost of prescription drugs." The policy specifically encourages physicians to be aware of prescription drug prices and the availability of generic versions of brand name drugs. Health plans such as CIGNA, Well Point, Aetna, and others are engaging in more and more programs to foster generic drug utilization. A coalition of leading governors, businesses, and labor leaders has also asked Congress to revisit Hatch-Waxman. The coalition, Business for Affordable Medicine, feels that loopholes in the current legislative scheme are undermining the intent of the law, and are being exploited to extend patents at considerable expense to employers and consumers/taxpayers.

BRAND PHARMACEUTICAL INNOVATION

It is important to understand that the position of GPHA on reforming Hatch-Waxman recognizes the value of brand innovation, and the need for preserving incentives that promote innovation. 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, including generic companies, have a responsibility to achieve a reasonable return on the shareholders' investment. However, the best way to promote innovation, to provide an incentive to develop the next, medical breakthrough product, is to foster competition. Allowing a brand product to have unlimited monopoly protection distorts the incentive, and

results in the adoption of a brand preservation strategy, rather than an innovation strategy.

It is interesting to note that America recognizes the dangers of monopolies in virtually every other area of our economy. The intent of Hatch-Waxman was to define and establish a natural and limited period of monopoly protection, in recognition of the value of brand innovation. But today, loopholes in the Act are being manipulated to expand this protection well beyond what Hatch-Waxman intended. It is time to recognize that these efforts—quote—"life cycle management" practices, are nothing more than attempts at monopoly extensions, which harm innovation and penalize consumers.

In 2000, the National Institute for Health Care Management (NICHM) released a study that analyzed the issue of brand innovation and patent extensions. The study suggested that changes in the law over the last two decades have increased by at least 50 percent the effective patent life for new drugs. That means drug companies have an extra four or 5 years to reap profits before low-priced generics enter the market. The NIHCM study concluded that delays in generic competition are forcing customers to incur billions of dollars in prescription drug costs they otherwise may not have paid.

PhRMA has been using a chart to bolster its case. This chart allegedly indicates that reform of Hatch-Waxman is not necessary by showing the cumulative value of brand products coming off patent in the next 10 years. What PhRMA neglects to mention is twenty (20) of the thirty (30) possible products that should have gone off patent in 2000 failed to have generic competition during that year. This represented $5.4 billion in sales. Likewise, in 2001, generic competition did not commence for twenty-three (23) of the twenty-six (26) products, representing $11.4 billion in sales.

BRAND PATENTS AND GENERIC DRUGS

PhRMA members use several tactics, and the combination thereof, to delay consumer access to affordable medicines. To understand these loopholes, it is first necessary to understand facts about pharmaceutical patents.

When we speak of pharmaceutical patents, the typical person would assume that a single patent protects the drug product and its usage. However, the fact is that pharmaceutical companies seek, and are granted, patents on a number of different aspects of each product and related products (secondary patents), in an effort to maintain monopoly product sales far beyond the 20 years of original protection. In fact, the average number of patents listed for a blockbuster product has increased from 2 to about 10 as a means to indefinitely extend their market exclusivity.

It is important to note that the patent application process at the U.S. Patent and Trademark Office is not an adversarial system. When a company files for a patent there is no consumer ombudsman or other party that questions the impact or validity of the patent. The decision regarding the validity of a patent is based generally on the data that is filed by the company seeking the patent. Moreover, once a patent is issued by PTO, it is presumed to be valid. Thus, the patent process does not automatically protect the interests of consumers.

RESTORING HATCH-WAXMAN

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 Act. 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 legislative solution should consider the following:

Reform the 30 Month Stay Provisions

Restore Hatch-Waxman Exclusivity Provisions

Reform the FDA Citizen Petition Process

Reaffirm the 180-Day Exclusivity Incentive

Interestingly, depending on the day, PhRMA seems to contradict itself on the impact of reforms such as those proposed by our association, and the coalition of people speaking on behalf of Hatch-Waxman reforms. On one hand, PhRMA says that 30 month stays are rare; late listed patents are rare; and that only 5.8% of generic applications have raised a patent issue since 1984. But they also say reform legislation, such as Schumer-McCain, which is compatible with our positions on this issue,

would destroy the balance of Hatch/Waxman. So which is it? If all these issues are rare then changing them should not have a significant impact.

Let's look at each loophole, and proposals to address the issue.

REFORM THE 30-MONTH STAY

To understand the need to reform the 30-month stay, let's look at the Hatch-Waxman generic drug approval process. 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 suit that is completely without merit enjoys the same 30-month stay as a meritorious one.

From a brand company's perspective, the 30-month stay, and its consequent windfall is almost too good to be true. 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 the 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 secondary patents with FDA. Many times these patents do NOT claim the approved marketed drug product or its approved medical 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.

