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CONGRESSIONAL RECORD
PROCEEDINGS AND DEBATES OF THE 98TH CONGRESS

HOUSE

BILL	DATE	PAGE(S)
H.R.3605	SEP 6 '84 (109)	H9105-51

ACTION:

Drug Price Competition: By a yea-and-nay vote of 362 yeas, Roll No. 379, the House passed H.R. 3605, to amend the Federal Food, Drug, and Cosmetic Act to authorize an abbreviated new drug applica-

tion under section 505 of that Act for generic new drugs equivalent to approved new drugs.

Agreed to the committee amendment in the nature of a substitute.

Agreed to the Judiciary Committee amendments.

Agreed to an amendment that provides new language for the abbreviated new drug applications provisions.

Rejected the following two amendments to the preceding amendment:

An amendment that sought to preclude FDA approval of generic substitutes until 18 months, instead of 30 months, after the generic drug application in cases where patent litigation is underway (rejected by a recorded vote of 66 ayes to 304 noes with 1 voting "present", Roll No. 375); and

An amendment that sought to remove over-the-counter drugs from coverage under the bill (rejected by a recorded vote of 24 ayes to 347 noes with 1 voting "present", Roll No. 376).

Agreed to an amendment that provides new language for the new patent extension provisions; and

An amendment, as amended, that strengthens the provisions of law requiring labeling of textile and wool products to indicate country of origin.

Rejected the following three amendments to the preceding amendment:

An amendment that sought to strike provisions requiring catalog descriptions to clearly indicate whether textile and wool products are domestically produced or imported (rejected by a division vote of 3 ayes to 23 noes);

An amendment that sought to strike language requiring catalog labeling on imported goods; and

An amendment that sought to change the effective date of catalog description provisions to items manufactured 180 days, rather than 90, after enactment (rejected by a recorded vote of 36 ayes to 323 noes with 1 voting "present", Roll No. 378).

Agreed to amend the title.

Subsequently, this passage was vacated and S. 1538, a similar Senate-passed bill, was passed in lieu after being amended to contain the language of the House bill as passed. Agreed to amend the title of the Senate bill.

The Clerk was authorized to make technical corrections in the engrossment of the House amendments to S. 1538.

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D.C. Business: It was made in order to consider legislation pertaining to the District of Columbia on Monday, September 17. Page H9152

Immigration Reform: House insisted on its amendment to S. 529, to revise and reform the Immigration and Nationality Act; and agreed to a conference. Appointed as conferees: From the Committee on the Judiciary: Representatives Rodino, Mazzoli, Sam B. Hall, Jr., Synar, Frank, Crockett, Schumer, Feighan, Smith of Florida, Berman, Fish, Moorhead, Hyde, Lungren, and McCollum.

As additional conferees: From the Committee on Agriculture, solely for consideration of section 101 of the bill and section 101 of the House amendment: Representatives de la Garza, Panetta, and Morrison of Washington.

From the Committee on Agriculture, solely for consideration of sections 211, 214, and 407 of the bill, of sections 211 and 214 of the House amendment, and of such portions of sections 301 and 302 of the bill and of sections 301 and 304 of the House amendment as relate to eligibility and funding for public assistance programs within the jurisdiction of the committee on Agriculture: Representatives de la Garza, Jones of Tennessee, Panetta, Morrison of Washington, and Chappie.

From the Committee on Education and Labor, solely for consideration of sections 101, 211, 214, and 407 of the bill, of sections 101, 211, 214, and 305 of the House amendment, of subsection 107(d) of the Immigration and Nationality Act as contained in section 122 of the House amendment, and of such portions of sections 301 and 302 of the bill and of sections 301 and 304 of the House amendment as relate to eligibility and funding for public assistance programs within the jurisdiction of the Committee on Education and Labor: Representatives Hawkins, Ford of Michigan, Miller of California, Erlenborn, and Packard.

From the Committee on Energy and Commerce, solely for consideration of such portions of sections 301 and 302 of the bill and of sections 301 and 304 of the House amendment as relate to eligibility and funding for public assistance programs within the jurisdiction of the Committee on Energy and Commerce: Representatives Dingell, Waxman, and Broyhill.

Solely for consideration of section 119 of the House amendment: Representative de la Garza.

Solely for consideration of sections 111, 115, 116, 117, 118, subsection 205(f), and title V of the House amendment, and modifications thereof committed to conference: Representative Roybal.

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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 further consideration of the bill, H.R. 3605.

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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 further 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. When the Committee of the Whole rose on Wednesday, August 8, 1984, all time for general debate had expired.

Pursuant to the rule, the committee amendment in the nature of a substitute recommended by the Committee on Energy and Commerce shall be considered by titles as an original bill for the purpose of amendment, and each title shall be considered as having been read. 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 adding a new title III consisting of the text of title II of H.R. 5929, which shall be considered as having been read.

The Clerk will designate section 1.

The text of section 1 is as follows:

H.R. 3605

Be it enacted by the Senate and House of Representatives of the United States of America in Congress assembled, That this Act may be cited as the "Drug Price Competition and Patent Term Restoration Act of 1984".

The CHAIRMAN. Are there any amendments to section 1? If not, the Clerk will designate title I.

The text of title I is as follows:

TITLE I—ABBREVIATED NEW DRUG APPLICATIONS

SEC. 101. Section 505 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 355) is amended by redesignating subsection (j) as

subsection (k) and inserting after subsection (i) the following:

"(j)(1) Any person may file with the Secretary an abbreviated application for the approval of a new drug.

"(2)(A) An abbreviated application for a new drug shall contain—

"(i) information to show that the conditions of use prescribed, recommended, or suggested in the labeling proposed for the new drug have been previously approved for a drug listed under paragraph (6) (hereinafter in this subsection referred to as a 'listed drug');

"(ii)(I) if the listed drug referred to in clause (i) has only one active ingredient, information to show that the active ingredient of the new drug is the same as that of the listed drug.

