OISS Form 52 (Rev. 11-82)

CONGRESSIONAL RECORD
PROCEEDINGS AND DEBATES OF THE 98TH CONGRESS

HOUSE

BILL	DATE	PAGE(S)
H.R. 3605	Aug. 8, 1984	H8701-13

ACTION

Drug Price Competition: House completed all general debate on H.R. 3605, to amend the Federal Food, Drug, and Cosmetic Act to authorize an abbreviated new drug application under section 505 of that Act for generic new drugs equivalent to approved new drugs; but came to no resolution thereon. Proceedings under the 5-minute rule will begin on Thursday, August 9.

H. Res. 569, the rule under which the bill was considered, was agreed to earlier by a yea-and-nay vote of 304 yeas to 74 nays, Roll No. 360. Agreed to consider the rule by a yea-and-nay vote of 313 yeas to 80 nays, Roll No. 359.

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PROVIDING FOR CONSIDERATION OF H.R. 3605, DRUG PRICE COMPETITION ACT OF 1983

Mr. DERRICK, from the Committee on Rules, submitted a privileged report (Rept. No. 98-974) on the resolution (H. Res. 569) providing for the consideration of the bill (H.R. 3605) to amend the Federal Food, Drug, and Cosmetic Act to authorize an abbreviated new drug application under section 505 of that act for generic new drugs equivalent to approved new drugs, which was referred to the House Calendar and ordered to be printed, as follows:

H. RES. 567

Resolved, That at any time after the adoption of this resolution the Speaker may, pursuant to clause 1(b) of rule XXIII, declare the House resolved into the Committee of the Whole House on the State of the Union for the consideration of the bill (H.R. 3605) to amend the Federal Food, Drug, and Cosmetic Act to authorize an abbreviated new drug application under section 505 of that Act for generic new drugs equivalent to approved new drugs, and the first reading of the bill shall be dispensed with. After general debate, which shall be confined to the bill and shall continue not to exceed two hours, one hour to be equally divided and controlled by the chairman and ranking minority member of the Committee on Energy and Commerce, and one hour to be equally divided and controlled by the chairman and ranking minority member of the Committee on the Judiciary, the bill shall be considered for amendment under the five-minute rule. It shall be in order to consider the amendment in the nature of a substitute recommended by the Committee on Energy and Commerce now printed in the bill as an original bill for the purpose of amendment under the five-minute rule, said substitute shall be considered for amendment by titles instead of by sections and each title shall be considered as having been read, and all points of order against said substitute for failure to comply with the provisions of clause 7 of rule XVI are hereby waived. It shall be in order to consider en bloc the amendments recommended by the Committee on the Judiciary now printed in the bill to each title. It shall be in order to consider an amendment offered by Representative Derrick of South Carolina adding a new title III consisting of the text of title II of the bill H.R. 5929. Said amendment shall be considered as having been read, and all points of order against said amendment for

failure to comply with provisions of clause 7 of rule XVI are hereby waived. At the conclusion of the consideration of the bill for amendment, the Committee shall rise and report the bill to the House with such amendments as may have been adopted, and any Member may demand a separate vote in the House on any amendment adopted in the Committee of the Whole to the bill or to the committee amendment in the nature of a substitute. The previous question shall be considered as ordered on the bill and amendments thereto to final passage without intervening motion except one motion to recommit with or without instructions. After the passage of H.R. 3605, it shall be in order to take from the Speaker's table the bill S. 1538 and to consider said bill in the House, and it shall then be in order to move to strike out all after the enacting clause of the said Senate bill and to insert in lieu thereof the provisions contained in H.R. 3605 as passed by the House, and all points of order against said motion for failure to comply with the provisions of clause 7, rule XVI are hereby waived.

Mr. DERRICK. Mr. Speaker, by direction of the Committee on Rules, I call up House Resolution 569 and ask for its immediate consideration.

The SPEAKER pro tempore. The Clerk will report the resolution.

The Clerk read the resolution.

The SPEAKER pro tempore. The question is, Will the House now consider House Resolution 569?

The question was taken.

Mr. FRENZEL. Mr. Speaker, I object to the vote on the ground that a quorum is not present and make the point of order that a quorum is not present.

The SPEAKER pro tempore. Evidently a quorum is not present.

The Sergeant at Arms will notify absent Members.

The vote was taken by electronic device, and there were—yeas 313, nays 80, not voting 39, as follows:

[Roll No. 359]

YEAS—313

Ackerman	Brown (CA)	Dowdy
Akaka	Broyhill	Downey
Albosta	Bryant	Duncan
Alexander	Burton (CA)	Durbin
Anderson	Byron	Dwyer
Andrews (NC)	Campbell	Dymally
Andrews (TX)	Carper	Dyson
Annunzio	Carr	Early
Anthony	Clarke	Eckart
Aspin	Clinger	Edgar
AuCoin	Coelho	Edwards (CA)
Barnard	Coleman (MO)	Edwards (OK)
Barnes	Coleman (TX)	English
Bateman	Collins	Erdreich
Bates	Conte	Evans (IL)
Bedell	Conyers	Fascell
Bellenson	Cooper	Feighan
Bennett	Coughlin	Ferraro
Bereuter	Courter	Fish
Berman	Coyne	Florio
Bethune	Crane, Daniel	Foglietta
Bevill	Crane, Philip	Foley
Biaggi	D'Amours	Ford (TN)
Bliley	Daniel	Fowler
Boehlert	Darden	Frank
Boggs	Daschle	Frost
Boland	Davis	Puqua
Boner	de la Garza	Garcia
Bonior	Dellums	Gejdenson
Bonker	Derrick	Gephardt
Borski	DeWine	Gibbons
Boucher	Dicks	Gilman
Boxer	Dingell	Gingrich
Breaux	Dixon	Glickman
Britt	Donnelly	Gonzalez
Broomfield	Dorgan	Gore
Gradison	Mazzoli	Savage
Gray	McCloskey	Sawyer
Green	McCollum	Scheuer
Guarini	McCurdy	Schneider
Hall (IN)	McDade	Schroeder
Hall, Ralph	McHugh	Schulze
Hall, Sam	McKernan	Schumer
Hamilton	McKinney	Selberling
Hance	McNulty	Sharp
Harkin	Mica	Shelby
Harrison	Mikulski	Sikorski
Hawkins	Miller (CA)	Sisisky
Hayes	Miller (OH)	Skelton
Heftel	Mineta	Slattery
Hertel	Minish	Smith (FL)
Hightower	Mitchell	Smith (IA)
Horton	Moakley	Smith (NE)
Howard	Molinari	Smith (NJ)
Hoyer	Mollohan	Smith, Robert
Hubbard	Montgomery	Snowe
Huckaby	Moody	Solarz
Hughes	Moore	Solomon
Hutto	Moorhead	Spence
Hyde	Morrison (CT)	Spratt
Ireland	Mrazek	St Germain
Jacobs	Murphy	Staggers
Jeffords	Natcher	Stenholm
Jenkins	Neal	Stokes
Johnson	Nelson	Stratton
Jones (OK)	Nichols	Studds
Kaptur	Nielson	Sundquist
Kasich	Nowak	Swift
Kastenmeier	O'Brien	Synar
Kazen	Oakar	Tallon
Kemp	Oberstar	Tauke
Kennelly	Obey	Tauzin
Kildee	Olin	Thomas (GA)
Kleczka	Ortiz	Torres
Kogovsek	Ottinger	Torricelli
Kolter	Owens	Traxler
Kostmayer	Panetta	Udall
Lantos	Patman	Valentine
Leach	Patterson	Vander Jagt
Lehman (CA)	Pease	Vandergriff
Lehman (FL)	Penny	Vento
Leland	Pepper	Volkmer
Levin	Pickle	Walgren
Levine	Porter	Watkins
Levitas	Price	Waxman
Lewis (FL)	Rahall	Weiss
Lipinski	Rangel	Wheat
Lloyd	Ratchford	Whitehurst
Long (LA)	Ray	Whitley
Long (MD)	Regula	Wilson
Lott	Reid	Wirth
Lowry (WA)	Richardson	Wise
Lujan	Rinaldo	Wolpe
Luken	Ritter	Wortley
Lundine	Rodino	Wright
Lungren	Roemer	Wyden
MacKay	Rogers	Wylie
Madigan	Rose	Yates
Markey	Rostenkowski	Yatron
Marlenee	Roth	Young (AK)
Martin (NC)	Rowland	Young (FL)
Martin (NY)	Roybal	Young (MO)
Martinez	Rudd	Zschau
Matsui	Russo	
Mavroules	Sabo	

NAYS—80

Archer	Gregg	Oxley
Badham	Gunderson	Packard
Bartlett	Hammerschmidt	Pashayan
Billrakis	Hansen (ID)	Paul
Brown (CO)	Hansen (UT)	Petri
Burton (IN)	Hartnett	Pursell
Carney	Hiler	Quillen
Chandler	Holt	Roberts
Chappie	Hopkins	Robinson
Cheney	Hunter	Schaefer
Coats	Kindness	Sensenbrenner
Conable	Lagomarsino	Shaw
Corcoran	Latta	Shumway
Craig	Lent	Shuster
Dannemeyer	Lewis (CA)	Skeen
Daub	Livingston	Smith, Denny
Dickinson	Loeffler	Snyder
Dreier	Lowery (CA)	Stangeland
Emerson	Mack	Stump
Erlenborn	Martin (IL)	Taylor
Evans (IA)	McCain	Vucanovich
Fiedler	McCandless	Walker
Fields	McEwen	Weber
Frenzel	McGrath	Whittaker
Gekas	Michel	Winn
Goodling	Morrison (WA)	Wolf
Gramm	Myers	

NOT VOTING—39

Addabbo	Hall (OH)	Ridge
Applegate	Hatcher	Roe
Bosco	Heftner	Roukema
Brooks	Hillis	Shannon
Chappell	Jones (NC)	Siljander
Clay	Jones (TN)	Simon
Crockett	Kramer	Stark
Edwards (AL)	LaFalce	Thomas (CA)
Fazio	Leath	Towns
Flippo	Marriott	Weaver
Ford (MI)	Murtha	Whitten
Franklin	Parris	Williams (MT)
Gaydos	Pritchard	Williams (OH)

□ 1910

Mr. NIELSON of Utah and Mr. SPENCE changed their votes from "nay" to "yea."

So (two-thirds having voted in favor thereof) the House agreed to consider House Resolution 569.

The results of the vote was announced as above recorded.

