

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

p.m.), under its previous order, the House adjourned until tomorrow, Tuesday, June 15, 1999, at 9 a.m., for morning hour debates.

EXECUTIVE COMMUNICATIONS, ETC.

Under clause 8 of rule XII, executive communications were taken from the Speaker's table and referred as follows:

2576. A letter from the Under Secretary, Department of the Navy, transmitting notification of the Department's decision to study certain functions performed by military and civilian personnel in the Department of the Navy for possible performance by private contractors, pursuant to 10 U.S.C. 2304 nt.; to the Committee on Armed Services.

2577. A letter from the Secretary of Defense, transmitting the approval of the retirement of Admiral Joseph W. Prueher, United States Navy, and his advancement to the grade of admiral on the retired list; to the Committee on Armed Services.

2578. A letter from the Secretary of Defense, transmitting approval of the retirement of Lieutenant General Martin R. Steele, United States Marine Corps, and his advancement to the grade of lieutenant general on the retired list; to the Committee on Armed Services.

2579. A letter from the Secretary of Defense, transmitting approval of the retirement of General Charles C. Krulak, United States Marine Corps, and his advancement to the grade of general on the retired list; to the Committee on Armed Services.

2580. A letter from the Assistant General Counsel for Regulations, Special Education and Rehabilitative Services, Department of Education, transmitting notice of Final Funding Priorities for Fiscal Years 1999-2000 for Certain Centers and Projects, pursuant to 20 U.S.C. 1232(f); to the Committee on Education and the Workforce.

2581. A letter from the Assistant Secretary, Department of Education, transmitting notice of Final Funding Priorities for Fiscal Years 1999-2000 for Certain Centers and Projects, pursuant to 20 U.S.C. 1232(f); to the Committee on Education and the Workforce.

2582. A letter from the Acting Assistant General Counsel for Regulatory Law, Office of Safeguards and Security, Department of Energy, transmitting the Manual for Nuclear Materials Management and Safeguards System Reporting and Data Submission, pursuant to 5 U.S.C. 801(a)(1)(A); to the Committee on Commerce.

2583. A letter from the Director, Regulations Policy and Management Staff, Food and Drug Administration, transmitting the Administration's final rule—Indirect Food Additives: Adhesives and Components of Coatings [Docket No. 98F-0823] received June 8, 1999, pursuant to 5 U.S.C. 801(a)(1)(A); to the Committee on Commerce.

2584. A letter from the Director, Regulations Policy and Management Staff, Food and Drug Administration, transmitting the Administration's final rule—Indirect Food Additives: Adjuvants, Production Aids, and Sanitizers; Technical Amendment [Docket No. 97F-0421] received June 3, 1999, pursuant to 5 U.S.C. 801(a)(1)(A); to the Committee on Commerce.

2585. A letter from the CFO and Plan Administrator, PCA Retirement Committee, First South Production Credit Association, transmitting the annual report of the Production Credit Association Retirement Plan for the year ending December 31, 1998, pursuant to 31 U.S.C. 9503(a)(1)(B); to the Committee on Government Reform.

2586. A letter from the Assistant Secretary for Fish and Wildlife and Parks, Office of Law Enforcement, Department of the Interior, transmitting the Department's final rule—Migratory Bird Hunting: Regulations Regarding Baiting and Baited Areas (RIN: 1018-AD74) received June 1, 1999, pursuant to 5 U.S.C. 801(a)(1)(A); to the Committee on Resources.

2587. A letter from the Fisheries Biologist, Office of Protected Resources, National Oceanic and Atmospheric Administration, transmitting the Administration's final rule—Sea Turtle Conservation; Shrimp Trawling Requirements [Docket No. 950427117-8275-04; I.D. No. 100598B] (RIN: 0648-AH97) received June 3, 1999, pursuant to 5 U.S.C. 801(a)(1)(A); to the Committee on Resources.

2588. A letter from the Fisheries Biologist, Office of Protected Resources, National Oceanic and Atmospheric Administration, transmitting the Administration's final rule—Sea Turtle Conservation; Shrimp Trawling Requirements [I.D. 102098A] (RIN: 0648-AH97) received June 8, 1999, pursuant to 5 U.S.C. 801(a)(1)(A); to the Committee on Resources.

2589. A letter from the President, American Academy of Arts and Letters, transmitting the annual report of the activities of the American Academy of Arts and Letters during the year ending December 31, 1997, pursuant to section 4 of its charter (39 Stat. 51); to the Committee on the Judiciary.

2590. A letter from the Program Analyst, Office of the Chief Counsel, Federal Aviation Administration, Department of Transportation, transmitting the Department's final rule—Airworthiness Directives; Pratt & Whitney JT8D-200 Series Turbofan Engines [Docket No. 98-ANE-43-AD; Amendment 39-11188; AD-99-12-04] (RIN: 2120-AA64) received June 8, 1999, pursuant to 5 U.S.C. 801(a)(1)(A); to the Committee on Transportation and Infrastructure.