"(II) if the listed drug referred to in clause (i) has more than one active ingredient, information to show that the active ingredients of the new drug are the same as those of the listed drug, or

"(III) if the listed drug referred to in clause (i) has more than one active ingredient and if one of the active ingredients of the new drug is different and the application is filed pursuant to the approval of a petition filed under subparagraph (C), information to show that the other active ingredients of the new drug are the same as the active ingredients of the listed drug, information to show that the different active ingredient is an active ingredient of a listed drug or of a drug which does not meet the requirements of section 201(p), and such other information respecting the different active ingredient with respect to which the petition was filed as the Secretary may require;

"(iii) information to show that the route of administration, the dosage form, and the strength of the new drug are the same as those of the listed drug referred to in clause (i) or, if the route of administration, the dosage form, or the strength of the new drug is different and the application is filed pursuant to the approval of a petition filed under subparagraph (C), such information respecting the route of administration, dosage form, or strength with respect to which the petition was filed as the Secretary may require;

"(iv) information to show that the new drug is bioequivalent to the listed drug referred to in clause (i), except that if the application is filed pursuant to the approval of a petition filed under subparagraph (C), information to show that the active ingredients of the new drug are of the same pharmacological or therapeutic class as those of the listed drug referred to in clause (i) and the new drug can be expected to have the same therapeutic effect as the listed drug when administered to patients for a condition of use referred to in clause (i);

"(v) information to show that the labeling proposed for the new drug is the same as the labeling approved for the listed drug referred to in clause (i) except for changes required because of differences approved under a petition filed under subparagraph (C) or because the new drug and the listed drug are produced or distributed by different manufacturers;

"(vi) the items specified in clauses (B) through (F) of subsection (b)(1);

"(vii) a certification, in the opinion of the applicant and to the best of his knowledge, with respect to each patent which claims the listed drug referred to in clause (i) or which claims a use for such listed drug for which the applicant is seeking approval under this subsection and for which information is required to be filed under subsection (b) or (c)—

"(I) that such patent information has not been filed,

"(II) that such patent has expired,

"(III) of the date on which such patent will expire, or

"(IV) that such patent is invalid or will not be infringed by the manufacture, use, or sale of the new drug for which the application is submitted; and

"(viii) if with respect to the listed drug referred to in clause (i) information was filed under subsection (b) or (c) for a method of use patent which does not claim a use for which the applicant is seeking approval under this subsection, a statement that the method of use patent does not claim such a use.

The Secretary may not require that an abbreviated application contain information in addition to that required by clauses (i) through (viii).

"(B)(i) An applicant who makes a certification described in subparagraph (A)(vii)(IV) shall include in the application a statement that the applicant has given the notice required by clause (ii) to—

"(I) each owner of the patent which is the subject of the certification or the representative of such owner designated to receive such notice, and

"(II) the holder of the approved application under subsection (b) for the drug which is claimed by the patent or a use of which is claimed by the patent or the representative of such holder designated to receive such notice.

"(ii) The notice referred to in clause (i) shall state that an application, which contains data from bioavailability or bioequivalence studies, has been submitted under this subsection for the drug with respect to which the certification is made to obtain approval to engage in the commercial manufacture, use, or sale of such drug before the expiration of the patent referred to in the certification. Such notice shall include a detailed statement of the factual and legal basis of the applicant's opinion that the patent is not valid or will not be infringed.

"(iii) If an application is amended to include a certification described in subparagraph (A)(vii)(IV), the notice required by clause (ii) shall be given when the amended application is submitted.

"(C) If a person wants to submit an abbreviated application for a new drug which has a different active ingredient or whose route of administration, dosage form, or strength differ from that of a listed drug, such person shall submit a petition to the Secretary seeking permission to file such an application. The Secretary shall approve or disapprove a petition submitted under this subparagraph within ninety days of the date the petition is submitted. The Secretary shall approve such a petition unless the Secretary finds that investigations must be conducted to show the safety and effectiveness of the drug or of any of its active ingredients of the drug or of the route of administration, the dosage form, or strength which differ from the listed drug.

"(3) Subject to paragraph (4), the Secretary shall approve an application for a drug unless the Secretary finds—

"(A) the methods used in, or the facilities and controls used for, the manufacture, processing, and packing of the drug are inadequate to assure and preserve its identity, strength, quality, and purity;

"(B) information submitted with the application is insufficient to show that each of the proposed conditions of use have been previously approved for the listed drug referred to in the application;

"(C)(i) if the listed drug has only one active ingredient, information submitted with the application is insufficient to show that the active ingredient is the same as that of the listed drug,

"(ii) if the listed drug has more than one active ingredient, information submitted with the application is insufficient to show that the active ingredients are the same as the active ingredients of the listed drug, or

"(iii) if the listed drug has more than one active ingredient and if the application is for a drug which has an active ingredient different from the listed drug, information submitted with the application is insufficient to show—

"(I) that the other active ingredients are the same as the active ingredients of the listed drug, or

"(II) that the different active ingredient is an active ingredient of a listed drug or a drug which does not meet the requirements of section 201(p),

or no petition to file an application for the drug with the different ingredient was approved under paragraph (2)(C);

"(D)(i) if the application is for a drug whose route of administration, dosage form, or strength of the drug is the same as the route of administration, dosage form, or strength of the listed drug referred to in the application, information submitted in the application is insufficient to show that the route of administration, dosage form, or strength is the same as that of the listed drug, or

"(ii) if the application is for a drug whose route of administration, dosage form, or strength of the drug is different from that of the listed drug referred to in the application, no petition to file an application for the drug with the different route of administration, dosage form, or strength was approved under paragraph (2)(C);

"(E) if the application was filed pursuant to the approval of a petition under paragraph (2)(C), the application did not contain the information required by the Secretary respecting the active ingredient, route of administration, dosage form, or strength which is not the same;

"(F) information submitted in the application is insufficient to show that the drug is bioequivalent to the listed drug referred to in the application or, if the application was filed pursuant to a petition approved under paragraph (2)(C), information submitted in the application is insufficient to show that the active ingredients of the new drug are of the same pharmacological or therapeutic class as those of the listed drug referred to in paragraph (2)A)(i) and that the new drug can be expected to have the same therapeutic effect as the listed drug when administered to patients for a condition of use referred to in such paragraph;

"(G) information submitted in the application is insufficient to show that the labeling proposed for the drug is the same as the labeling approved for the listed drug referred to in the application except for changes required because of differences approved under a petition filed under paragraph (2)(C) or because the drug and the listed drug are produced or distributed by different manufacturers;

"(H) information submitted in the application or any other information available to the Secretary shows that (i) the inactive ingredients of the drug are unsafe for use under the conditions prescribed, recommended, or suggested in the labeling proposed for the drug, or (ii) the composition of the drug is unsafe under such conditions because of the type or quantity of inactive ingredients included or the manner in which the inactive ingredients are included;

"(I) the approval under subsection (c) of the listed drug referred to in the application

under this subsection has been withdrawn or suspended for grounds described in the first sentence of subsection (e), the approval under this subsection of the listed drug referred to in the application under this subsection has been withdrawn or suspended under paragraph (5), or the Secretary has determined that the listed drug has been withdrawn from sale for safety or effectiveness reasons;

"(J) the application does not meet any other requirement of paragraph (2)A); or

"(K) the application contains an untrue statement of material fact.