The SPEAKER pro tempore. The gentleman from South Carolina [Mr. DERRICK] is recognized for 1 hour.

Mr. DERRICK. Mr. Speaker, for purposes of debate only, I yield the customary 30 minutes to the gentleman from Missouri [Mr. TAYLOR], pending which I yield myself such time as I may consume.

(Mr. DERRICK asked and was given permission to revise and extend his remarks.)

Mr. DERRICK. Mr. Speaker, the rule before the House provides for the consideration of H.R. 3605, the Drug Price Competition and Patent Term Restoration Act of 1984. It is an open rule providing for 2 hours of general debate. With 1 hour to be equally divided and controlled by the chairman and ranking minority member of the Committee on Energy and Commerce and 1 hour to be equally divided and controlled by the chairman and ranking minority member of the Committee on the Judiciary.

The rule makes in order the Energy and Commerce Committee amendment in the nature of a substitute to be considered as original text for purposes of amendment. The substitute is to be read for amendment by titles instead of by sections with each title considered as read. Clause 7 of rule XVI, which requires that the subject matter of amendments be germane to the measure being amended, is waived against the substitute. The germaneness waiver is necessary because H.R. 3605, as introduced, dealt only with Food and Drug Administration approval of generic drugs, while the scope of the substitute was broadened to deal with the terms of patents for drugs as well.

The rule provides for the consideration en bloc of the Judiciary Committee amendments to each of the bill's two titles. In addition, an amendment I will be offering to add a new title III is made in order. That amendment consists of the text of title II of H.R. 5929. Clause 7 of rule XVI, germaneness, is waived against the amendment. This waiver is necessary because the subject of the amendment, label-

ing of textile and apparel goods, is beyond the scope of the underlying text. The amendment is critical to the health and vitality of the U.S. textile industry and is very similar to language included in S. 1538, as passed the Senate.

The rule further provides that any Member may demand a separate vote in the House on any amendment adopted in the Committee of the whole to the bill or to the substitute and that one motion to recommit with or without instructions is in order.

Finally, the rule provides that, after passage of H.R. 3605, it shall be in order to take S. 1538 from the Speaker's table and consider it in the House. Then it shall be in order to move to strike all after the enacting clause of the Senate bill and insert the provisions of H.R. 3605, as passed by the House. Clause 7 of rule XVI, germaneness, is waived against consideration of that motion.

Mr. Speaker, the energy and commerce amendment in the nature of a substitute contains two titles. The first deals with the process by which drug companies can obtain approval to sell drugs which have already been certified by the Food and Drug Administration and marketed by one of the pioneer drug companies, but on which the patent has expired. Currently, pharmaceutical companies which produce generic drugs must undertake a lengthy and expensive procedure in order to gain FDA approval for sale of a drug with an expired patent. These tests are currently required despite the fact that identical tests have already been conducted and the FDA has previously approved the sale of the exact same drug by the company holding the patent. This bill seeks to end this duplication of effort and, more importantly, make it easier for pharmaceutical companies to market cheaper, generic alternatives to name-brand drugs when the patents on the name-brand drugs have expired.

Title II of the energy and commerce substitute amends U.S. patent law to authorize time extensions on patents for certain drugs. Extensions of up to 5 years can be granted when the patent holder can show that, after the patent was granted, marketing of the drugs was delayed due to the FDA approval process. It is hoped that this extension of exclusive rights will encourage increased research and development efforts by pharmaceutical companies.

The amendment in the nature of a substitute also contains provisions clarifying congressional intent with regard to the definition of patent infringement in the drug industry. The provision, which has the effect of reversing a recent ruling of the Court of Appeals for the Federal Circuit, states that it is not an act of patent infringement for a drug company to test a drug prior to the expiration date of a patent if the testing is in preparation of gaining FDA approval to market the drug after the patent expires.

The Energy and Commerce Committee version of the bill would give to manufacturers of unpatentable drugs an exclusive market life of 4 years on that product. The Judiciary Committee adopted an amendment striking that provision. The Judiciary Committee also amended the energy and commerce amendment to delete any references to animal and veterinary drugs.

Mr. Speaker, this is probably one of the most significant pieces of legislation to be considered by this body. It will help millions of elderly and ill people by getting safe and less expensive generic drugs on the market in an expeditious fashion. It also helps to restore the incentive of patent protection to those drug manufacturers that spend millions upon millions of dollars in the search for new drugs.

Mr. Speaker, the rule before us is an open rule that would permit all Members to offer germane amendments to H.R. 3605. I urge my colleagues to vote in favor of the rule so that we can move to the expeditious consideration of this legislation.

□ 1920

Mr. TAYLOR. Mr. Speaker, I yield myself such time as I may consume.

(Mr. TAYLOR asked and was given permission to revise and extend his remarks.)

Mr. TAYLOR. Mr. Speaker, House Resolution 569 is an open rule under which the House will consider legislation changing the application process for generic drugs and extending the patent protection afforded developers of new drugs.

The rule, which was reported earlier today from the Committee on Rules, is an open rule and provides for 2 hours of general debate.

The rule makes in order an amendment in the nature of a substitute from the Committee on Energy and Commerce for consideration an original text for the purpose of amendment under the 5-minute rule.

Mr. Speaker, the rule provides a waiver of germaneness for the Energy and Commerce Committee amendment, because the bill as introduced dealt only with the approval process used by the Food and Drug Administration for generic drugs.

The scope of the substitute reported from committee, however, is broader than the original bill since it also deals with the term of patents for drugs.

The substitute is to be read by titles, and the rule provides for en block consideration of amendments to be offered by the Judiciary Committee.

Mr. Speaker, the rule also makes in order a specific amendment, to be offered by the gentleman from South Carolina, and provides a waiver of germaneness for that amendment.

The substance of the amendment to be offered by Mr. DERRICK deals with the labeling of textile and apparel goods, and is beyond the scope of the committee substitute. Since the committee thought the gentleman from South Carolina made a good case for the consideration of his amendment, the waiver was provided.

Mr. Speaker, the rule also provides for linkage of H.R. 3605 to the bill, S. 1538, after passage of H.R. 3605, in order to facilitate a conference with the other body.

The rule makes the consideration of S. 1538 in order, and permits a motion to strike out all after the enacting clause of that bill and to insert the provisions of H.R. 3605 as passed by the House. In addition, a waiver of germaneness is provided for that motion.

Mr. Speaker, our consideration of this legislation culminates a long, bipartisan effort to make it easier for pharmaceutical companies to market cheaper, generic drugs as alternatives to name-brand drugs when the patents on the name-brand drugs have expired.

There was no controversy about the provisions of this rule during our hearing earlier today, and I urge adoption of the rule.

Mr. Speaker, I yield 5 minutes to the gentleman from Minnesota [Mr. FRENZEL].

(Mr. FRENZEL asked and was given permission to revise and extend his remarks.)

Mr. FRENZEL. Mr. Speaker, this resolution is a very complicated one, which is one of the reasons that I ask for a vote before it be considered. As most Members know, this rule will require a two-thirds vote for passage because it is being presented to us without benefit of a report, and within an hour or so after it has been passed. I believe the last vote required a two-thirds vote, as well.

It is a little hard to track what we are talking about in this rule. We are first given a bill on which there is a committee report. We are then told that that bill is not really going to be the bill we shall actually consider. There is another bill which will be substituted for it.

Finally, there is a third bill which is wholly nongermane to the first two. Under the rule we shall take title II, of H.R. 5929, and stick it onto the bill. When we are done with that, if anybody understands what we are doing, it will be purely by accident.

Mr. Speaker, the part of the bill that baffles me is the part of the bill which will be introduced as a substitute by Mr. DERRICK. It is half of a bill, in fact. Title II of that bill provides for amendments to the Textile Fiber Products Identification Act and the Wool Products Labeling Act of 1939, neither of which has any slight degree of germaneness to the main bill.

Item No. 1: There was no showing anywhere that the main bill in question was an urgent one and had to be considered under a rule which was

passed 1 hour or 2 before under a two-thirds vote.

Rule No. 2: I do not know if we have a committee report on the Derrick substitute. I suspect we do not. I do not know if there were committee hearings on it. I just heard about it a few minutes ago. I do not know what it means. All I know is that it is not germane, and that this House has no reason whatsoever to consider it now.

I also suspect, Mr. Speaker, that after we adopt this rule and if the Derrick amendment is passed, then any sort of labeling amendment will be in order, and that means that we are likely to have leather identification amendments, perhaps footwear identification amendments, certainly tubular steel identification amendments, and perhaps a whole raft of others.

In my judgment, the packaging of these two items together is not only unwise, it is rather silly for this House. We should not be indulging in this kind of spur-of-the-moment legislation when we are looking for an adjournment the day after tomorrow.

If we would have handled this rule in the normal way, it would have laid over for a couple of days. We would have then handled the bill in the normal course of events and under the regular procedures of this House. To force the consideration of a nongermane amendment makes this body look like the other body, which does not present a very good picture to our constituents of orderly process. This rule will take two-thirds to pass. I would urge the House that it not be passed.

Mr. DERRICK. Mr. Speaker, will the gentleman yield?

Mr. FRENZEL. I yield to the gentleman.

Have I made a mistake on that?

Mr. DERRICK. The gentleman is incorrect. It took a two-thirds vote for consideration. It will take a majority vote for passage.

Mr. FRENZEL. I thank the gentleman for straightening me out. This resolution requires only a majority vote. The previous vote that I mentioned did require two-thirds, and those who opposed it and assisted me in the opposition were not successful in gaining two-thirds, which I regret greatly.

Mr. Speaker, to sum up, this is an unusual, unnecessary, unwarranted procedure. The resolution should be rejected by the House.

Mr. TAYLOR. Mr. Speaker, I yield 3 minutes to the gentleman from Ohio [Mr. KINDNESS].

Mr. KINDNESS. I thank the gentleman for yielding, no matter what they say.

Mr. Speaker, I take this time to inform my colleagues that I have filed for printing in the RECORD of today 136 amendments to H.R. 3605, the Drug Price Competition and Patent Term Restoration Act of 1984, in order to assure the opportunity for their consideration in the event the leadership calls for the bill to be considered under the 5-minute rule during the remainder of this week, which might result in my colleagues' impatience in turn calling for time limitations being imposed. We know how that works. And this is exactly the right time for that to occur.