One good example is represented by the anticonvulsant drug, Neurontin . By listing patents with FDA that do not claim the FDA approved form of the drug or its approved uses, 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. Furthermore, by strategically timing the submission of patents 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. 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 examples that demonstrate that in the brand industry's eyes, anything can, and will be, considered suitable for monopoly extension.

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. Eliminating the 30-month stay provision also reduces the incentive to list patents that the innovator knows are invalid. Accordingly, eliminating the 30-month stay provision would infuse legal discipline and accountability into the system.

RESTORE HATCH-WAXMAN EXCLUSIVITY PROVISIONS

Blockage of generic competition can also occur 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 "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 Glucophage (for adult onset diabetes). Information derived from these limited studies yielded minor labeling changes. BMS

used the outcome of minor pediatric studies to delay a generic version of this 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 3 years of exclusivity which precludes generic firms from having that information on their product label. The limited Glucophage pediatric studies (72 subjects) resulted in the development of certain pediatric information. Bristol had received 6 months of exclusivity for conducting the study. Bristol also received 3 years of exclusivity for changing its labeling to include this "new" pediatric information, which in turn yielded a second 6 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. Generic firms ultimately prevailed in fighting this abuse, but the brand's tactics delayed generic competition for 6 months, creating a windfall for them on a drug with annual sales in excess of $1 billion a year.

GPHA proposes 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.

REFORM THE FDA CITIZENS PETITION PROCESS

Questionable timing and use of FDA citizen petition process is an issue. 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.

A good example of the opportunity to use the Citizen Petition process to delay generic competition, while switching patients to a newer, patent protected product, is seen in the recent activities surrounding generic Adderall.

Widely used for attention deficit disorder, the brand version of this product had annual sales of approximately $350 million. Waxman/Hatch

exclusivity protecting Adderall ended in February 2001. In December 2001, the brand company filed a citizen petition on the eve of generic competition that asked the FDA to require more stringent bioequivalence standards for generics to Adderall because of the addictive nature of the drug. The petition, which was ultimately rejected, delayed generic competition for several months.

And just last week, the brand announced that it had sued the generic manufacturer charging generic Adderall uses trade dress that brand claims is similar in appearance to it's Adderall product. This is despite the fact that numerous products have the same shape and color as Adderall, and despite the fact that the shape of the generic tablet is different, the generic logo is imprinted on each tablet and is clearly different from the logo on the brand product, and all labeling and packaging is different

Citizen petitions filed with FDA should be subject to requirements similar to those that govern Federal court filings. For example, a petitioner should have to certify that it (i) has submitted a document that is well grounded in fact and law; (ii) has not submitted a petition for an improper purpose, such as to harass or delay; and (iii) has not knowingly included any false, misleading, or fraudulent statement in the petition. Further, an entity submitting a petition should have to provide written notice to the FTC if the person received any consideration for submitting the petition, as does an amicus curiae submitting a brief to the U.S. Supreme Court. Finally, Congress should provide FDA or another Federal agency, such as the FTC, with authority to investigate allegations of bad faith filing of a citizen petition.

REAFFIRM THE 180-DAY EXCLUSIVITY INCENTIVE

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 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 6 months of exclusivity. On January 29, 2002, the firm's period of exclusivity ended, and multiple generic versions of Prozac entered the mar-

ketplace. Rapidly and predictably, the price of Prozac dropped from approximately $2.70 per dose for the brand to less than ten 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. Over the past several years, a total of 11 patent challenges, including Prozac, have created more than $27 billion in savings for consumers. These patent challenges include:

Buspar: 17 Years early at a cost savings of $8.8 Billion
Terazosin: 13 Years early at a cost savings of $4.6 Billion
Taxol: 11 Years early at a cost savings of $3.5 Billion
Zantac: 4 Years early at a cost savings of$2.45 Billion
Procardia: 8 Years early at a cost savings of $2.4 Billion
Plantinol: 11 Years early at a cost savings of $1.0 Billion
Ticlid: 3½ Years early at a cost savings of $492 Million
Lodine: 7 Years early at a cost savings of $414 Million
Relafen: 2 Years early at a cost savings of $413 Million
Climara: 7 years early at a cost savings of $378 million

The 180-day generic exclusivity provision works for consumers. Clearly it provides the incentive that Congress intended for the generic 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. Patent and Trademark Office does not provide.

Conversly, creating a rolling generic drug exclusivity 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.

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. The operative word is "should." Of course, the brand industry would like to forestall this event as long as possible. Without modernizing 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 huge windfall profits currently enjoyed by the brand industry, and the enormous savings available to the American public through generic utilization. The brand pharmaceutical industry would have Congress believe that the system isn't broken, so it doesn't need fixing. The brand industry would have Congress and the American public believe that the patent challenge provisions of Hatch-Waxman, with its 180-day generic exclusivity incentive, results in increased litigation and deserves 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. The fact is that competition spurs true innovation.

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