"(4)(A) Within one hundred and eighty days of the initial receipt of an application under paragraph (2) or within such additional period as may be agreed upon by the Secretary and the applicant, the Secretary shall approve or disapprove the application.

"(B) The approval of an application submitted under paragraph (2) shall be made effective on the last applicable date determined under the following:

"(i) If the applicant only made a certification described in subclause (I) or (II) of paragraph (2)(A)(vii) or in both such subclauses, the approval may be made effective immediately.

"(ii) If the applicant made a certification described in subclause (III) of paragraph (2)(A)(vii), the approval may be made effective on the date certified under subclause (III).

"(iii) If the applicant made a certification described in subclause (IV) of paragraph (2)(A)(vii), the approval shall be made effective immediately unless an action is brought for infringement of a patent which is the subject of the certification before the expiration of forty-five days from the date the notice provided under paragraph (2)(B)(i) is received. If such an action is brought before the expiration of such days, the approval shall be made effective upon the expiration of the eighteen month period beginning on the date of the receipt of the notice provided under paragraph (2)(B)(i) or such shorter or longer period as the court may order because either party to the action failed to reasonably cooperate in expediting the action, except that—

"(I) if before the expiration of such period the court decides that such patent is invalid or not infringed, the approval shall be made effective on the date of the court decision, or

"(II) if before the expiration of such period the court decides that such patent has been infringed, the approval shall be made effective on such date as the court orders under section 271(e)(4)(A) of title 35, United States Code.

In such an action, each of the parties shall reasonably cooperate in expediting the action. Until the expiration of the forty-five-day period beginning on the date the notice made under paragraph (2)(B)(i) is received, no action may be brought under section 2201 of title 28, United States Code, for a declaratory judgment with respect to the patent. Any action brought under section 2201 shall be brought in the judicial district where the defendant has its principal place of business or a regular and established place of business.

"(iv) If the application contains a certification described in subclause (IV) of paragraph (2)(A)(vii) and is for a drug for which a previous application has been submitted under this subsection containing such a certification, the application shall be made effective not earlier than one hundred and eighty days after—

"(I) the date the Secretary receives notice from the applicant under the previous application of the first commercial marketing of the drug under the previous application, or

"(II) the date of a decision of a court in an action described in clause (iii) holding the patent which is the subject of the certification to be invalid or not infringed,

whichever is earlier.

"(C) If the Secretary decides to disapprove an application, the Secretary shall give the applicant notice of an opportunity for a hearing before the Secretary on the question of whether such application is approvable. If the applicant elects to accept the opportunity for hearing by written request within thirty days after such notice, such hearing shall commence not more than ninety days after the expiration of such thirty days unless the Secretary and the applicant otherwise agree. Any such hearing shall thereafter be conducted on an expedited basis and the Secretary's order thereon shall be issued within ninety days after the date fixed by the Secretary for filing final briefs.

"(D)(i) If an application (other than an abbreviated new drug application) submitted under subsection (b) for a drug, no active ingredient (including any ester or salt of the active ingredient) of which has been approved in any other application under subsection (b), was approved during the period beginning January 1, 1982, and ending on the date of the enactment of this subsection, the Secretary may not make the approval of an application submitted under this subsection which refers to the drug for which the subsection (b) application was submitted effective before the expiration of ten years from the date of the approval of the application under subsection (b).

"(ii) If an application submitted under subsection (b) for a drug, no active ingredient (including any ester or salt of the active ingredient) of which has been approved in any other application under subsection (b), is approved after the date of the enactment of this subsection and if the holder of the approved application certifies to the Secretary that no patent has ever been issued to any person for such drug or for a method of using such drug and that the holder cannot receive a patent for such drug or for a method of using such drug because in the opinion of the holder a patent may not be issued for such drug or for a method of using such drug for any known therapeutic purposes the Secretary may not make the approval of an application submitted under this subsection which refers to the drug for which the subsection (b) application was submitted effective before the expiration of four years from the date of the approval of the application under subsection (b) unless the Secretary determines that an adequate supply of such drug will not be available or the holder of the application approved under subsection (b) consents to an earlier effective date for an application under this subsection.

"(5) If a drug approved under this subsection refers in its approved application to a drug the approval of which was withdrawn or suspeneded for grounds described in the first sentence of subsection (e) or was withdrawn or suspended under this paragrpah or which, as determined by the Secretary, has been withdrawn from sale for safety or effectiveness reasons, the approval of the drug under this subsection shall be withdrawn or suspended—

"(A) for the same period as the withdrawal or suspension under subsection (e) or this paragraph, or

"(B) if the listed drug has been withdrawn from sale, for the period of withdrawal from sale or, if earlier, the period ending on the date the Secretary determines that the withdrawal from sale is not for safety or effectiveness reasons.

"(6)(A)(i) Within sixty days of the date of the enactment of this subsection, the Secretary shall publish and make available to the public—

"(I) a list in alphabetical order of the official and propietary name of each drug which has been approved for safety and effectiveness under subsection (c) before the date of the enactment of this subsection;

"(II) the date of approval if the drug is approved after 1981 and the number of the application which was approved; and

"(III) whether in vitro or in vivo bioequivalence studies, or both such studies, are required for applications filed under this subsection which will refer to the drug published.

"(ii) Every thirty days after the publication of the first list under clause (i) the Secretary shall revise the list to include each drug which has been approved for safety and effectiveness under subsection (c) or approved under this subsection during the thirty-day period.

"(iii) When patent information submitted under subsection (b) or (c) respecting a drug included on the list is to be published by the Secretary the Secretary shall, in revisions made under clause (ii), include such information for such drug.

"(B) A drug approved for safety and effectiveness under subsection (c) or approved under this subsection shall, for purposes of this subsection, be considered to have been published under subparagraph (A) on the date of its approval or the date of enactment, whichever is later.

"(C) If the approval of a drug was withdrawn or suspended for grounds described in the first sentence of subsection (e) or was withdrawn or suspended under paragraph (5) or if the Secretary determines that a drug has been withdrawn from sale for safety or effectiveness reasons, it may not be published in the list under subparagraph (A) or, if the withdrawal or suspension occurred after its publication in such list, it shall be immediately removed from such list—

"(i) for the same period as the withdrawal or suspension under subsection (e) or paragraph (5), or

"(ii) if the listed drug has been withdrawn from sale, for the period of withdrawal from sale or, if earlier, the period ending on the date the Secretary determines that the withdrawal from sale is not for safety or effectiveness reasons.

A notice of the removal shall be published in the Federal Register.