I support the concept underlying the legislation, namely the combining of patent term restoration for new pharmaceuticals with a faster approval of generic pharmaceuticals. However, the process in which we are involved partly described by the gentleman from Minnesota [Mr. FRENZEL] just a few minutes ago is a fast process at this point. The matter has been considered in a rather peculiar way. The bill is not the bill that a lot of people thought it was. And it is combined with other elements that would otherwise be nongermane.

My concern is that the bill as presently proposed is a result, in part, of ignorance or unfamiliarity with certain parts of our laws, in particular the patent laws of our country. It has a great deal to do with our position in international trade. The bill would cost American jobs by jeopardizing exports. It would create disincentives to the development of new drugs for health minorities. It would undermine the financial viability of many universities, delay approvals of new life-saving medicines, sacrifice the American biotechnology industry and its edge in the world, make unenforceable patents on inventions used to test drugs. And the list goes on.

These are problems associated with the bill that is being brought to us in a very quick manner at a time when there is very little room for consideration of some pretty complex matters. If H.R. 3605 is considered under the 5-minute rule this week, I think we will be forced to address the multitude of issues in the bill on a piecemeal basis rather than being able to combine these concepts that are included in the 136 amendments.

□ 1930

So I would urge that the bill not be considered this week; the rule might just as well not be adopted at this point. I would urge a no vote.

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

Mr. DERRICK. Mr. Speaker, I move the previous question on the resolution.

The previous question was ordered.

The SPEAKER pro tempore. The question is on the resolution.

The question was taken, and on a division (demanded by Mr. FRENZEL) there were—yeas 87, nays 21.

Mr. FRENZEL. Mr. Speaker, I object to the vote on the ground that a quorum is not present and make the point of order that a quorum is not present.

The SPEAKER pro tempore. Evidently a quorum is not present.

The Sergeant at Arms will notify absent Members.

The vote was taken by electronic device, and there were—yeas 304, nays 74, not voting 54, as follows:

[Roll No. 360]

YEAS—304

Ackerman	Florio	Mikulski
Addabbo	Foglietta	Miller (CA)
Akaka	Foley	Miller (OH)
Albosta	Ford (TN)	Mineta
Anderson	Fowler	Minish
Andrews (NC)	Frank	Moakley
Andrews (TX)	Frost	Mollohan
Annunzio	Fuqua	Montgomery
Anthony	Gaydos	Moody
Applegate	Gejdenson	Moore
Aspin	Gephardt	Moorhead
AuCoin	Gibbons	Morrison (CT)
Barnard	Gilman	Mrazek
Barnes	Gingrich	Murphy
Bartlett	Glickman	Murtha
Bateman	Gonzalez	Myers
Bates	Gore	Natcher
Bedell	Gray	Neal
Bellenson	Green	Nelson
Bennett	Gunderson	Nichols
Berman	Hall (IN)	Nielson
Bevill	Hall (OH)	Nowak
Biaggi	Hall, Ralph	O'Brien
Billey	Hall, Sam	Oakar
Boehlert	Hamilton	Oberstar
Boggs	Hammerschmidt	Obey
Boland	Hance	Olin
Boner	Harkin	Ortiz
Bonior	Harrison	Ottinger
Bonker	Hartnett	Owens
Borski	Hayes	Oxley
Boucher	Hertel	Panetta
Boxer	Hightower	Patman
Breaux	Howard	Patterson
Britt	Hoyer	Pease
Brooks	Huckaby	Penny
Broyhill	Hughes	Pepper
Bryant	Hutto	Pickle
Burton (CA)	Hyde	Price
Byron	Jacobs	Quillen
Campbell	Jeffords	Rahall
Carney	Jenkins	Rangel
Carper	Jones (OK)	Ratchford
Carr	Kaptur	Ray
Cheney	Kasich	Regula
Clarke	Kastenmeier	Reid
Clinger	Kazen	Richardson
Coelho	Kemp	Rinaldo
Coleman (TX)	Kennelly	Ritter
Collins	Kildee	Robinson
Conte	Kleczka	Rodino
Conyers	Kogovsek	Roemer
Cooper	Kolter	Rogers
Coughlin	Kostmayer	Rose
Courter	LaFalce	Rostenkowski
Coyne	Lantos	Roth
Crane, Daniel	Leach	Rowland
Crane, Philip	Lehman (CA)	Roybal
D'Amours	Lehman (FL)	Russo
Daniel	Leland	Sabo
Darden	Levin	Savage
Davis	Levine	Scheuer
de la Garza	Levitas	Schneider
Dellums	Lewis (FL)	Schroeder
Derrick	Lipinski	Schulze
DeWine	Livingston	Schumer
Dicks	Lloyd	Sharp
Dingell	Long (LA)	Shelby
Dixon	Long (MD)	Shuster
Donnelly	Lowry (WA)	Sikorski
Dowdy	Lujan	Sisisky
Downey	Luken	Skeen
Duncan	Lundine	Slattery
Durbin	MacKay	Smith (FL)
Dwyer	Madigan	Smith (IA)
Dymally	Markey	Smith (NJ)
Dyson	Martin (IL)	Smith, Robert
Early	Martin (NC)	Snowe
Eckart	Martinez	Snyder
Edgar	Matsui	Solarz
Edwards (CA)	Mavroules	Spence
English	McCloskey	Spratt
Erdreich	McCollum	St Germain
Erlenborn	McCurdy	Staggers
Evans (IA)	McDade	Stark
Evans (IL)	McHugh	Stenholm
Fascell	McKernan	Stokes
Feighan	McKinney	Stratton
Ferraro	McNulty	Studds
Fish	Mica	Sundquist

Swift	Vander Jagt	Wise
Synar	Vandergriff	Wolf
Tallon	Vento	Wolpe
Tauke	Volkmer	Wyden
Tauzin	Walgren	Wylie
Taylor	Watkins	Yates
Thomas (GA)	Waxman	Yatron
Torres	Weiss	Young (AK)
Torricelli	Wheat	Young (FL)
Traxler	Whitley	Young (MO)
Udall	Whittaker	
Valentine	Wirth	

NAYS—74

Archer	Gregg	Packard
Badham	Hansen (ID)	Pashayan
Bereuter	Hansen (UT)	Paul
Bilirakis	Hiler	Petri
Broomfield	Hopkins	Porter
Brown (CO)	Hunter	Pursell
Burton (IN)	Johnson	Roberts
Chandler	Kindness	Rudd
Chappie	Lagomarsino	Sawyer
Coats	Latta	Schaefer
Coleman (MO)	Lent	Sensenbrenner
Conable	Lewis (CA)	Shaw
Craig	Loeffler	Shumway
Dannemeyer	Lott	Smith (NE)
Daub	Lowery (CA)	Smith, Denny
Dickinson	Lungren	Solomon
Dreier	Mack	Stangeland
Emerson	Marlenee	Stump
Fiedler	Martin (NY)	Vucanovich
Fields	McCain	Walker
Frenzel	McCandless	Weber
Gekas	McEwen	Winn
Goodling	McGrath	Wortley
Gradison	Michel	Zschau
Gramm	Molinari	

NOT VOTING—54

Alexander	Hatcher	Pritchard
Bethune	Hawkins	Ridge
Bosco	Hefner	Roe
Brown (CA)	Heftel	Roukema
Chappell	Hillis	Seiberling
Clay	Holt	Shannon
Corcoran	Horton	Siljander
Crockett	Hubbard	Simon
Daschle	Ireland	Skelton
Dorgan	Jones (NC)	Thomas (CA)
Edwards (AL)	Jones (TN)	Towns
Edwards (OK)	Kramer	Weaver
Fascio	Leath	Whitehurst
Flippo	Marriott	Whitten
Ford (MI)	Mazzoli	Williams (MT)
Franklin	Mitchell	Williams (OH)
Garcia	Morrison (WA)	Wilson
Guarini	Parris	Wright

□ 1940

Mr. SAWYER changed his vote from "yea" to "nay."

Mr. LONG of Maryland changed his vote from "nay" to "yea."

So the resolution was agreed to.

The result of the vote was announced as above recorded.

A motion to reconsider was laid on the table.

□ 1950

CORPORAT[ION FOR] PUBLIC BROADC[ASTING A]UTHORIZA-TION

Mr. WIRT[H. Mr. Speak]er, pursuant to House R[esolution 563]. I move to take from [the Speaker]'s table the Senate bill [... to a]uthorize appropriation[s for ...] activities of the Corpor[ation for Publ]ic Broadcasting, and fo[r other purp]oses, and ask for its imm[ediate conside]ration.

The Cle[rk read the] title of the Senate bill.

The SPE[AKER pro] tempore. The question is [on the moti]on offered by the gentle[man from C]olorado [Mr. WIRTH].

The motion [was agreed to].

The Clerk [read the Sen]ate bill, as follows:

*Be it enacted [by the Senate a]nd House of Representatives [of the Unite]d States of America in Co[ngress assemble]d. That section 391 of the [Communication]s Act of 1934 (47 U.S.C. 391) [...]

(1) by striking [...19]83."; and

(2) by insertir[g ... f]or fiscal year 1985, $53,000,0[00 for fiscal ye]ar 1986, and $56,000,000 for [...]" immediately after "1984."

SEC. 2. Sectio[n ... of the] Communications Act of [1934 (47 U.S.C]. 393(c)) is amended by str[iking ... se]ntence.

SEC. 3. Sectio[n ...] of the Communications [Act of 1934] (47 U.S.C. 396(k)(1)(C) is [...]

(1) by strikin[g ... amount" and] inserting in lie[u ...], 1987, 1988, and 1989, an an[...]

(2) by striki[ng ...] "fiscal year 1985."; and

(3) by insert[ing ... $...,000,0]00 for fiscal year 1987, $25[... fisc]al year 1988, and $270,000,0[00 for fiscal year] 1989" immediately before [th]e end thereof.

MOTION [OFFERED BY MR.] WIRTH

Mr. WIRT[H. Mr. Speak]er, I offer a motion.

The Clerk [read as follows]:

Mr. WIRTH [moves to strike] out all after the enacting [clause of the S]enate bill, S. 2436, and to in[sert in lieu ther]eof the provisions of H.R. [5541, as passed b]y the House.

The SPEA[KER pro te]mpore. The gentleman [from Colo]rado [Mr. WIRTH] is re[cognized for one] hour.

Mr. WIRT[H. Mr. Spea]ker, I yield myself such [time as I may] consume.

