

**COST OF PHARMACEUTICAL
DRUGS AT RECORD HIGH**

The SPEAKER pro tempore. Under a previous order of the House, the gentleman from Rhode Island (Mr. KENNEDY) is recognized for 5 minutes.

Mr. KENNEDY of Rhode Island. Madam Speaker, the cost of prescription drugs is certainly at a record high.

Prescription drugs represent the highest out-of-pocket medical care cost for 75 percent of the elderly. Only long-term care costs more than these prescription drugs. And approximately 37 percent of seniors do not have the drug coverage necessary for them to be able to buy these drugs and afford them.

But here in the Congress, a bill has been introduced that will further, I repeat, further increase the cost. That is right, not lower cost, not reduce the burden on our senior citizens, but a bill that will actually increase the cost to consumers and to market monopolies.

H.R. 1598, the Patent Fairness Act, is anything but fair. What the bill would do is simple. It allows a back door for multi-billion-dollar patent extensions to go to seven pharmaceutical companies, possibly more. It continues monopolies for these drugs for more than 3 years and, therefore, deprives senior citizens as well as other consumers the choice of selecting a more affordable generic version.

The estimated windfall for pharmaceutical companies for the extension will be at minimum \$6 billion.

The bill ignores a compromise reached in 1984 that gave those drugs under review by the FDA a 2-year extension and gave a future eligibility for extensions to drugs that have been filed at the FDA.

In order to be fair, however, they still received an additional 2 years of patent protection in order to foster their growth. These extensions have added up and have had the effect of giving these companies a monopoly on the marketplace. As a matter of fact, one of these drugs, Claritin, had a 1998 U.S. sales total of \$1.8 billion.

There is no need to continue the monopoly and, therefore, to continue the market exclusivity of these drugs and the high cost.

In the meantime, however, several companies that are gearing up to provide more affordable generic versions of these drugs are being stifled because of these patent extensions. These patent extensions subvert the drug patent system and turn it into an anti-competitive shield to protect profits.

And while the companies suffer, so do the average American citizens who are trying to afford these prescription drugs. The monopolies allow increased prices for their drugs and, therefore, the consumers pay more.

Prescription drug costs have risen 85 percent in the last 5 years. Every day we hear more and more about the fact that many seniors and their families are forced to choose between dinner on the table and medicine in their bodies.

As my colleagues can see from this graph here to my right, the average

prescription drug price to consumers in the past 5 years has risen nearly \$18 per prescription. Given the fact that generic drugs are usually priced between 30 and 60 percent less than the brand name drugs, we are seeing this monopoly raise prices and profits for these companies.

Conservative groups like Citizens for a Sound Economy and Citizens Against Government Waste have criticized this proposal in the past. The Consumer Federation of America said that "this is yet another attempt to slip a special-interest provision into an appropriations bill which will prove very costly to consumers."

Public Citizen called it the "greedy special-interest grab at the expense of consumers and the health care industry."

This year we will let this issue be brought up and we will make sure that the affordability of prescription drugs will be paramount amongst our side, on the Democratic side, to make sure that we will not extend this drug monopoly and block generic drug competition.

H.R. 1598 continues this high prescription drug prices, which we intend to fight every step of the way and make sure that we have more affordable generic medicines to provide our senior citizens with a choice.

Prescription drug costs have skyrocketed. Senior citizens' cost for out-of-pocket expenses for these prescription drugs are occupying an ever increasing percentage of their out-of-pocket expenses. And if my colleagues think about it, we will actually save money by covering prescription drugs and reducing these drug prices by going for generic brands, as well.

Because if senior citizens can afford these drugs, guess what, they do not end up in the hospital sick because they are not able to take the medications that their doctors tell them they must take if they are to remain well.

This is a classic case of an ounce of prevention is worth a pound of cure. I would ask my colleagues to keep in mind that this is an important issue that we need to keep alive so that we focus our attention on this issue and preserve generic drugs for the consumers in this country.

Mr. PALLONE. Madam Speaker, will the gentleman yield?

Mr. KENNEDY of Rhode Island. I yield to the gentleman from New Jersey.

Mr. PALLONE. Madam Speaker, I just want to thank my colleague the gentleman from Rhode Island (Mr. KENNEDY) for organizing this special order.

I want to add my voice to his tonight because we share the view that H.R. 1598 is a misguided and bad piece of legislation.

One of the most pressing issues on Congress' agenda this year, if not the most pressing issue, has been looking for a way to make prescription drugs more for all Americans, and seniors in particular. It is unfortunate, however, that there is a movement in this body to

do just the opposite. And let there be no mistake about it, the "Patent Fairness Act of 1999" is an attempt by some in the pharmaceutical industry to protect market share, and force consumers to continue to pay the highest possible price for prescription drugs.

The brand name industry is well aware that generic competition has a dramatic impact on pharmaceutical costs. When a generic comes to market, it typically costs 30 percent less than the brand name version. After two years on the market, the prices drop further to 60 or 70 percent of the brand name drug. The price of some generic drugs drop by as much as 90 percent.