"(7) For purposes of this section:

"(A) the term 'bioavailability' means the rate and extent to which the active ingredient or therapeutic ingredient is absorbed from a drug and becomes available at the site of drug action.

"(B) A drug shall be considered to be bioequivalent to a listed drug if—

"(i) the rate and extent of absorption of the drug do not show a significant difference from the rate and extent of absorption of the listed drug when administered at the same molar dose of the therapeutic ingredient under similar experimental conditions in either a single dose or multiple doses; or

"(ii) the extent of absorption of the drug does not show a significant difference from the extent of absorption of the listed drug when administered at the same molar dose of the therapeutic ingredient under similar experimental conditions in either a single dose or multiple doses and the difference from the listed drug in the rate of absorption of the drug is intentional, is reflected in its proposed labeling, is not essential to the

attainment of effective body drug concentrations on chronic use, and is considered medically insignificant for the drug.".

SEC. 102. (a)(1) Section 505(b) of such Act is amended by adding at the end the following: "The applicant shall file with the application the patent number and the expiration date of any patent which claims the drug for which the applicant submitted the application or which claims a method of using such drug and with respect to which a claim of patent infringement could reasonably be asserted if a person not licensed by the owner engaged in the manufacture, use, or sale of the drug. If an application is filed under this subsection for a drug and a patent which claims such drug or a method of using such drug is issued after the filing date but before approval of the application, the applicant shall amend the application to include the information required by the preceding sentence. Upon approval of the application, the Secretary shall publish information submitted under the two preceding sentences.".

(2) Section 505(c) of such Act is amended by inserting "(1)" after "(c)", by redesignating paragraphs (1) and (2) as subparagraphs (A) and (B), respectively, and by adding at the end the following:

"(2) If the patent information described in subsection (b) could not be filed with the submission of an application under subsection (b) because the application was filed before the patent information was required under subsection (b) or a patent was issued after the application was approved under such subsection, the holder of an approved application shall file with the Secretary the patent number and the expiration date of any patent which claims the drug for which the application was submitted or which claims a method of using such drug and with respect to which a claim of patent infringement could reasonably be asserted if a person not licensed by the owner engaged in the manufacture, use, or sale of the drug. If the holder of an approved application could not file patent information under subsection (b) because it was not required at the time the application was approved, the holder shall file such information under this subsection not later than thirty days after the date of the enactment of this sentence, and if the holder of an approved application could not file patent information under subsection (b) because no patent had been issued when the application was filed or approved, the holder shall file such information under this subsection not later than thirty days after the date the patent involved is issued. Upon the submission of patent information under this subsection, the Secretary shall publish it.".

(3)(A) The first sentence of section 505(d) of such Act is amended by redesignating clause (6) as clause (7) and inserting after clause (5) the following: "(6) the application failed to contain the patent information prescribed by subsection (b); or".

(B) The first sentence of section 505(e) of such Act is amended by redesignating clause (4) as clause (5) and inserting after clause (3) the following: "(4) the patent information prescribed by subsection (c) was not filed within thirty days after the receipt of written notice from the Secretary specifying the failure to file such information; or".

(b)(1) Section 505(a) of such Act is amended by inserting "or (j)" after "subsection (b)".

(2) Section 505(c) of such Act is amended by striking out "this subsection" and inserting in lieu thereof "subsection (b)".

(3) The second sentence of section 505(e) of such Act is amended by inserting "submitted under subsection (b) or (j)" after "an application".

(4) The second sentence of section 505(e) is amended by striking out "(j)" each place it occurs in clause (1) and inserting in lieu thereof "(k)"

(5) Section 505(k)(1) of such Act (as so redesignated) is amended by striking out "pursuant to this section" and inserting in lieu thereof "under subsection (b) or (j)".

(6) Subsection (a) and (b) of section 527 of such Act are each amended by striking out "505(b)" each place it occurs and inserting in lieu thereof "505".

SEC. 103. (a) Section 505(b) of such Act is amended by inserting "(1)" after "(b)", by redesignating clauses (1) through (6) as clauses (A) through (F), respectively, and by adding at the end the following:

"(2) An application submitted under paragraph (1) for a drug listed under subsection (j)(6) for which investigations described in clause (A) of such paragraph and relied upon by the applicant for approval of the application were not conducted by or for the applicant or for which the applicant has not obtained a right of reference or use from the person by or for whom the investigations were conducted shall also include—

"(A) a certification, in the opinion of the applicant and to the best of his knowledge, with respect to each patent which claims the drug for which such investigations were conducted or which claims a use for such drug for which the applicant is seeking approval under this subsection and for which information is required to be filed under paragraph (1) or subsection (c)—

"(i) that such patent information has not been filed,

"(ii) that such patent has expired,

"(iii) of the date on which such patent will expire, or

"(iv) that such patent is invalid or will not be infringed by the manufacture, use, or sale of the new drug for which the application is submitted; and

"(B) if with respect to the drug for which investigations described in paragraph (1)(A) were conducted information was filed under paragraph (1) or subsection (c) for a method of use patent which does not claim a use for which the applicant is seeking approval under this subsection, a statement that the method of use patent does not claim such a use.

"(3)(A) An applicant who makes a certification described in paragraph (2)(A)(iv) shall include in the application a statement that the applicant has given the notice required by subparagraph (B) to—

"(i) each owner of the patient which is the subject of the certification or the representative of such owner designated to receive such notice, and

"(ii) the holder of the approved application under subsection (b) for the drug which is claimed by the patent or a use of which is claimed by the patent or the representative of such holder designated to receive such notice.

"(B) The notice referred to in subparagraph (A) shall state that an application has been submitted under this subsection for the drug with respect to which the certification is made to obtain approval to engage in the commercial manufacture, use, or sale of the drug before the expiration of the patent referred to in the certification. Such notice shall include a detailed statement of the factual and legal basis of the applicant's opinion that the patent is not valid or will not be infringed.

"(C) If an application is amended to include a certification described in paragraph (2)(A)(iv), the notice required by subparagraph (B) shall be given when the amended application is submitted.".

(b) Section 505(c) of such Act (as amended by section 102(a)(2)) is amended by adding at the end the following:

"(3) The approval of an application filed under subsection (b) which contains a certification required by paragraph (2) of such subsection shall be made effective on the last applicable date determined under the following:

"(A) If the applicant only made a certification described in clause (i) or (ii) of subsection (b)(2)(A) or in both such clauses, the approval may be made effective immediately.

"(B) If the applicant made a certification described inclause (iii) of subsection (b)(2)(A), the approval may be made effective on the date certified under clause (iii).