2591. A letter from the Program Analyst, Office of the Chief Counsel, Federal Aviation Administration, Department of Transportation, transmitting the Department's final rule—Airworthiness Directives; Pratt & Whitney JT8D-1, -1A, -1B, -7, -7A, -7B, -9, -9A, -11, -15, -15A, -17, -17A, -17R, and -17AR Series Turbofan Engines [Docket No. 98-ANE-48-AD; Amendment 39-11187; AD 99-12-03] (RIN: 2120-AA64) received June 8, 1999, pursuant to 5 U.S.C. 801(a)(1)(A); to the Committee on Transportation and Infrastructure.

2592. A letter from the Program Analyst, Office of the Chief Counsel, Federal Aviation Administration, Department of Transportation, transmitting the Department's final rule—Modification of Class E Airspace; Santa Rosa, CA [Airspace Docket No. 99-AWP-3] received June 8, 1999, pursuant to 5 U.S.C. 801(a)(1)(A); to the Committee on Transportation and Infrastructure.

2593. A letter from the Chief, Regs and Admin Law, USCG, Department of Transportation, transmitting the Department's final rule—Safety Zone; Marblehead, MA to Halifax, Nova Scotia Ocean Race [CGD01-99-062] (RIN: 2115-AA97) received June 8, 1999, pursuant to 5 U.S.C. 801(a)(1)(A); to the Committee on Transportation and Infrastructure.

2594. A letter from the Chief, Regs and Admin Law, USCG, Department of Transportation, transmitting the Department's final rule—Drawbridge Regulations; Grand Canal, Florida [CGD07-98-048] (RIN: 2115-AE47) received June 8, 1999, pursuant to 5 U.S.C. 801(a)(1)(A); to the Committee on Transportation and Infrastructure.

2595. A letter from the Chief, Regs and Admin Law, USCG, Department of Transportation, transmitting the Department's final rule—Safety Zone: Hospitalized Veterans Cruise, Boston Harbor, Boston, MA [CGD01-99-055] (RIN: 2115-AA97) received June 8, 1999,

pursuant to 5 U.S.C. 801(a)(1)(A); to the Committee on Transportation and Infrastructure.

2596. A letter from the Chief, Regs and Admin Law, USGC, Department of Transportation, transmitting the Department's final rule—Special Local Regulations: Independence Day Celebration, Cumberland River mile 190.0-191.0, Nashville, TN [CGD08-99-036] (RIN: 2115-AE46) received June 8, 1999, pursuant to 5 U.S.C. 801(a)(1)(A); to the Committee on Transportation and Infrastructure.

2597. A letter from the Governor, State of North Dakota, transmitting a request for assistance in bringing some relief to the people of the Devils Lake basin; to the Committee on Transportation and Infrastructure.

2598. A letter from the Deputy Director, National Institute of Standards and Technology, Department of Commerce, transmitting the Department's final rule—Community Alliance for Math, Science, and Technology Literacy (CASTL) [Docket No. 990517136-9136-01] (RIN: 0693-ZA30) received June 1, 1999, pursuant to 5 U.S.C. 801(a)(1)(A); to the Committee on Science.

2599. A letter from the Director, Office of Regulations Management, Veterans Benefits Administration, Department of Veterans Affairs, transmitting the Department's final rule—Service Connection of Dental Conditions for Treatment Purposes (RIN: 2900-AH41) received June 3, 1999, pursuant to 5 U.S.C. 801(a)(1)(A); to the Committee on Veterans' Affairs.

2600. A letter from the Director, Office of Regulations Management, Veterans Benefits Administration, Department of Veterans Affairs, transmitting the Department's final rule—Surviving spouse's benefit for month of veteran's death (RIN: 2900-AJ64) received June 3, 1999, pursuant to 5 U.S.C. 801(a)(1)(A); to the Committee on Veterans' Affairs.

2601. A letter from the Chief, Regulations Unit, Internal Revenue Service, transmitting the Service's final rule—Section 6621.—Determination of Interest Rate [Rev. Rul. 99-27] received June 3, 1999, pursuant to 5 U.S.C. 801(a)(1)(A); to the Committee on Ways and Means.

2602. A letter from the Chief, Regulations Unit, Internal Revenue Service, transmitting the Service's final rule—Secured Employee Benefits Settlement Initiative [Revenue Ruling 99-26] received June 1, 1999, pursuant to 5 U.S.C. 801(a)(1)(A); to the Committee on Ways and Means.

REPORTS OF COMMITTEES ON PUBLIC BILLS AND RESOLUTIONS

Under Clause 2 of the rule XIII, reports of committees were delivered to the Clerk for printing and reference to the proper calendar, as follows:

[Omitted from the Record of June 10, 1999]

Mr. ARCHER: Committee on Ways and Means. H.R. 1802. A bill to amend part E of title IV of the Social Security Act to provide States with more funding and greater flexibility in carrying out programs designed to help children make the transition from foster care to self-sufficiency, and for other purposes; with an amendment (Rept. 106-182 Pt. 1). Ordered to be printed.

[Submitted June 14, 1999]

Mr. GILMAN: Committee on International Relations. H.R. 17. A bill to amend the Agricultural Trade Act of 1978 to require the President to report to Congress on any selective embargo on agricultural commodities, to provide a termination date for the embargo, to provide greater assurance for contract sanctity, and for other purpose (Rept. 106-154 Pt. 2). Referred to the Committee of the Whole House on the State of the Union.