Mr. Speak[er, on ...]), the House debated and [passed H.R.] 5541, which authorizes f[unds for the] Corporation for Public [Broadcasting] for fiscal years 1987, 1[988, and 1989,] and for the facilities pro[gram for fisca]l years 1985, 1986, and 19[87. Amme]ndments designed to cu[t ...] these programs were [... an]d H.R. 5541 passed the [House over]whelmingly, under an op[en rule, by a v]ote of 302 to 91.

Immediate[ly following] passage of H.R. 5541, I [asked unan]imous consent to take up [S. 2436, whic]h was introduced by Se[nator GOLDWA]TER, and was passed by th[e Senate by v]oice vote on June 15. My [intention wa]s to move to strike all aft[er the enactin]g clause and insert the te[xt of H.R. 554]1. The funding levels i[n S. 2436 are] identical to those in H.[R. 5541, and g]iven Senator GOLDWATER'[s ... leade]rship on this public broa[dcasting, I] believe it is appropriate [that the leg]islation bear the number [of the Senato]r's bill.

However, [an objection] was registered to t[his ... pr]ocedural request, and t[he ... overw]helming will of the Hou[se was frustr]ated due to this tactic t[o ... fin]al consideration of th[e bill. Mr. S]peaker, the House has d[... H.R. 55]41 under an open rule [and overwhelmingly] passed that [... S]. 2436 contains provisi[ons identical t]o H.R. 5541. It is very u[nfortunate, a wa]ste of this body's time [and ...] to pass this bill again, [...] that was [...] House's will [...]

I wish to [...] more that [...] this legisla[tion ...] margin of [...] doing toda[y ...] number fo[r ...] colleagues [...] lation whi[...] future of o[...] sources, pu[...]

[...pro]cedural effort [to fr]ustrate the [...]cessary. [...co]lleagues once [...alre]ady adopted [...ex]tremely wide [...]d all we are [...]g the Senate [...]on. I ask my [...supp]ort this legis[lation ...impo]rtant to the [...] t national re[...]ng.

Mr. SPE[AKER ...]no further requests for [... y]ield back the balance of [my time].

The SPE[AKER pro te]mpore. Pursuant to Ho[use Resolution] 563, the previous ques[tion is conside]red as ordered on the mo[tion].

The que[stion is on th]e motion offered by t[he gentleman f]rom Colorado [Mr. WIRT[H].

The mot[ion was agreed] to.

The Se[nate bill was] ordered to be read a th[ird time, was] read the third time, and [passed].

The titl[e was amended] so as to read: "An Act [to amend th]e Communications Act [of 1934 to exte]nd certain authorizatio[ns of appro]priations contained in [... and] for other purposes."

A moti[on to reconsid]er was laid on the table.

DRUG PRICE COMPETITION AND PATENT TERM RESTORATION ACT OF 1984

The SPEAKER pro tempore. Pursuant to House Resolution 569 and rule XXIII, the Chair declares the House in the Committee of the Whole House on the State of the Union for the consideration of the bill, H.R. 3605.

IN THE COMMITTEE OF THE WHOLE

Accordingly the House resolved itself into the Committee of the Whole House on the State of the Union for the consideration of the bill (H.R. 3605) to amend the Federal Food, Drug, and Cosmetic Act to authorize an abbreviated new drug application under section 505 of that act for generic new drugs equivalent to approved new drugs, with Mr. DANIEL in the chair.

The Clerk read the title of the bill.

The CHAIRMAN. Pursuant to the rule, the first reading of the bill is dispensed with.

Under the rule, the gentleman from California [Mr. WAXMAN] will be recognized for 30 minutes; the gentleman from Illinois [Mr. MADIGAN] will be recognized for 30 minutes; the gentleman from Wisconsin [Mr. KASTENMEIER] will be recognized for 30 minutes; and the gentleman from California [Mr. MOORHEAD] will be recognized for 30 minutes.

The Chair recognizes the gentleman from California [Mr. WAXMAN].

Mr. WAXMAN. Mr. Chairman, I yield myself such time as I may consume.

(Mr. WAXMAN asked and was given permission to revise and extend his remarks.)

Mr. WAXMAN. Mr. Chairman, H.R. 3605, the Drug Price Competition and Patent Term Restoration Act, is the most important drug legislation to come before the Congress since the 1962 changes in the drug laws. It is also the most important consumer legislation to be considered this Congress.

The bill will save consumers over $1 billion by making more low cost generic drugs available. The legislation will also provide the incentives necessary for this country to maintain its worldwide leadership in pharmaceutical research by restoring patent time lost due to Government review.

Let me briefly explain the bill. Title I of H.R. 3605 extends the Food and Drug Administration's [FDA] generic drug approval procedures used for brand name drugs approved before 1962 to those approved after 1962. For pre-1962, the FDA does not require complete retesting of generic copies. Instead, the generic drugmaker must show that his drug is the same as the pioneer drug which was previously determined to be safe and effective. Unfortunately, these abbreviated generic drug approval procedures do not apply to pioneer drugs approved after 1962. The lack of such procedures is an effective bar to generic competition because the generic companies cannot afford the millions of dollars to duplicate the test results already in the FDA's files.

There are 150 post-1962 drugs which are off patent including best sellers such as valium, motrin, dyazide, and inderal. By making these drugs available as generics, H.R. 3605 will reduce the cost of drugs for all consumers. Approximately 84 percent of our citizens pay their drug bill without any form of government assistance. Consequently, the FDA estimates the cost savings of this bill to be $1 billion. Older Americans, in particular, will benefit from the legislation because they are the largest consumers of medicines, using almost 25 percent of all prescription drugs.

Federal and State governments will also save millions of dollars. For example, the Department of Defense saved $1.2 million in 1 year on one dosage form of a drug as a result of the availability of a generic alternative.

Title II of the bill would extend the patents for drugs and other substances subject to premarket approval for up to 5 years. Because a patent continues to toll when a manufacturer is testing and awaiting Government approval, the amount of patent time remaining after approval is less than the normal 17 years. For example, representatives of the drug industry have testified that the average patent time left after approval is between 8 and 10 years. Research-intensive firms predict that declining patent term will result in the development of fewer innovative products.

The bill restores patent time lost due to Government review. Consequently, the legislation will create a significant incentive for the development of new products. In the case of drugs, this could mean new cures for untreatable diseases and less expensive treatments for controllable diseases.

This bill represents a compromise among divergent and sharply differing interests. Previously, extended approval of generic drugs has been opposed by the brand name drug companies and supported by consumer, senior citizen, and labor groups as well as the generic drug industry. Conversely, patent extension was supported by the brand name drug industry and opposed by consumer, labor, and senior citizen groups as well as the generic drug companies.

After almost a year of data analysis and negotiations, we were able to fashion a compromise bill. This legislation has been endorsed by the FDA, the Pharmaceutical Manufacturers Association representing the brand name drug companies, the generic drug industry, the American Association of Retired People, the National Council of Senior Citizens, Consumer Federation of America, AFL-CIO, AFSCME, UAW, and SEIU.

Mr. Chairman, this bill fairly and carefully balances the public's need for low cost generic drugs and private industry's need for sufficient patent life to encourage the development of innovative products such as drugs. I urge the passage of the bill without amendment.

Mr. MADIGAN. Mr. Chairman, I yield myself such time as I may consume.

(Mr. MADIGAN asked and was given permission to revise and extend his remarks.)

Mr. MADIGAN. Mr. Chairman, I rise in support of H.R. 3605, which initiates an expedited, abbreviated application process for generic drugs and extends the patent protection afforded the pioneer developers of new medications. This legislation culminates a long bipartisan effort to combine and balance these two objectives and promote innovative changes to the Federal Food, Drug and Cosmetic Act. Both the Energy and Commerce and the Judiciary Committees have now provided ample time for discussion, testimony and rebuttal by groups favoring the legislation and by those who seek to change it.

On the average, it takes $85 million and over 10 years to bring a new drug to the marketplace. This tremendous investment of time and dollars by the pharmaceutical industry must be protected. The majority of time expended in meeting the regulations set forth by the FDA involves the careful testing of drugs for use in humans. After this period of clinical testing, additional administrative review further delays the period before the drug comes to the marketplace. As I previously noted, the combined time lost in meeting the FDA procedures averages approximately 10 years. These are years of lost profitability to the pioneer developer. This detracts from the resources and ability of drug companies to bring new products to the marketplace. Continued research and development by the drug industry is vital to maintain our preeminent position in medical therapeutics. It is, therefore, important to ensure that these companies be provided ample patent protection to recoup their investment.

Under the provisions of this legislation, patent protection can be extended up to 5 years as long as the extension, when added to the patent time remaining, does not exceed 14 years.

We must provide this extension to guarantee the continued commitment of resources for the development of innovative drugs to address the changing health needs of our citizens.

At the same time, I am concerned with the containment of health care costs. H.R. 3605 will allow the marketing of generic counterparts which are identical to post-1962 pioneer drugs, following the expiration of the original patent term. The contribution of medications to the overall cost of health care can be reduced drastically if these generic equivalents are brought to the marketplace in a timely fashion. It is estimated that $1 billion can be saved over a 12-year period by the increased use of generic equivalents.

This proposal is a balanced, bipartisan effort that has benefits for all—for the patients who require medication, for that part of the pharmaceutical industry that researches and develops new drugs, for that part of the industry that produces the generic equivalents of the pioneer drugs, and for the Federal agency that is charged with the protection of the public in the proper use of safe and effective drug products.

I support this important balanced approach to the marketing of drugs in this country, and I urge your support for the bill.

Mr. WAXMAN. Mr. Chairman, I yield 5 minutes to the gentleman from Oklahoma [Mr. SYNAR].

Mr. Chairman, I want to point out the very significant role the gentleman from Oklahoma has played in this legislation as the author of the Drug Price Competition and Patent Term Restoration Act, which has been folded into this compromise.

Mr. MADIGAN. Mr. Chairman, will the gentleman yield?

Mr. WAXMAN. I would be pleased to yield to my colleague, but I wanted to yield time first to the gentleman from Oklahoma, who in his absence, I praise as a very important participant in this compromise, as the author of the Drug Price Competition and Patent Term Restoration Act. The gentleman has played a most construc-

tive role in fashioning the compromise and he is to be commended for his statesmanship that he has offered, and since the gentleman is returning to the floor at this time, I yield the gentleman five minutes.

(Mr. SYNAR asked and was given permission to revise and extend his remarks.)

Mr. SYNAR. Mr. Chairman, I thank the gentleman from California.

Let me join in my praise not only for the gentleman from California, but the gentleman from Illinois, for their outstanding efforts. This bill comes after a long and hard and arduous compromise proposal that we have negotiated over the last 18 months.