While these competitively priced alternatives are good for consumers, employers, government purchasers, and particularly the elderly, they are not good for the brand name producer trying to maintain monopolistic pricing. If there is no generic alternative available, consumers who need medicine have no choice but to buy the available brand drug and pay whatever it costs. It is for precisely this reason that a few brand name drug companies have been working so hard to get the so called "Patent Fairness Act of 1999" signed into law. A patent extension is the only way to protect the windfall profits these blockbuster drugs have been generating.

In addition to keeping low cost, generic alternatives out of the reach of consumers, the "Patent Fairness Act" of 1999 is bad public policy for two other reasons. The first is that it turns the whole intent of the drug patent system on its head.

The purpose of the patent system is to promote the research and development of new drugs. By granting patent extension above and beyond what is called for in current law, the Patent Fairness Act would create an anti-competitive environment, which is precisely opposite the intention of the 1984 Hatch-Waxman bill. That bill, which is in part named after my colleague from California, HENRY WAXMAN, was designed to lower drug prices through competition, not to protect monopolies. It has been enormously successful in achieving that objective and Congress should not carve out a special exemption for a few companies seeking to squeeze a few more billion dollars out of American consumers.

Secondly, it would also affect the federal government's ability to control health care costs. There are a number of legislative proposals that have been introduced to add a prescription drug benefit to Medicare, which is essential to modernizing the program. Indeed, the President is expected to unveil his plan to achieve this goal before the month is out. Carving out special exemptions for companies seeking to extend patents on blockbuster drugs for no good reason will complicate efforts to include a prescription drug benefit by driving up costs for the federal government. If the "Patent Fairness Act" becomes law, every major drug producer in America will be knocking on Congress' door for a patent extension, and the fight Democrats are already waging to include a meaningful prescription drug benefit in Medicare will get that much harder.

Congress' energy would be much spent trying to make prescription drugs more affordable, not more expensive. I urge all of my colleagues in the House to recognize the Patent Fairness Act of 1999 for what is and oppose this misguided and ill-conceived effort to charge the American people billions of dollars

to line the pockets of a few pharmaceutical companies.

Mr. KENNEDY of Rhode Island. Madam Speaker, reclaiming my time, that these drugs are so costly; and we need to do everything in our power in this Congress to make sure seniors and other consumers are not overburdened by the cost of prescription drugs.

Mr. PALLONE. Madam Speaker, if the gentleman would continue to yield, I appreciate that; and I agree.

Mr. WAXMAN. Mr. Speaker, I rise to join my colleagues in speaking against the ill advised, anti-consumer legislation, H.R. 1598, "The Patent Fairness Act of 1999."

My first observation is that, having reviewed this bill, I would suggest it deserves a more appropriate title, like "The Claritin Monopoly Extension Act" or "The Patently Unfair to Consumers Act of 1999."

This proposal is a multibillion dollar assault on consumers. By keeping out competition, the drug companies which benefit from H.R. 1598 can rake in money out of the pockets of Americans who already find it hard to pay for their medicines.

The best estimates of this bill's cost to consumers range in the billions of dollars. We have no idea as yet of its potential costs to the Federal government, but it will undoubtedly line the pockets of a handful of companies with money taken directly from the pockets of American taxpayers, including the indigent and the elderly.

H.R. 1598 is nothing more than a recycled version of the patent extension which the pharmaceutical manufacturer, Schering-Plough, has attempted on repeated occasions to sneak into law. For many years, Schering has sought to extend its patent protections for Claritin, a prescription antihistamine with over \$900 million in annual U.S. sales.

Let me share with my colleagues the sordid history of this bill. Last year, Schering tried to sneak this patent extension into the omnibus appropriations bill. You may recall this is the legislation renowned for having been enacted into law with scarcely any Member claiming to have read it in its entirety. Only through vigorous opposition and publicity was this effort defeated.

The year before, Schering lobbied the Senate for an amendment to omnibus patent reform legislation granting outright five-year patent term extensions for a number of drugs, including Claritin. And in 1996, Schering tried unsuccessfully to attach Claritin patent extensions to the omnibus appropriations bill, the continuing resolution and the agriculture appropriations bill. In the first half of that year alone, Schering spent over \$1 million in lobbying the Congress.

This year, H.R. 1598 has been introduced. I have reviewed this legislation and can state unequivocally that, owing to many serious problems this legislation should not be enacted into law.

First, I am deeply concerned by the misreading of legislative history which has characterize the introduction of H.R. 1598. As the coauthor of the 1984 Waxman-Hatch Act, I want to set the record straight about the legislative history of the Act.