"(C) If the applicant made a certification described in clause (iv) of subsection (b)(2)(A), the approval shall be made effective immediately unless an action is brought for infringement of a patent which is the subject of the certification before the expiration of forty-five days from the date the notice provided under paragraph (3)(B) is received. If such an action is brought before the expiration of such days, the approval may be made effective upon the expiration of the eighteen-month period beginning on the date of the receipt of the notice provided under paragraph (3)(B) or such shorter or longer period as the court may order because either party to the action failed to reasonably cooperate in expediting the action, except that—

"(i) if before the expiration of such period the court decides that such patent is invalid or not infringed, the approval may be made effective on the date of the court decision, or

"(ii) if before the expiration of such period the court decides that such patent has been infringed, the approval may be made effective on such date as the court orders under section 271(e)(4)(A) of title 35, United States Code.

In such an action, each of the parties shall reasonably cooperate in expediting the action. Until the expiration of the forty-five-day period beginning on the date the notice made under paragraph (3)(B) is received, no action may be brought under section 2201 of title 28, United States Code, for a declaratory judgment with respect to the patent. Any action brought under such section 2201 shall be brought in the judicial district where the defendant has its principal place of business or a regular and established place of business.

"(D)(i) If an application (other than an abbreviated new drug application) submitted under subsection (b) for a drug, no active ingredient (including any ester or salt of the active ingredient) of which has been approved in any other application under subsection (b), was approved during the period beginning January 1, 1982, and ending on the date of the enactment of this subsection, the Secretary may not make the approval of another application for a drug for which investigations described in clause (A) of subsection (b)(1) and relied upon by the applicant for approval of the application were not conducted by or for the applicant or which the applicant has not obtained a right of reference or use from the person by or for whom the investigations were conducted effective before the expiration of ten years from the date of the approval of the application previously approved under subsection (b).

"(ii) If an application submitted under subsection (b) for a drug, no active ingredient (including any ester or salt of the active ingredient) of which has been approved in any other application under subsection (b),

is approved after the date of the enactment of this subsection and if the holder of the approved application certifies to the Secretary that no patent has ever been issued to any person for such drug or for a method of using such drug and that the holder cannot receive a patent for such drug or for a method of using such drug because in the opinion of the holder a patent may not be issued for such drug or for a method of using for any known therapeutic purposes such drug, the Secretary may not make the approval of another application for a drug for which investigations described in clause (A) of subsection (b)(1) and relied upon by the applicant for approval of the application were not conducted by or for the applicant or which the applicant has not obtained a right of reference or use from the person by or for whom the investigations were conducted effective before the expiration of four years from the date of the approval of the application previously approved under subsection (b) unless the Secretary determines that an adequate supply of such drug will not be available or the holder of the application approved under subsection (b) consents to an earlier effective date for an application under this subsection.".

SEC. 104. Section 505 of such Act is amended by adding at the end the following:

"(l) Safety and effectiveness data and information which has been submitted in an application under subsection (b) for a drug and which has not previously been disclosed to the public shall be made available to the public, upon request, unless extraordinary circumstances are shown—

"(1) if no work is being or will be undertaken to have the application approved,

"(2) if the Secretary has determined that the application is not approvable and all legal appeals have been exhausted,

"(3) if approval of the application under subsection (c) is withdrawn and all legal appeals have been exhausted,

"(4) if the Secretary has determined that such drug is not a new drug, or

"(5) upon the effective date of the approval of the first application under subsection (j) which refers to such drug or upon the date upon which the approval of an application under subsection (j) which refers to such drug could be made effective if such an application had been submitted.

"(m) For purposes of this section, the term 'patent' means a patent issued by the Patent and Trademark Office of the Department of Commerce.".

SEC. 105. (a) The Secretary of Health and Human Services shall promulgate, in accordance with the notice and comment requirements of section 553 of title 5, United States Code, such regulations as may be necessary for the administration of section 505 of the Federal Food, Drug, and Cosmetic Act, as amended by sections 101, 102, and 103 of this Act, within one year of the date of enactment of this Act.

(b) During the period beginning on the date of the enactment of this Act and ending on the date regulations promulgated under subsection (a) take effect, abbreviated new drug applications may be submitted in accordance with the provisions of section 314.2 of title 21 of the Code of Federal Regulations and shall be considered as suitable for any drug which has been approved for safety and effectiveness under section 505(c) of the Federal Food, Drug, and Cosmetic Act before the date of the enactment of this Act. If any such provision is inconsistent with the requirements of section 505(j) of the Federal Food, Drug, and Cosmetic Act, the Secretary shall consider the application under the applicable requirements of such section. The Secretary of Health and Human Services may not approve such an abbvreviated new drug application which is filed for a drug which is described in sections 505(c)(3)(D) and 505(j)(4)(D) of the Federal Food, Drug, and Cosmetic Act except in accordance with such section.

SEC. 106. Section 2201 of title 28, United States Code, is amended by inserting "(a)" before "In a case" and by adding at the end the following:

"(b) For limitations on actions brought with respect to drug patents see section 505 of the Federal Food, Drug, and Cosmetic Act.".

JUDICIARY COMMITTEE AMENDMENTS

Mr. KASTENMEIER. Mr. Chairman, I offer amendments recommended by the Committee on the Judiciary.

The CHAIRMAN. The Clerk will report the committee amendments to title I.

The Clerk read as follows:

Amendments recommended by the Committee on the Judiciary: Page 15, line 3, strike out "(i)."

Page 15, beginning on line 15, strike out all through line 10, page 16.

Page 27, line 5, strike out "(i)."

Page 27, insert close quotation marks at the end of line 21, and beginning on line 22, strike out all down through line 23, page 28.

Mr. KASTENMEIER. Mr. Chairman, this is a very simple amendment. What we propose to do here I think can be agreed to. A little later in the debate in the context of a much larger amendment this issue will surface again.

The amendment, which was approved by the Committee on the Judiciary, deleted from the bill authority of the Commissioner of the Food and Drug Administration to grant exclusive marketing authority for up to 4 years for unpatentable substances. The Judiciary Committee concluded that such authority to issue second class patents should not be granted without a strong showing of urgent need. There was no such showing. Further, the committee concluded that authority to grant the equivalent of a monopoly is something which should be limited to the appropriate Federal agencies, namely the Patent and Trademark Office in the case of nonobvious, useful inventions.

Having said that, I will say that subsequent to agreeing to this amendment, we will consider the question of whether similar authority should be granted, either for terms of 3 years or 5 years. It is my understanding this issue will come up at a later point in time in the form of an amendment that the gentleman from California [Mr. WAXMAN] will offer. I think at this point the amendment offered by the Committee on the Judiciary is not controversial. I urge adoption of the amendment.