Mr. Chairman, we have a unique opportunity here tonight and in the next couple days to pass one of the best consumer bills this Congress will consider, not only in this Congress, but all future Congresses.

□ 2000

We are going to accomplish two purposes by passing this bill. First of all, we are going to provide new and better incentives for drug companies to go out and find better drugs; and, second, we are going to provide cheaper drugs by better competition in the marketplace that will benefit not only our elderly but all of those people who buy medicine.

We have a unique opportunity today to bring together all of those groups that are concerned about medical costs in this country and about better medicine. That is why this bill is being supported across the board by business, consumers, elderly, and medical groups throughout this country.

I ask you to consider it closely, to review the merits of the bill. But most importantly, remember that this is a compromise bill between all of those various groups that have concerns about better medicine in this country and providing better incentives and cheaper drugs for the future.

Yes, we do have an opportunity tonight to do something which we rarely get to do, which is to provide for a bill that will give us better drugs and cheaper drugs for the future. I endorse this bill enthusiastically and I ask my colleagues to do so.

Mr. Chairman, I rise in strong support of the Drug Price Competition and Patent Term Restoration Act. This bill accomplishes two important goals:

It provides incentives for research on new drugs by restoring a portion of the patent life that is lost during the FDA approval process; and

It increases price competition in the drug marketplace by simplifying the approval process for generic drugs

Together, these two will bring about cheaper drugs today and better drugs tomorrow.

I introduced the Patent Term Restoration Act over a year ago with 100 cosponsors—today there are 151.

My colleagues and I were concerned about the integrity of our patent system, and the adverse effect of increasingly lengthy FDA approval on drug research in this country:

Drug research as a percentage of sales is declining.

The cost of developing a new drug averages $87 million

The average effective patent life of a pioneer drug is reduced by 7 years because of FDA review.

The bill before us today would return fairness to the patent process by restoring a protion of a drug's 17-year patent term that has been consumed during the Government-mandated testing and approval process.

The restoration would be limited to 5 years and in no case could give a drug product more than 14 years of market exclusivity.

The other title of this bill improves price competition in the drug marketplace. It establishes an expedited approval process for generic drugs that are identical to a pioneer drug which has already been approved.

Currently, the FDA requires the same lengthy testing and application procedure for generics that it requires for entirely new drugs.

The effect has been to limit drug competition by keeping generics off the market. This bill will result in the immediate availability of 150 off-patent drugs at a cost of one-tenth to one-half of existing prices.

Consumers will save nearly $1 billion over the next 12 years. And it's important to remember that senior citizens are the primary consumers of health care.

This bill is an important compromise that improves research and development and increases price competition in the drug marketplace.

As sponsor of the Patent Term Restoration Act, and as a consponsor of this legislation, I encourage my colleagues to support this landmark legislation.

Mr. WAXMAN. Mr. Chairman, at this time I yield myself so much additional time as I may consume.

This bill represents a compromise among divergent and sharply differing interests. Previously, extended approval of generic drugs has been opposed by the brand name drug companies and supported by consumer, senior citizens, and labor groups as well as the generic drug industry.

Conversely, patent extension was supported by the brand name drug industry and opposed by consumer, labor, and senior citizen groups as well as the generic drug companies.

After the work on this legislation and the work on this compromise bill, the legislation has now been endorsed by the FDA, the Pharmaceutical Manufacturers Association representing the brand name drug companies, the generic drug industry, the American Association of Retired People, the National Council of Senior Citizens the Consumer Federation of America, the AFL-CIO, AFSCME, the UAW, the USW, and SEIU.

Mr. Chairman, this compromise represents broad bipartisan support. It would not have been possible to fashion this compromise without the work of the gentleman from Oklahoma [Mr. SYNAR] the gentleman from Illinois [Mr. MADIGAN] and our Committee on Energy and Commerce, and particularly I want to pay tribute to the gentleman from Wisconsin [Mr. KASTENMEIER] who has been involved in this legislation for two Congresses. His contribution has been enormous and without it we would not have had the legislation that is before us.

I want also to pay a special tribute to the gentleman from Tennessee [Mr. GORE] and the gentleman from Massachusetts [Mr. FRANK] for their role as well in fashioning the legislation.

I have no further requests for time from our side and I would therefore yield back the balance of our time.

Mr. CHAIRMAN. Does the gentleman from Illinois [Mr. MADIGAN] desire additional time?

Mr. MADIGAN. Mr. Chairman, I have yielded back the balance of my time.

The CHAIRMAN. The gentleman from Wisconsin [Mr. KASTENMEIER] is recognized for 30 minutes.

Mr. KASTENMEIER. Mr. Chairman, I yield myself so much time as I may consume.

(Mr. KASTENMEIER asked and was given permission to revise and extend his remarks.)

Mr. KASTENMEIER. Mr. Chairman, I rise in strong support of H.R. 3605, the Drug Price Competition and Patent Term Restoration Act of 1984. This carefully crafted compromise is both proconsumer and proresearch. I hope in the next few minutes to outline to my colleagues both how important this legislation is and how we got here.

American intellectual property law in general, and patent law in particular, is designed to reward innovation. The founders of our Nation recognized the importance of promoting the use of arts and sciences by providing Congress with a specific grant of authority in this area. Pursuant to that grant of authority, the Congress has enacted a series of patent and copyright laws. Since 1861 our patent laws have provided that in return for the public disclosure of a useful invention that an inventor may obtain a period of 17 years to exclude others from practicing that invention.

As many Americans have recognized in recent years, it is our intelligence and inventiveness which sets us apart from many of our trading partners and foreign competitors. An important element of fostering that spirit of inventiveness is a strong patent system. One ingredient to such a system is that inventors have a reasonable assurance that their inventions will be in the commercial marketplace for a long enough period of time for them to recoup their investment in research. It

is this issue of effective patent life which originally motivated this legislation.

During the late 1970's, many research-based pharmaceutical firms began to complain that the effective market life of their patented inventions was being eroded by excessively long periods of regulatory review—and delay—at the Food and Drug Administration. They argued that unlike other patented inventions, they had to obtain premarketing clearance or approval from a Federal regulatory agency, the FDA. They claimed that the approval process reduced the effective patent life of drugs by about 7 years. This view was affirmed by two high-level, bipartisan panels, the National Productivity Advisory Committee and the President's Commission on Industrial Competitiveness.

In response to the problems of the research-based pharmaceutical houses, legislation was offered to restore patent life lost through regulatory review. Before acting on this legislation, last Congress the Committee on the Judiciary commissioned a study by the Office of Technology Assessment [OTA]. The OTA study, "Patent Term Extension and the Pharmaceutical Industry," found that since 1966 the average effective patent terms of drugs had declined. The study also found that the research and development costs for new chemical entities have increased at the same time.

The OTA findings standing along might have convinced some about the need for legislation on the patent side. However, the OTA study went on to point out that the current policies of the FDA served to offer additional protection to FDA-approved drugs even after they go off patent. This is so, because the FDA has erected a set of substantial barriers to the market entry of generic substitutes. The OTA also raised several cautions about any patent term legislation. They pointed out that expenditures for research and development appeared to be stable, despite reduced effective patent life. Second, they predicted that drug prices were likely to be higher during a period of patent extension. Third, they feared that patent term extension may merely increase the attractiveness of research on drugs to be sold to large markets at the expense of research on rare diseases or orphan drugs.[1] Finally, the OTA noted that reforms were underway at FDA to reduce the period of regulatory delay.

Last Congress, when faced with the task of implementing the recommendations of the OTA study, the Senate chose to enact patent term legislation alone, but the House balked. The failure of patent term legislation last Congress was primarily the result of our failure to view the regulatory and patent problems of the drug industry as a whole, as recommended by OTA.

This Congress, through the mediation/arbitration efforts of Congressman WAXMAN and others, a carefully crafted compromise has been developed. This compromise totally satisfies no one, but pleases most responsible parties. As you will hear from others today, this bill is the single most important set of patent law amendments in decades and the most fundamental alternative to the Food, Drug and Cosmetic Act since 1962. This bill is also both the most important consumer bill and medical cost containment measure before us this Congress.

SUMMARY OF THE BILL

H.R. 3605 contains two titles. The first title of the bill creates a new system for the approval of generic drugs by the Food and Drug Administration. This approval process for drugs approved by the FDA after 1962 has been severely criticized as too cumbersome and expensive. In essence the provisions of title I of H.R. 3605 extend the procedures for approval of generics for pre-1962 drugs to the later class of drugs.

Thus, under H.R. 3605 a generic manufacturer may submit to FDA a request for approval of a generic substitute for any post-1962 drug. The generic manufacturer must establish that the proposed substitute is the same or therapeutically equivalent to the drug which has already been approved.

Under the approval process in H.R. 3605, a generic manufacturer may submit an application for approval to FDA before the so-called pioneer drug goes off patent. The generic may submit data establishing bioequivalency during this time period. In order to complete this application the generic manufacturer must conduct certain drug tests. In order to facilitate this type of testing, section 202 of the bill creates general exception to the rules of patent infringement. Thus, a generic manufacturer may obtain a supply of a patented drug product during the life of the patent and conduct tests using that product if the purpose of those tests is to submit an application to FDA for approval.

H.R. 3605 permits generic applications to be effective after a patent expires. In addition, H.R. 3605 provides that a generic manufacturer may request FDA approval to begin marketing before the patent on the drug has expired. Under current law, this situation is not an issue because of the cumbersome approval process. If the generic manufacturer seeks such an approval it must allege that the existing patent is invalid or will not be infringed. In this instance notification must be given by the generic to the patent holder concerning the application for FDA approval. In these cases the FDA may not approve the generic application until either: One, 18 months have expired or two, a court has determined that no infringement will take place. After the expiration of 18 months, if there has been no intervening judicial determination, the FDA will approve the generic application, even if the drug is still on patent.

Finally, title I also provides for a 4-year grant of market exclusivity to be granted by the Commissioner of the FDA for unpatentable substances which have been approved for use as drugs by the FDA.

TITLE II

This title of the bill addresses the question of patent term extension. As noted above, proponents of this type of legislation have argued that the reduction of the effective market life of a patent because of Federal regulatory review should be restored through an extension of the patent term. Alternatively, or additionally, some proponents of this approach have argued that without some form of legislative relief in this area there would be a diminished stimulus in innovation and research. Thus, it is argued that patent term extensions will create incentives for increased research expenditures.