It has been alleged that Schering and the five other companies which would benefit from this special-interest, pork barrel legislation—Smith Kline Beecham, Bristol Myers Squibb,

Bayer, Rhone Poulenc Rhorer and Hoechst Marion Roussel—somehow were arbitrarily or unexpectedly penalized by the Waxman-Hatch Act. Because these companies were the sponsors of drugs in the "pipeline" seeking approval at the time of the Act's enactment in 1984, those products are only eligible for a 2-year patent extension, and not the 5-year patent extension available to products approved after 1984.

The proponents of H.R. 1598 have called this provision in the Act "arbitrary" and unfair. It is no such thing. It is eminently fair and motivated by sound public policy. The pipeline drugs were not made eligible for 5 years of patent extension precisely because the point of the patent extensions was to encourage the research and development of future products. All products which had not yet undergone testing or review by the Food and Drug Administration (FDA) were judged to be appropriately eligible for the full 5 years of patent extension.

I seriously doubt that Schering has told anyone that it already received a 2-year patent extension under this law. The company just wants another pass at the trough. But to make clear why the Act's intent in this regard is precise and fair, I want to quote the legislative history from the 1984 House committee report on this point:

By extending patents for up to five years for products developed in the future . . . the Committee expects that research intensive companies will have the necessary incentive to increase their research and development activities.

This is the clear policy which motivated this provision—to encourage additional research, not to simply increase profits on existing products. Only now, faced with their imminent patent expirations, are a handful of companies lobbying vigorously to defeat this policy. They have no interest in research or feature products. Their sole concern is preserving their existing monopoly at the expense of consumers.

Let me make a final point about H.R. 1598. If this patent extension bill is snuck into law, it will create a huge loophole which will allow other drug companies to come and use it for other patent extensions at the Patent Office, a bad policy and worse precedent.

As consumer groups have made clear, H.R. 1598 is a back-door for drug companies to lucrative patent extensions. The bill creates a stacked deck in favor of drug companies. It forces the burden of proof into opponents of pork-barrel patent extensions. It creates a rebuttable presumption in favor of the drug companies. It restricts the FDA from providing input about the scientific judgments it had to make about safety and effectiveness. And it puts the Patent Office in the categorically inappropriate role of second-guessing the FDA about those scientific issues. As I've said before, this is like putting the IRS in charge of reviewing how NIH grants biomedical research funding.

This bill creates a terrible precedent of second guessing our public health agencies, which protect the public by ensuring drug safety and efficacy. What Schering calls "regulatory delay" may well be the result of its own delays through miscalculations, complications in its research and safety problems with its product. Schering conveniently never mentions that Claritin's "regulatory delay" resulted in no small part from the need to be sure that

Claritin was not linked to cancer, as scientific data suggested during its review by FDA.

One of the points of the Waxman-Hatch Act was to stop companies like Schering from lobbying Congress for patent extensions. It has been generally successful, with the exception of rogue companies like Schering. If Schering believes it was unduly delayed, we have only to await the General Accounting Office's review of the circumstances surrounding the approval of Claritin. The introduction of H.R. 1598 leads me to believe that Schering is simply afraid of what the GAO will find.

Mr. Speaker, H.R. 1598 is a terrible deal for consumers. It creates a blatantly unfair administrative process which undercuts the public health. It does violence to the 1984 Waxman-Hatch Act. And it fulfills the public's worst expectations of Congress as a body motivated by the interests of lucrative industries, like the prescription drug industry, and not of average Americans struggling to afford their medicines.

LEAVE OF ABSENCE

By unanimous consent, leave of absence was granted to:

Mr. GREEN of Texas (at the request of Mr. GEPHARDT) for today on account of weather delay.

Mr. KIND (at the request of Mr. GEPHARDT) for today on account of airport weather delay.

Mr. STUPAK (at the request of Mr. GEPHARDT) for today on the account of weather delay.

SPECIAL ORDERS GRANTED

By unanimous consent, permission to address the House, following the legislative program and any special orders heretofore entered, was granted to:

(The following Member (at the request of Mr. PALLONE) to revise and extend his remarks and include extraneous material:)

Mr. PALLONE, for 5 minutes, today.

(The following Members (at the request of Mr. GUTKNECHT) to revise and extend their remarks and include extraneous material:)

Mr. FLETCHER, for 5 minutes, today.

Mr. BURTON of Indiana, for 5 minutes, on June 16.

Mrs. JOHNSON of Connecticut, for 5 minutes, today.

Ms. ROS-LEHTINEN, for 5 minutes each day, on today and June 15.

Mr. BILIRAKIS, for 5 minutes, on June 17.

Mr. MICA, for 5 minutes, today.

Mr. MORAN of Kansas, for 5 minutes, on June 15.

Mr. JONES of North Carolina, for 5 minutes, on June 15.

Mr. GUTKNECHT, for 5 minutes, today.

Mr. PAUL, for 5 minutes, today.

Mr. THUNE, for 5 minutes, today.

ADJOURNMENT

Mr. KENNEDY of Rhode Island. Madam Speaker, I move that the House do now adjourn.

The motion was agreed to; accordingly (at 9 o'clock and 11 minutes