The CHAIRMAN. The question is on the committee amendments recommended by the Committee on the Judiciary.

The committee amendments were agreed to.

The CHAIRMAN. Are there any other amendments to title I?

AMENDMENT OFFERED BY MR. WAXMAN

Mr. WAXMAN. Mr. Chairman, I offer an amendment.

The Clerk read as follows:

Amendment offered by Mr. WAXMAN:

Page 2, strike out line 17 and all that follows through line 6 on page 31 and insert in lieu thereof the following:

TITLE I—ABBREVIATED NEW DRUG APPLICATIONS

SEC. 101. Section 505 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 355) is amended by redesignating subsection (j) as subsection (k) and inserting after subsection (i) the following:

"(j)(1) Any person may file with the Secretary an abbreviated application for the approval of a new drug.

"(2)(A) An abbreviated application for a new drug shall contain—

"(i) information to show that the conditions of use prescribed, recommended, or suggested in the labeling proposed for the new drug have been previously approved for a drug listed under paragraph (6) (hereinafter in this subsection referred to as a 'listed drug');

"(ii)(I) if the listed drug referred to in clause (i) has only one active ingredient, information to show that the active ingredient of the new drug is the same as that of the listed drug,

"(II) if the listed drug referred to in clause (i) has more than one active ingredient, information to show that the active ingredients of the new drug are the same as those of the listed drug, or

"(III) if the listed drug referred to in clause (i) has more than one active ingredient and if one of the active ingredients of the new drug is different and the application is filed pursuant to the approval of a petition filed under subparagraph (C), information to show that the other active ingredients of the new drug are the same as the active ingredients of the listed drug, information to show that the different active ingredient is an active ingredient of a listed drug or of a drug which does not meet the requirements of section 201(p), and such other information respecting the different active ingredient with respect to which the petition was filed as the Secretary may require;

"(iii) information to show that the route of administration, the dosage form, and the strength of the new drug are the same as those of the listed drug referred to in clause (i) or, if the route of administration, the dosage form, or the strength of the new drug is different and the application is filed pursuant to the approval of a petition filed under subparagraph (C), such information respecting the route of administration, dosage form, or strength with respect to which the petition was filed as the Secretary may require;

"(iv) information to show that the new drug is bioequivalent to the listed drug referred to in clause (i), except that if the application is filed pursuant to the approval of a petition filed under subparagraph (C), information to show that the active ingredients of the new drug are of the same pharmacological or therapeutic class as those of the listed drug referred to in clause (i) and the new drug can be expected to have the same therapeutic effect as the listed drug when administered to patients for a condition of use referred to in clause (i);

"(v) information to show that the labeling proposed for the new drug is the same as the labeling approved for the listed drug referred to in clause (i) except for changes required because of differences approved under a petition filed under subparagraph

(C) or because the new drug and the listed drug are produced or distributed by different manufacturers;

"(vi) the items specified in clauses (B) through (F) of subsection (b)(1);

"(vii) a certification, in the opinion of the applicant and to the best of his knowledge, with respect to each patent which claims the listed drug referred to in clause (i) or which claims a use for such listed drug for which the applicant is seeking approval under this subsection and for which information is required to be filed under subsection (b) or (c)—

"(I) that such patent information has not been filed,

"(II) that such patent has expired,

"(III) of the date on which such patent will expire, or

"(IV) that such patent is invalid or will not be infringed by the manufacture, use, or sale of the new drug for which the application is submitted; and

"(viii) if with respect to the listed drug referred to in clause (i) information was filed under subsection (b) or (c) for a method of use patent which does not claim a use for which the applicant is seeking approval under this subsection, a statement that the method of use patent does not claim such a use.

The Secretary may not require that an abbreviated application contain information in addition to that required by clauses (i) through (viii).

"(B)(i) An applicant who makes a certification described in subparagraph (A)(vii)(IV) shall include in the application a statement that the applicant will give the notice required by clause (ii) to—

"(I) each owner of the patent which is the subject of the certification or the representative of such owner designated to receive such notice, and

"(II) the holder of the approved application under subsection (b) for the drug which is claimed by the patent or a use of which is claimed by the patent or the representative of such holder designated to receive such notice.

"(ii) The notice referred to in clause (i) shall state that an application, which contains data from bioavailability or bioequivalence studies, has been submitted under this subsection for the drug with respect to which the certification is made to obtain approval to engage in the commercial manufacture, use, or sale of such drug before the expiration of the patent referred to in the certification. Such notice shall include a detailed statement of the factual and legal basis of the applicant's opinion that the patent is not valid or will not be infringed.

"(iii) If an application is amended to include a certification described in subparagraph (A)(vii)(IV), the notice required by clause (ii) shall be given when the amended application is submitted.

"(C) If a person wants to submit an abbreviated application for a new drug which has a different active ingredient or whose route of administration, dosage form, or strength differ from that of a listed drug, such person shall submit a petition to the Secretary seeking permission to file such an application. The Secretary shall approve or disapprove a petition submitted under this subparagraph within ninety days of the date the petition is submitted. The Secretary shall approve such a petition unless the Secretary finds—

"(i) that investigations must be conducted to show the safety and effectiveness of the drug or of any of its active ingredients, the route of administration, the dosage form, or strength which differ from the listed drug; or

"(ii) that any drug with a different active ingredient may not be adequately evaluated for approval as safe and effective on the basis of the information required to be submitted in an abbreviated application.

"(3) Subject to paragraph (4), the Secretary shall approve an application for a drug unless the Secretary finds—

"(A) the methods used in, or the facilities and controls used for, the manufacture, processing, and packing of the drug are inadequate to assure and preserve its identity, strength, quality, and purity;

"(B) information submitted with the application is insufficient to show that each of the proposed conditions of use have been previously approved for the listed drug referred to in the application;

"(C)(i) if the listed drug has only one active ingredient, information submitted with the application is insufficient to show that the active ingredient is the same as that of the listed drug,

"(ii) if the listed drug has more than one active ingredient, information submitted with the application is insufficient to show that the active ingredients are the same as the active ingredients of the listed drug, or

"(iii) if the listed drug has more than one active ingredient and if the application is for a drug which has an active ingredient different from the listed drug, information submitted with the application is insufficient to show—

"(I) that the other active ingredients are the same as the active ingredients of the listed drug, or

"(II) that the different active ingredient is an active ingredient of a listed drug or a drug which does not meet the requirements of section 201(p),

or no petition to file an application for the drug with the different ingredient was approved under paragraph (2)(C);