The patent term extension provisions of the bill are relatively complex, and differ in many respects from the bill approved by the Committee on the Judiciary last Congress. In general, the bill provides that a patent may be extended for a period of up to 5 years if the patented drug—or other item subject to regulatory review by the FDA—has undergone regulatory review. The bill provides several general rules for calculating the period of the extension. First, only one-half of the testing phase may be counted. Second, a year-for-year matching extension is available for any time in the drug approval process that the drug spends awaiting a decision by the FDA. The 5-year rule is available to all drugs which have not yet undergone testing by the FDA. With respect to drugs which have been patented and tested but not yet approved by the FDA, the maximum period of extension is 2 years.

In addition to the 5-year rule listed above, the bill places an additional cap on the possible extension. In no case may the period of patent extension, when added to the patent life left after approval of the product, exceed 14 years. Finally, any part or all of the patent extension may be canceled if the applicant for an extension failed to act with due diligence in conducting tests or in the submission of data to the FDA.

As noted above, the other feature of the drug patent part of the bill is to statutorily modify the rules with respect to patent infringement.

OPPOSITION TO THE BILL

In closing let me take note of some of the opposition to this bill. It should not come as any great surprise that some pharmaceutical houses are opposed to this legislation. In fact, if we were voting on the ANDA provisions of title I of this bill alone, probably all of the drug companies would be op-

[1] I note parenthetically this problem has been treated, in part, by the passage of the Orphan Drug Act last Congress.

posed. The enactment of this bill will open up to generic competition, within the next few years, billions of dollars of off-patent drugs. The dissident drug companies know full well that if they do not stymie enactment of this bill they will face stiff competition on their leading drugs. For example, within the next year the patents will expire on three of the top selling drugs: One, inderal—used for cardiovascular purposes; two, Aldomet—also used for cardiovascular purposes; and three, valium—an antistress drug. It is not a coincidence that the companies that hold these soon-to-expire patents are leading the opposition to this bill.

The amendments—in the patent area—that you will be asked to vote on have all been considered and rejected by the Judiciary Committee. For the most part these amendments have one common purpose: to provide for longer patent term extensions. Some of the amendments will be disguised as technical amendments, others as clarifying in nature; yet in fact, they all go to the heart of the compromise and should be rejected.

CONCLUSIONS

When the negotiations on this subject began over a year ago, there were two goals: a fair and workable system for the approval of generic drugs at the FDA; and a sensible patent term restoration to compensate for regulatory delay. In my view these goals have been achieved. The ANDA approval process will mandate the FDA to remove the unnecessary barriers to competition. The provisions of title I of the bill will also assure that generic substitutes are just as safe and effective as the pioneer drugs. The patent term restoration provisions are less generous than what the industry requested, but are a fair accommodation.

I urge my colleagues to support this bill.

Mr. GORE. Mr. Chairman, will the gentleman yield?

Mr. KASTENMEIER. I am pleased to yield to the gentleman from Tennessee.

Mr. GORE. I did not take time earlier, but I appreciate my colleague yielding for me to just say a few brief words in strong support of this legislation. I was one of those who found myself on the other side of the debate last year. Without reopening that issue at all, which would be most inappropriate, I felt that that version was overly balanced toward the large pharmaceutical companies and did not have enough in the bill for consumers.

□ 2010

I think this bill is very balanced. It is still generous toward the large companies and will assist those companies in being successful against the increasingly stiff competition from companies in foreign countries.

At the same time, however, this bill will provide more new competition in drug pricing in the form of competition from the newly approved generic drugs which will be able to come onto the market much faster after the patent period has expired, so that overall, this bill is good both for the industry and for the consumers.

That is why all the major consumer groups are for it, the senior citizen groups are for it, and the Pharmaceutical Manufacturers Association is for it.

Rarely do we have a chance in this body to vote on a piece of legislation that is as well crafted as this bill is, and which has been worked on as long as this bill has been worked on.

I want to express my strong support for it and ask my colleagues to vote for it in overwhelming numbers.

I appreciate my colleague's courtesy in yielding.

Mr. KASTENMEIER. Mr. Chairman, I say in response to the gentleman from Tennessee, the bill 2 years ago did not have the ability, because of the germaneness rule, to consider the generic aspects that this bill has which gives it the balance that the gentleman says is present, and I agree with that assessment.

On the other hand in some respects this bill is more generous to pharmaceutical manufacturers; the other bill was entirely prospective. They could not have had an extension to the year 2000. It addressed no drugs currently under application or under test in the pipeline.

This bill does. I do not think that is unfair, but I will say that it is something that the pharmaceutical manufacturers certainly wanted and they got in this bill that they did not get in the bill 2 years ago.

Mr. GORE. If the gentleman would yield further, I am so delighted and thrilled that we are on the same side this year that I am not even going to pursue that debate. I am just happy that we are together on this bill, it is in the best interests of the American people, industry and consumers alike.

Mr. KASTENMEIER. I thank my colleague from Tennessee for his participation of 2 years ago, even though we were in continuing opposition for his continuing support.

Actually being from Tennessee, he serves in a long tradition not only of his father but the other Senator from Tennessee no longer on the scene who was so well-known nationally.

Mr. GORE. Indeed, this bill can be compared in its significance with the 1962 Kefauver amendments which was the landmark in the laws governing pharmaceuticals in this country.

This bill is comparable in significance to that bill. Again, I thank my colleague for yielding and urging support for the bill.

Mr. KASTENMEIER. Mr. Chairman, I reserve the balance of my time.

The CHAIRMAN. The gentleman reserves the balance of his time. The gentleman has consumed 11 minutes.

The gentleman from California [Mr. MOORHEAD] is recognized for 30 minutes.

Mr. MOORHEAD. Mr. Chairman, I yield 1 minute tothe gentleman from Illinois [Mr. HYDE].

(Mr. HYDE asked and was given permission to revise and extend his remarks.)

Mr. HYDE. I thank my friend for yielding time to me.

Mr. Chairman, our colleague [Mr. FISH] joins me in the remarks that follow:

I rise in support of H.R. 3605. This legislation is designed to correct a current inequity in the patent law. Present patent law provides an inventor 17 years of exclusivity. However, for certain products such as chemicals and medications, the 17-year patent term has been unintentionally eroded by Federal premarket testing and regulations.

When Congress settled on 17 years of patent life on March 2, 1861, it never took into account today's massive Federal bureaucracy. Granted these tests are important and can't be rushed. But we can't ignore the fact that inventors in this industry do not get anywhere close to 17 years of exclusive use of their inventions.

As the patent life has eroded over the last decade, the cost of developing new medication has skyrocketed. However, out of every $1 spent on health care in the United States, only about 8 cents is paid for medicines.

Drug prices have been one component of health-care costs that has remained relatively stable over the last 20 years. While the Consumer Price Index has risen 178 percent and health-care costs have increased 629 percent, the cost of prescription drugs has increased only 34 percent over that 20-year period. The beneficial effects that new medicines have on medical costs can be graphically illustrated. Tagamet, the new ulcer drug, could save some $250 million a year in forgone surgery and physician visits if the drug were used by all who could benefit from it. The average hospitalization cost for a case of pneumococcal pneumonia in an elderly person is approximately $3,300. The vaccine to prevent this disease costs only about $100. The vaccine for rubella has produced savings in health-care costs and lost working time 47 times that of the price of the vaccine. Additionally, sodium valproate, a new medicine to treat epilepsy, has been estimated to save $612 million yearly.

Shorter patent life translates into falling rates of return, which translates into falling investment in research and development, which translates into fewer and fewer new medicines coming on the market.

This phenomenon, coupled with the inability of many new products to recover their investment, discourages innovation. For example, from 1955 through 1962, an average of 46 drugs were introduced annually in the United States; today, undoubtedly for a variety of reasons, that average is

only 17 drugs a year, a decline of 63 percent.

Gradually, the time needed to complete and clear the regulatory review process has grown longer, as products and tests have become more sophisticated and the regulatory resource of agencies like the FDA have become stretched to their limit. In 1962, for example, it took approximately 2 years and $6 million to bring a new medicine from the laboratory to the marketplace. It now takes an average 7 to 10 years and about $70-$85 million to complete this testing period. Thus, it is not uncommon for a drug product to have lost up to one-half of its patent life without having yet been marketed.

This reduction in the number of drug innovations strongly indicates that the public is being deprived of new therapies. The decline in pharmaceutical patent lives, the result of inadvertence rather than congressional intent, will erode the investment research incentive provided by the tradional 17-year patent term.

This is important legislation, it is important to the consumer, especially the elderly and it is important to industry and I urge colleagues to vote favorably for its passage.

At the proper time, Mr. MOORHEAD will offer an amendment which he offered in subcommittee and lost and a modified version of which was offered at the full Judiciary Committee by Mr. HUGHES and supported by our chairman Mr. RODINO. I urge you to support that amendment.

Mr. Chairman, I yield back the balance of my time.

Mr. MOORHEAD. Mr. Chairman, I yield 2 minutes to the gentleman from Ohio [Mr. DEWINE].

(Mr. DEWINE asked and was given permission to revise and extend his remarks.)

Mr. DEWINE. Mr. Chairman, basically, there are many good things in this bill, but I regret there are several things that some of us on this side of the aisle are having problems, with, and we hoped they would be able to be rectified in the committee, but they were not.

I would like to talk briefly about one particular aspect of this bill which is the overturning of the Bolar case.

It has been long accepted patent law, at least it is my understanding, not being a patent lawyer, but it is my understanding that for years in this country, it has been considered a patent infringement for a company to test or market or use a particular item. This particular bill would overturn the Bolar decision.

In that case, the U.S. Court of Appeals for the Federal Circuit held, consistent with prior law, that a generic drug company may not formulate and test its version of another company's patented drug until the patent term expires.

The Bolar decision is sound law and in my opinion should be retained. However, this particular bill would overrule Bolar and thereby permit a generic company to engage in acts which heretofore would have constituted patent infringement.

I understand the committee has received a legal advice that this is constitutional. I am not sure it is constitutional, to be taking property rights away from people and away from companies. But whether or not it is constitutional, it seems to me it is bad public policy and should be rejected by this Congress.

Mr. MOORHEAD. Mr. Chairman, I yield myself such time as I may consume.

Mr. Chairman, I rise in support of H.R. 3605, the Drug Price Competition and Patent Term Restoration Act of 1984.

When most people hear the words patent law reform, they do not consider those words as having a life-or-death ring. But what about words like penicillin or polio, pneumonia, smallpox and measles vaccines—do they have more of a life-or-death ring? The present impact of patent law on the drug industry is inhibiting those very kinds of discoveries.

