

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 teasing 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