"(D)(i) if the application is for a drug whose route of administration, dosage form, or strength of the drug is the same as the route of administration, dosage form, or strength of the listed drug referred to in the application, information submitted in the application is insufficient to show that the route of administration, dosage form, or strength is the same as that of the listed drug, or

"(ii) if the application is for a drug whose route of administration, dosage form, or strength of the drug is different from that of the listed drug referred to in the application, no petition to file an application for the drug with the different route of administration, dosage form, or strength was approved under paragraph (2)(C);

"(E) if the application was filed pursuant to the approval of a petition under paragraph (2)(C), the application did not contain the information required by the Secretary respecting the active ingredient, route of administration, dosage form, or strength which is not the same;

"(F) information submitted in the application is insufficient to show that the drug is bioequivalent to the listed drug referred to in the application or, if the application was filed pursuant to a petition approved under paragraph (2)(C), information submitted in the application is insufficient to show that the active ingredients of the new drug are of the same pharmacological or therapeutic class as those of the listed drug referred to in paragraph (2)(A)(i) and that the new drug can be expected to have the same therapeutic effect as the listed drug when administered to patients for a condition of use referred to in such paragraph;

"(G) information submitted in the application is insufficient to show that the labeling proposed for the drug is the same as the labeling approved for the listed drug referred to in the application except for changes required because of differences approved under a petition filed under paragraph (2)(C) or because the drug and the listed drug are produced or distributed by different manufacturers;

"(H) information submitted in the application or any other information available to the Secretary shows that (i) the inactive ingredients of the drug are unsafe for use under the conditions prescribed, recommended, or suggested in the labeling proposed for the drug, or (ii) the composition of the drug is unsafe under such conditions because of the type or quantity of inactive ingredients included or the manner in which the inactive ingredients are included;

"(I) the approval under subsection (c) of the listed drug referred to in the application under this subsection has been withdrawn or suspended for grounds described in the first sentence of subsection (e), the Secretary has published a notice of opportunity for hearing to withdraw approval of the listed drug under subsection (c) for grounds described in the first sentence of subsection (e), the approval under this subsection of the listed drug referred to in the application under this subsection has been withdrawn or suspended under paragraph (5), or the Secretary has determined that the listed drug has been withdrawn from sale for safety or effectiveness reasons;

"(J) the application does not meet any other requirement of paragraph (2)(A); or

"(K) the application contains an untrue statement of material fact.

"(4)(A) Within one hundred and eighty days of the initial receipt of an application under paragraph (2) or within such additional period as may be agreed upon by the Secretary and the applicant, the Secretary shall approve or disapprove the application.

"(B) The approval of an application submitted under paragraph (2) shall be made effective on the last applicable date determined under the following:

"(i) If the applicant only made a certification described in subclause (I) or (II) of paragraph (2)(A)(vii) or in both such subclauses, the approval may be made effective immediately.

"(ii) If the applicant made a certification described in subclause (III) of paragraph (2)(A)(vii), the approval may be made effective on the date certified under subclause (III).

"(iii) If the applicant made a certification described in subclause (IV) of paragraph (2)(A)(vii), the approval shall be made effective immediately unless an action is brought for infringement of a patent which is the subject of the certification before the expiration of forty-five days from the date the notice provided under paragraph (2)(B)(i) is received. If such an action is brought before the expiration of such days, the approval shall be made effective upon the expiration of the thirty-month period beginning on the date of the receipt of the notice provided under paragraph (2)(B)(i) or such shorter or longer period as the court may order because either party to the action failed to reasonably cooperate in expediting the action, except that—

"(I) if before the expiration of such period the court decides that such patent is invalid or not infringed, the approval shall be made effective on the date of the court decision,

"(II) if before the expiration of such period the court decides that such patent has been infringed, the approval shall be made effective on such date as the court orders under section 271(e)(4)(A) of title 35, United States Code, or

"(III) if before the expiration of such period the court grants a preliminary injunction prohibiting the applicant from engaging in the commercial manufacture or sale of the drug until the court decides the issues of patent validity and infringement and if the court decides that such patent is not invalid or not infringed, the approval shall be made effective on the date of such court decision.

In such an action, each of the parties shall reasonably cooperate in expediting the action. Until the expiration of forty-five days from the date the notice made under paragraph (2)(B)(i) is received, no action may be brought under section 2201 of title 28, United States Code, for a declaratory judgment with respect to the patent. Any action brought under section 2201 shall be brought in the judicial district where the defendant has its principal place of business or a regular and established place of business.

"(iv) If the application contains a certification described in subclause (IV) of paragraph (2)(A)(vii) and is for a drug for which a previous application has been submitted under this subsection containing such a certification, the application shall be made effective not earlier than one hundred and eighty days after—

"(I) the date the Secretary receives notice from the applicant under the previous application of the first commercial marketing of the drug under the previous application, or

"(II) the date of a decision of a court in an action described in clause (iii) holding the patent which is the subject of the certification to be invalid or not infringed,

whichever is earlier.

"(C) If the Secretary decides to disapprove an application, the Secretary shall give the applicant notice of an opportunity for a hearing before the Secretary on the question of whether such application is approvable. If the applicant elects to accept the opportunity for hearing by written request within thirty days after such notice, such hearing shall commence not more than ninety days after the expiration of such thirty days unless the Secretary and the applicant otherwise agree. Any such hearing shall thereafter be conducted on an expedited basis and the Secretary's order thereon shall be issued within ninety days after the date fixed by the Secretary for filing final briefs.

"(D)(i) If an application (other than an abbreviated new drug application) submitted under subsection (b) for a drug, no active ingredient (incuding any ester or salt of the active ingredient) of which has been approved in any other application under subsection (b), was approved during the period beginning January 1, 1982, and ending on the date of the enactment of this subsection, the Secretary may not make the approval of an application submitted under this subsection which refers to the drug for which the subsection (b) application was submitted effective before the expiration of ten years from the date of the approval of the application under subsection (b).

"(ii) If an application submitted under subsection (b) for a drug, no active ingredient (including any ester or salt of the active ingredient) of which has been approved in any other application under subsection (b), is approved after the date of the enactment of this subsection, no application may be submitted under this subsection which refers to the drug for which the subsection (b) application was submitted before the expiration of five years from the date of the approval of the application under subsection (b), except that such an application may be submitted under this subsection after the expiration of four years from the date of the approval of the subsection (b) application if it contains a certification of patent invalidity or noninfringement described in subclause (IV) of paragraph (2)(A)(vii). The approval of such an application shall be made effective in accordance with subparagraph (B) except that, if an action for patent infringement is commenced during the one-year period beginning forty-eight months after the date of the approval of the subsection (b) application, the thirty-month period referred to in subparagraph (B)(iii) shall be extended by such amount of time (if any) which is required for seven and one-half years to have elapsed from the date of approval of the subsection (b) application.