Our patent system is crucial to the drug and the agricultural chemical industries. Ironically, these industries, while especially needing the patent system, do not receive its full benefit. It's very costly, very time consuming, and very risky to develop a new medicine. Currently, to bring a medicine to market takes about 10 years, costs $70 million and has a failure rate of 90 percent. The promise of 17 years of patent protection kept things rolling until, in 1962, the thalidomide tragedy convinced everybody that new medicines needed more rigorous testing. This, in turn, meant more time elapsed before drugs could be brought to the market.

Therefore, the length of time between patenting a medicine and getting FDA approval gradually ballooned from about 1 year pre-1962 to nearly 10 years now. In other words, a life-saving medicine making its debut today will have less than 7 years of patent life, whereas a toy or new medicine will receive the full 17 years of protection. This, in my opinion, is not fair.

I believe this legislation will mean more and better medications, resulting in better and earlier treatment. This point was well made by a Chicago Tribune editorial (May 1, 1982) which said:

> Some objections have been raised to the proposed legislation because it would lengthen the time until a drug could be copied by the developer's competitors and marketed as a generic product, presumably at a lower price. But in the long run, we all stand to benefit much more from the discovery and availability of new medications. It is far less expensive to treat patients with drugs than with surgery or long hospitalization, which may be the only alternatives. And one of the most effective ways to cut health care costs is to develop new medications. Enormous savings, for example, could be made if we had more effective drugs for heart disease, cancer, genetic disorders, respiratory diseases, and a long list of other ailments for which better treatment is urgently needed.

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Mr. Chairman, I strongly support this bill, but I believe there are some inequities that are still left in the bill that should be corrected.

The Patent Office has requested me to offer two amendments which would correct some of the problems in the bill. The procedures are too complicated in this legislation and can be rather simply corrected, taking care of the needs that are legitimate to the legislation but cutting down the long procedural delays.

Another problem with the bill, is that it unfairly treats so-called, second-class patents, which are patents that are developed from a former patent. Many people have said it would prevent these drugs from becoming generic and coming on the market as rapidly as they should. But I would tell you that the original patented product can be put on the market as a generic. It would be only the old product patent, the one that is approved, that could get an extension under H.R. 3605. For that reason, I do not think we should have a second class patent.

There are other problems which will be addressed in amendments that are presented tomorrow. But obviously, one of the problems that we have in the bill is that it compromises the rights of present patent holders by permitting their adverse use of that particular product by potential competitors prior to the time that the patent expires.

I have an amendment that would take care of some of the problems suggested by the gentleman from Ohio [Mr. DEWINE] by requiring that when a person applies for an extension of patent rights that he give up the right to exclusive use of that patent for experimental purposes during the last year of his extended patent rights. This would give the generics a right to work on that product and get a product ready for the market. But his rights in that patent would be given up by him in order to get the extension, and for that reason we would not be taking property rights from any American.

While I would appreciate an aye vote on these amendments when they are offered, I do believe the bill is a step forward, it is an improvement in the present law, and I would ask for an aye vote on the bill.

Mr. Chairman, I yield 5 minutes to the gentleman from Minnesota [Mr. FRENZEL].

(Mr. FRENZEL asked and was given permission to revise and extend his remarks.)

Mr. FRENZEL. Mr. Chairman, in the discussion on the rule, I missed the

objection to the procedure, first of all, of bringing a rule to this floor within an hour or so after it was passed, without the customary layover, which is contrary to our procedures unless there is a showing of great urgency. In this case, I am not aware of any showing of urgency having been made either before the committee, before the committees of jurisdiction or before this Committee of the Whole.

In the second place, the rule provided that the bill which is presented to the Committee of the Whole be amended by a substitute amendment and that there further be allowed a nongermane amendment to be offered by the gentleman from South Carolina [Mr. DERRICK].

I object to the nongermane amendment being a part of our process. I believe that one of the very few distinctions this House has is orderly process. We compare it with the nongermane procedure arrangements which obtain in the other body, and we have always been proud of our procedures. Now, occasionally some of our Members get urges for speed, urges of greed or other urges, and they are able to piggyback one idea which has nothing to do with the main bill onto another. That is obviously bad procedure. Every observer of our system understands that. Naturally, all of us would make the same observation, of course, unless it was our bill which was the hitchhiker in the case.

The hitchhiker itself is a highly controversial bill. It has not been heard in any committee report following this bill. There is no testimony on it. There has been no showing whatsoever that there is a need for it or that, in fact, it will do any good for whatever the authors intend for it.

On the other hand, there is some clear evidence that it is mischievous to importers of textile goods and woolen goods.

Mr. Chairman, I believe that the worst of the mischievous items in there lies in the effective date and the requirement of labeling within mail order catalogs. If you are a catalog retailer selling goods to the public, you are required under this bill within 90 days to have all of your catalogs showing what goods are U.S.-made and what goods are imported, and if you do not, those goods are prima facie misbranded and subject to the penalties of this wonderful law of 1939 that none of us know anything about. I could not even tell you what the penalties are. But I suspect that they could be substantial if they are multiplied. Therefore, one of the amendments which I will offer later on is to change that effective date to a reasonable time so that somebody placing forward orders, either for printing or for goods that are to be sold to the public, will have a reasonable chance of making good on what has been rational planning on the part of that particular retail agent.

I think it is just manifestly unfair to suddenly attack a pile of goods and say:

This was not misbranded yesterday, but today it is. Never mind if you ordered it 6 months ago, never mind if you printed your catalog 6 months ago, too bad, you are out of it.

Well, how about if you are Sears Roebuck and you print a couple million catalogs and they are that thick, do you mean you have to throw out your spring catalog? That is what that effective date says to that kind of a company. The same thing is true, to a lesser extent, and is probably more harmful, to small importers of textile goods, who will suddenly find the goods that they have received which they have ordered 6 months ago are illegal, misbranded in the United States. This is obviously an unfair, unreasonable kind of a law. I have yet to understand what is good about it. I suspect that it will encourage consumers to go for imported goods over U.S. goods, and I suspect that that is counter to the motivations of the proponents of the bill.

I shall hope that this bill is defeated. With the luck I had on the rule today, I harbor no great enthusiasm or any great expectation that it will be defeated. It should be defeated, and I shall offer as many amendments as are necessary so that the House has a fine chance to discuss all of the aspects of the bill.

Mr. KASTENMEIER. Mr. Chairman, I yield 3 minutes to the gentleman from Florida [Mr. PEPPER], the distinguished chairman of the Rules Committee whose generosity in granting us this time accounts for our being here in the first place.

Mr. PEPPER. I thank the distinguished gentleman for his kindness in yielding to me.

Mr. Chairman, I think this bill is a fair bill. I think it corrects an injustice which has often fallen upon the big drug companies of this Nation who are in general contributing much to new and extended research in trying to find the answers, the cause and the cure of some of the dreaded diseases like heart disease and cancer that afflict so many of our people. But we in this bill have done something more than provide a greater measure of justice for the drug companies by giving them a right to extend their patents, to a certain degree, to compensate for the time they have lost while their application is being considered by the Food and Drug Administration or the companies themselves have been engaged in their own preparation for putting their drug upon the market. But the benefit to the elderly, which many of us have been particularly concerned about, they tell me, will reach something like a billion dollars in the next few years. The way the benefit will derive to the elderly is that the generic producing drug companies would be able to get the right to produce these critical drugs earlier than they otherwise would be able to do, and therefore they will be selling cheaper generic drugs, which those who are informed about the matter know simply means that you are buying aspirin, let us say, not by trade name, but by a name that really means aspirin. You get it cheaper in the marketplace when you buy it that way, as they call it, a generic drug, than you do when you buy a drug that has a brand name that is sold generally in the market.

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So this is, I think, a fair compromise between the drug companies, giving them justice for the time that they have heretofore been losing, through no fault of their own, and at the same time, giving the elderly people of this country perhaps a savings of a billion dollars in the next few years by being able to buy more and cheaper generic drugs than they would otherwise be able to buy without this legislation.

I add on to this, Mr. Chairman, medicare does not cover the drugs that an elderly person consumes in the home. What I am talking about is the ability of the elderly to buy drugs that they have to pay for themselves, and on the average, 13 prescriptions a year, is the number obtained by the average elderly person. They are going to be able to save a lot of money and get a lot of care that they richly deserve.

Mr. MOORHEAD. Mr. Chairman, I yield 15 minutes to the gentleman from Ohio [Mr. KINDNESS].

(Mr. KINDNESS asked and was given permission to revise and extend his remarks.)

Mr. KINDNESS. I thank the gentleman for yielding me this time.

Mr. Chairman, my purpose at this point is to make some observations for the RECORD, because it surely is not for the purpose of pursuading anyone present. Here we are, a nice, warm, friendly little group. I wish at this point in time the cameras could scan the House Chamber to show how empty it is. That will not happen until later when we have special orders, if we have any special orders tonight.

I feel as though maybe I am involved in a special order right now, because that is what happens when nobody listens, or at least hardly anyone listens. That is what has been happening right along the line with the progress of H.R. 3605. It has gotten all this way without really anyone paying enough attention to certain aspects of it. It started out with a good purpose, a wonderful purpose. I agree with it thoroughly. I think that the concept of getting the clearance of generic drugs and getting them to the marketplace just as soon as possible is a great idea. It can indeed solve a lot of financial problems or help with a lot of financial problems of many people who need medicines and drugs for the sake of their health on a regular basis.

Mr. WALKER. Mr. Chairman, will the gentleman yield?

Mr. KINDNESS. I yield to the gentleman.

Mr. WALKER. I thank the gentleman for yielding because I think that it might be worth underscoring the point that the gentleman made as he led off his argument. I have just done a count of the House and, if TV cameras were in fact spanning the Chamber right now, they would discover that there are only 9 Members of Congress on the floor to listen to the gentleman.

Mr. KINDNESS. If the gentleman would forgive my using the term, I think this is what we call a "Walker House."

I agree with what we attempt to do in extending the term or restoring the term of patents that get run down or run out while the patented product is being put through a long, tortuous regulatory process before it is approved for use on the market. Those are two good concepts that have been much discussed by those who have heaped praise upon this bill.

But, my gosh, do we have to depreciate the value of our patent laws to do this? No, I do not think so. It has been done, I believe, accidentally in the main. It has been done, in the main, by people who did not know anything about patent law, and I am not claiming to be an expert. I have had the problems pointed out to me by people who are more expert at patent law. But the problems are there.

