

this research gap. We also need to provide accurate and balanced information to the public and allow Americans to make their own medical decisions. Additionally, we need to work to extend access to therapies that are both safe and effective in government-funded programs where feasible.

Mr. FORBES. Mr. Speaker, I rise in support of the Best Pharmaceuticals for Children Act, to ensure that our children get the medicines that are best suited to their growing bodies.

Four years ago, Congress authorized incentives for pharmaceutical manufacturers to do pediatric research for their products and to provide pediatric labeling information. That legislation has been an extraordinary success for our children. In the six years prior to enactment of that change in law, only 11 pediatric studies were conducted by the pharmaceutical industry. But, in the four years since its enactment, the industry has agreed to more than 400 such studies.

Mr. Speaker, children are not simply small adults. They have special needs for nutrition and medical care, and the pharmaceutical products we develop should reflect these needs. The pediatric exclusivity provision Congress passed in 1997 ensures that they do. Today's legislation simply reauthorizes that expiring provision through Fiscal Year 2007.

I appreciate the bipartisan effort of the Energy and Commerce Committee to move this bill so swiftly through the legislative process, and I encourage my colleagues to support it.

Mr. DINGELL. Mr. Speaker, I rise to oppose passage of S. 1789, a bill that would continue a program that grants drug companies an additional six month period of market exclusivity, if they conduct tests on the use of their drugs for children. This bill is a slight improvement on H.R. 2887 that passed this House last month. We all agree that improved testing and labeling of prescription drugs for use in children is a good thing. The only question for debate is how to accomplish that important public health objective.

The bill does close a potential loophole by instructing the FDA to approve generic drugs without proprietary pediatric labeling awarded to product sponsors under the Hatch-Waxman Act. But I continue to oppose the bill because its central feature, exclusivity, is about further increasing the profits of an already bloated industry—an industry that does not seem to be able to moderate its pricing practices even as it increasingly burdens its customers, American consumers, and taxpayers.

The impact of pediatric exclusivity falls directly on those who consume the drugs that get the exclusivity. Who are these people? They include seniors, many that cannot afford the prescription drugs they need. And, ironically, pediatric exclusivity can hurt the very people it is intended to help because many unemployed, uninsured, and working poor cannot afford the expensive drugs needed by their children.

What benefit have consumers and taxpayers received for this multi-billion dollar extension of monopoly prices? Of the 38 drugs that have been granted pediatric exclusivity, less than 20 of them now have pediatric labeling. The Committee and the Senate rejected, unwisely in my view, an amendment by Representative STUPAK that would have closed

this dangerous loophole in the law by conditioning the grant of exclusivity to actual pediatric labeling.

This bill forces our citizens to overpay drug companies for pediatric testing that should simply be required by law. I oppose it.

Mr. BILIRAKIS. Mr. Speaker I rise today in support of S. 1789, The Best Pharmaceuticals for Children Act. If it's not broken—don't fix it. By all accounts Mr. Speaker, this program is a resounding success. According to the Food and Drug Administration, "the pediatric exclusivity provision has been highly effective in generating pediatric studies on many drugs and in providing useful new information in product labeling." The American Academy of Pediatrics states that they "can not overstate how important this legislation has been in advancing children's therapeutics."

The legislation before us today is virtually identical to H.R. 2887, which passed the House on November 15, 2001 by a 338–86 vote. Moreover, this legislation has recently passed the Senate unanimously.

The legislation reauthorizes the pediatric exclusivity program for an additional six years. It keeps the present incentive in place, and makes important improvements. The legislation ensures that off-patent generic drugs are studied, and tightens the timeline for making labeling changes.

The bill retains the improvements that were in both the Senate and House versions to ensure timely labeling changes occur. First, we make pediatric supplements "priority supplements," which will dramatically speed up the process for getting new labels. Second, by giving the Secretary authority to deem drugs misbranded we guarantee that label changes will be made. We believe, and children's groups agree, that the changes we make are the right compromises to maintain the incentives and get labels changed.

I would also like to acknowledge the hard work of my colleagues Representatives JIM GREENWOOD and ANNA ESHOO. These two Members have worked tirelessly to bring this process to a conclusion, and it has been a pleasure working with them. I again would also like to thank the staff that worked so long and hard on this legislation, including John Ford, David Nelson, Eric Olson, Brent Del Monte, Alan Eisenberg, and Steve Tilton. And, yet again a special thanks to Pete Goodloe our legislative counsel. We are so thankful for all of this help.

Mr. Speaker, this is great legislation that the Subcommittee and Full Committee put a lot of thought and effort into. It does wonders for children's health and is widely supported. I urge all Members to support its swift passage.

Mr. BROWN of Ohio. Mr. Speaker, I have no further requests for time, and I yield back the balance of my time.

Mr. TAUZIN. Mr. Speaker, I yield back the balance of my time.

The SPEAKER pro tempore (Mr. SIMPSON). The question is on the motion offered by the gentleman from Louisiana (Mr. TAUZIN) that the House suspend the rules and pass the Senate bill, S. 1789.

The question was taken; and (two-thirds having voted in favor thereof) the rules were suspended and the Senate bill was passed.

A motion to reconsider was laid on the table.

RECESS

The SPEAKER pro tempore. Pursuant to clause 12 of rule I, the Chair declares the House in recess subject to the call of the Chair.

Accordingly (at 4 o'clock and 10 minutes p.m.), the House stood in recess subject to the call of the Chair.

□ 1837

AFTER RECESS

The recess having expired, the House was called to order by the Speaker pro tempore (Mr. LATOURETTE) at 6 o'clock and 37 minutes p.m.

ANNOUNCEMENT BY THE SPEAKER PRO TEMPORE

The SPEAKER pro tempore. Pursuant to clause 8 of rule XX, the Chair will now put the question on motions to suspend the rules on which further proceedings were postponed earlier today.

Votes will be taken in the following order:

H.R. 3379, by the yeas and nays;

H.R. 3054, de novo.

The Chair will reduce to 5 minutes the time for any electronic vote after the first such vote in this series.

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The SPEAKER pro tempore. The pending business is the question of suspending the rules and passing the bill, H.R. 3379.

The Clerk read the title of the bill.

The SPEAKER pro tempore. The question is on the motion offered by the gentlewoman from Virginia (Mrs. JO ANN DAVIS) that the House suspend the rules and pass the bill, H.R. 3379, on which the yeas and nays are ordered.

The vote was taken by electronic device, and there were—yeas 393, nays 0, not voting 40, as follows:

[Roll No. 499]

YEAS—393

Abercrombie	Berkley	Brown (OH)
Ackerman	Berman	Brown (SC)
Aderholt	Berry	Bryant
Akin	Biggert	Burr
Allen	Bilirakis	Burton
Andrews	Bishop	Buyer
Armey	Blagojevich	Calvert
Baca	Blumenauer	Camp
Bachus	Boehlert	Cannon
Baird	Boehner	Capito
Baldacci	Bonilla	Capps
Baldwin	Bonior	Capuano
Ballenger	Bono	Cardin
Barcia	Borski	Carson (IN)
Barrett	Boswell	Carson (OK)
Bartlett	Boucher	Castle
Barton	Boyd	Chabot
Bass	Brady (PA)	Chambliss
Bentsen	Brady (TX)	Clayton
Bereuter	Brown (FL)	Clement