Let me tell the Members about an experience that I had this spring at the appointment of the Speaker of the House, I was, on the recommendation of others in the Judiciary Committee, and the chairman thereof, I was appointed to be an observer, adviser to the U.S. delegation to the fourth in a series of negotiations concerning possible or potential amendments to the Paris Convention on Protection of Industrial Properties.

Now, that is an old international agreement, a treaty having to do with the protection of patent laws. We have had a struggle going on for a number of years in which Third World countries, together as a group in those negotiations are saying, let us detract more and more from the patent laws of the industrialized nations. The developed nations have too much by way of property rights under their patent protections. We do not want to recognize those rights in our countries, and we want to be able to take the value of that intellectual property at as early a date as possible and use it for the benefit of our countries and the development of our underdeveloped countries.

Well, that is one side of the argument. Our side of the argument, the U.S. side of the argument is that we have, the developed nations of the world have for many years respected each other's patent laws, we have respected the rights of individuals to own intellectual property.

The Third World nations, however, have strongly argued that we should weaken that concept. They are backed by the Soviet Union and the socialist countries that group themselves in these negotiations with the Soviet Union. That is sort of in the background. The Soviet Union and its allies in industrial terms, in terms of international trade, would like to have the Western nations' patent laws weakened, just like H.R. 3605 does.

Do we realize how much of our commerce throughout the world involves pharmaceuticals? That is what we are talking about mainly here, drugs. That is an important area in which the United States does have some areas of advantage. We do sell pharmaceuticals to other countries. It is a part of our international trade picture.

There are other countries that would like to do more by way of taking on intellectual property in the form of patented drugs or pharmaceuticals and marketing them throughout the world without regard to, and without respect for, our U.S. patent laws and the concepts that we believe or have believed, as a nation, are appropriate to the protection of intellectual property in the form of patents.

Well, what happened in regard to H.R. 3605 now? A lot of people wanted to have this patent term restoration matter dealt with. A lot of people wanted to do something about shortening the time for generic drug manufacturers, the Third World countries of U.S. pharmaceutical operations, I guess, to be able to market more quickly these patented products when the patent runs out.

In wedding those two concepts, very worthwhile concepts, we have come together in some areas of this bill with provisions that simply derogate too much from the intellectual property rights of people in the United States. They ought to have been given serious consideration, but what happened? Nobody gives it serious consideration. Why is that? Because this is a negotiated bill; it is not a legislated bill, it is a negotiated bill.

There is nothing wrong with negotiations; it happens all the time. But when you substitute somebody's statement that, "Oh, you cannot touch a tiddle in this bill because it has all been carefully negotiated and balanced and set forth in such a manner that if anybody slips a little bit, the whole thing falls.

No, I do not believe it. Anyone who has been involved in the legislative process for any appreciable period of time or has observed it closely knows that every time that argument is made it is false.

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Negotiated legislation is just that. It is subject to negotiation and change all the way through the legislative process. H.R. 3605 is no different and should be no different. We should ascribe no particular sanctity to this bill simply because some few individuals were involved in negotiating its contents and others went along with what was decided.

Nonetheless, I understand that negotiations continue, perhaps even as we speak, in an attempt to arrive at some conclusion, some amendments that might be the final package of negotiated provisions that would end the remaining controversy.

I am not that easily satisfied unless the patent laws of the United States are kept reasonably intact with respect to the preservation of the protection of intellectual property. Any time we reduce that too seriously, we are cutting the ground out from under our negotiators in the international process that I described a moment ago that goes on and on.

The amendment process is a part of the legislative process to which we often give too little attention, but the amendment process could be used to improve H.R. 3605 to where, practically speaking, I do not think there would be any opposition to the bill. But we have encountered an attitude in the Committee on the Judiciary that says, "Oh, no, you cannot," and somehow along partisan lines the votes fell in the Committee on the Judiciary.

That is an oddity because this is not a partisan matter, from what I understand. I do not know of any reason for Democrats and Republicans to generically view the bill from different aspects, different points of view. But in the Committee on the Judiciary, all attempts at amendment were rebuffed, and where votes were taken, they were along party lines.

Why should that be? I think it is the stubbornness that arises out of the arrogance of power when the majority party has been in power too long, and reason is pushed aside, logic is pushed aside, and power takes over. All right. That is the way it seems to function all too frequently. It does not mean it is right and it does not mean that it is making good law.

I would just like to suggest, for example, another gentleman from Ohio, [Mr. DEWINE,] earlier pointed out that the Bolar case is being overturned by this bill, a case that really precipitated the conclusion of the earlier negotiations on this bill. That case made it clear that the law all along really was, as most everyone in patent field thought it was, that someone who does not own a patent cannot put the patented product to a commercial use during the life of the patent, and that includes testing it and preparing it for marketing to begin as soon as the patent expires.

The Bolar case, then, will be overruled by this bill, H.R. 3605, in that this bill would provide that the generic drug manufacturers can start playing around with the drug on which the patent is about to expire within a year. They can use that year to get

ready for the marketplace. If they did it right now, they would be violating the patent rights of the patent holder.

That is one of the areas that ought to be, it seems to me, addressed intelligently, not on a prejudiced basis, not on a partisan basis; it is not a partisan issue. I do not think there is really a partisan issue in the whole bill that would be addressed by any of the amendments that I have filed for printed in the RECORD. I only filed those for the purpose of protecting the right to have those amendments considered because we are here at a time when we are just about to recess for the month of August and until after Labor Day. The patience of the Members of the House is becoming short already. It will be shorter tomorrow and the day after, and certainly limitations on time will be sought and imposed.

If the important considerations that are the subject matter of amendments to be considered to this bill are not going to be considered carefully, at least we are guaranteeing that they have 5 minutes for each amendment to be considered. I certainly hope we are not pressed to that procedure. There are some amendments that can be blocked together, if we can just be assured that there will be consideration of those amendments, rather than simply brushing them off. I have no reason to expect that we will receive such consideration or any commitment to it.

Therefore, at this point I simply propose to go through it bit by bit, something that should have been done in committee, something that was brushed off in committee, and I hope that the bill can be improved and we can all join in support of H.R. 3605.

● Mr. RODINO. Mr. Chairman, I rise in support of the Drug Price Competition and Patent Term Restoration Act of 1984. I urge my colleague to vote in favor of final passage of this measure. This bill will benefit both the industry and consumers.

The pharmaceutical industry in the United States has long been an important element of our economic physical well-being. American pharmaceutical companies have long led the world in the research and development of new drugs and therapies for our citizens. Moreover, American pharmaceutical companies contribute to our economy through both direct employment and by enhancing our balance-of-payments position.

The pharmaceutical industry will benefit substantially under this bill. The need for the legislation was succinctly outlined by the Pharmaceutical Manufacturing Association [PMA]:

The cause of the loss of patent life for pharmaceuticals is simply explained. When a firm discovers a promising new drug compound, it patents it immediately or risks losing the new technology to a competitor. Generally, a patent is issued within two or three years of patent filing, and the 17 years of protection begins immediately to expire. But the patent clock begins ticking long before a new product is ready for production and distribution. In fact, at the time its patent issues, a new drug compound is, on average, 7 to 10 years away from the marketplace—7 to 10 years that are needed to satisfy important statutory requirements for safety and efficacy administered by the Food and Drug Administration.

Although Congress never intended it, the time consumed in meeting these FDA requirements is, in effect, subtracted from the patent lives of drugs. The pharmaceutical innovator's new product typically enters the market with less than 10 of the 17 years of patent protection provided by statute and, therefore, with only a fraction of the related investment incentives provided innovators in other industries. This is neither fair nor good public policy.

Under the bill H.R. 3605, for every drug they test and have reviewed at the Food and Drug Administration [FDA], a generally corresponding patent term extension will be available. The availability of such a patent term extension has long been an important legislative goal for the industry. It is my hope that with enactment of this bill we will see a blossoming of new research and development activities. Once patent term restoration becomes law there will be an added incentive to pursue research for new drug products. I hope that in several years I will be able to return to this Chamber with the facts to substantiate the reality of this prediction.

CONSUMER INTEREST

According to the Food and Drug Administration this bill will save the American consumers upward of $1 billion. These savings will be achieved through the availability of generic substitutes.

As my colleagues know, the FDA currently has in place an approval process for pioneer drugs approved before 1962. Under this procedure nearly 3,000 generics have been approved. In this market, 80 percent of the generic market is controlled by research-based pharmaceuticals and only 20 percent by the production-intensive generic houses.

All this legislation does is to permit FDA to give approval of generics for the so-called post-1962 drugs. The net result of this change will be to open up several billion dollars of the $15.6 billion prescription drug market to competition. The winner in this competition will be the average American consumer.

Currently a substantial majority, nearly 80 percent according to the AFL-CIO of the prescriptions filled in the United States are paid by individuals without substantial assistance from the Government or insurers. As a result of this legislation, price competition will drive down the price of many prescription drugs, thus saving the consumer significant amounts. In addition, the Government as a health care provider—both through medicaid/medicare and more directly to Government employees and military personnel—will save millions through the increased availability of generic drug substitutes.

CONCLUSION

It is little wonder that this legislation has been endorsed by the American Association of Retired Persons [AARP] and the National Council of Senior Citizens [NCSC], because it is our senior citizens who bear the heaviest burden of high-cost medical care. I am also pleased to note that this bill has been enthusiastically endorsed by virtually all consumer groups and major labor organizations.

As a fervent and long-time supporter of patent term legislation, I am pleased to see that concept closer to enactment. I am equally pleased to see patent term legislation coupled with the long-needed reform of the FDA process of approving generic drugs. I urge my colleagues to support this measure.●

Mr. MOORHEAD. Mr. Chairman, I have no further requests for time, and I yield back the balance of my time.

Mr. KASTENMEIER. Mr. Chairman, I have no further requests for time, and I yield back the balance of my time.

Mr. Chairman, I move that the Committee do now rise.

The motion was agreed to.

Accordingly the Committee rose; and the Speaker pro tempore [Mr. BRITT] having assumed the chair, Mr. DANIEL, Chairman of the Committee of the Whole House on the State of the Union, reported that that Committee, having had under consideration the bill (H.R. 3605) to amend the Federal Food, Drug, and Cosmetic Act to authorize an abbreviated new drug application under section 505 of that Act for generic new drugs equivalent to approved new drugs, and for other purposes, had come to no resolution thereon.

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