"(iii) If an application submitted under subsection (b) for a drug, which includes an active ingredient (including any ester or salt of the active ingredient) that has been approved in another application approved under subsection (b), is approved after the date of enactment of this subsection and if such application contains reports of new clinical investigations (other than bioavailability studies) essential to the approval of the application and conducted or sponsored by the applicant, the Secretary may not make the approval of an application submitted under this subsection for the conditions of approval of such drug in the subsection (b) application effective before the expiration of three years from the date of the approval of the application under subsection (b) for such drug.

"(iv) If a supplement to an application approved under subsection (b) is approved after the date of enactment of this subsection and the supplement contains reports of new clinical investigations (other than bioavailability studies) essential to the approval of the supplement and conducted or sponsored by the person submitting the supplement, the Secretary may not make the approval of an application submitted under this subsection for a change approved in the supplement effective before the expiration of three years from the date of the approval of the supplement under subsection (b).

"(v) If an application (or supplement to an application) submitted under subsection (b) for a drug, which includes an active ingredient (including any ester or salt of the active ingredient) that has been approved in another application under subsection (b), was approved during the period beginning January 1, 1982, and ending on the date of the enactment of this subsection, the Secretary may not make the approval of an application submitted under this subsection which refers to the drug for which the subsection (b) application was submitted or which refers to a change approved in a supplement to the subsection (b) application effective before the expiration of two years from the date of enactment of this subsection.

"(5) If a drug approved under this subsection refers in its approved application to a drug the approval of which was withdrawn or suspended for grounds described in the first sentence of subsection (e) or was withdrawn or suspended under this paragraph or which, as determined by the Secretary, has been withdrawn from sale for safety or effectiveness reasons, the approval of the drug under this subsection shall be withdrawn or suspended—

"(A) for the same period as the withdrawal or suspension under subsection (e) or this paragraph, or

"(B) if the listed drug has been withdrawn from sale, for the period of withdrawal from sale or, if earlier, the period ending on the date the Secretary determines that the withdrawal from sale is not for safety or effectiveness reasons.

"(6)(A)(i) Within sixty days of the date of the enactment of this subsection, the Secretary shall publish and make available to the public—

"(I) a list in alphabetical order of the official and proprietary name of each drug which has been approved for safety and effectiveness under subsection (c) before the date of the enactment of this subsection:

"(II) the date of approval if the drug is approved after 1981 and the number of the application which was approved; and

"(III) whether in vitro or in vivo bioequivalence studies, or both such studies, are required for applications filed under this subsection which will refer to the drug published.

"(ii) Every thirty days after the publication of the first list under clause (i) the Secretary shall revise the list to include each drug which has been approved for safety and effectiveness under subsection (c) or approved under this subsection during the thirty day-period.

"(iii) When patent information submitted under subsection (b) or (c) respecting a drug included on the list is to be published by the Secretary the Secretary shall, in revisions made under clause (ii), include such information for such drug.

"(B) A drug approved for safety and effectiveness under subsection (c) or approved under this subsection shall, for purposes of this subsection, be considered to have been published under subparagraph (A) on the date of its approval or the date of enactment, whichever is later.

"(C) If the approval of a drug was withdrawn or suspended for grounds described in the first sentence of subsection (e) or was withdrawn or suspended under paragraph (5) or if the Secretary determines that a drug has been withdrawn from sale for safety or effectiveness reasons, it may not be published in the list under subparagraph (A) or, if the withdrawal or suspension occurred after its publication in such list, it shall be immediately removed from such list—

"(i) for the same period as the withdrawal or suspension under subsection (e) or paragraph (5), or

"(ii) if the listed drug has been withdrawn from sale, for the period of withdrawal from sale or, if earlier, the period ending on the date the Secretary determines that the withdrawal from sale is not for safety or effectiveness reasons.

A notice of the removal shall be published in the Federal Register.

"(7) For purposes of this subsection:

"(A) The term 'bioavailability' means the rate and extent to which the active ingredient or therapeutic ingredient is absorbed from a drug and becomes available at the site of drug action.

"(B) A drug shall be considered to be bioequivalent to a listed drug if—

"(i) the rate and extent of absorption of the drug do not show a significant difference from the rate and extent of absorption of the listed drug when administered at the same molar dose of the therapeutic ingredient under similar experimental conditions in either a single dose or multiple doses; or

"(ii) the extent of absorption of the drug does not show a significant difference from the extent of absorption of the listed drug when administered at the same molar dose of the therapeutic ingredient under similar experimental conditions in either a single dose or multiple doses and the difference from the listed drug in the rate of absorption of the drug is intentional, is reflected in its proposed labeling, is not essential to the

attainment of effective body drug concentrations on chronic use, and is considered medically insignificant for the drug.".

SEC. 102. (a)(1) Section 505(b) of such Act is amended by adding at the end the following: "The applicant shall file with the application the patent number and the expiration date of any patent which claims the drug for which the applicant submitted the application or which claims a method of using such drug and with respect to which a claim of patent infringement could reasonably be asserted if a person not licensed by the owner engaged in the manufacture, use, or sale of the drug. If any application is filed under this subsection for a drug and a patent which claims such drug or a method of using such drug is issued after the filing date but before approval of the application, the applicant shall amend the application to include the information required by the preceding sentence. Upon approval of the application, the Secretary shall publish information submitted under the two preceding sentences.".

(2) Section 505(c) of such Act is amended by inserting "(1)" after "(c)", by redesignating paragraphs (1) and (2) as subparagraphs (A) and (B), respectively, and by adding at the end the following:

"(2) If the patent information described in subsection (b) could not be filed with the submission of an application under subsection (b) because the application was filed before the patent information was required under subsection (b) or a patent was issued after the application was approved under such subsection, the holder of an approved application shall file with the Secretary the patent number and the expiration date of any patent which claims the drug for which the application was submitted or which claims a method of using such drug and with respect to which a claim of patent infringement could reasonably be asserted if a person not licensed by the owner engaged in the manufacture, use, or sale of the drug. If the holder of an approved application could not file patent information under subsection (b) because it was not required at the time the application was approved, the holder shall file such information under this subsection not later than thirty days after the date of the enactment of this sentence, and if the holder of an approved application could not file patent information under subsection (b) because no patent had been issued when the application was filed or approved, the holder shall file such information under this subsection not later than thirty days after the date the patent involved is issued. Upon the submission of patent information under this subsection, the Secretary shall publish it.".

(3)(A) The first sentence of section 505(d) of such Act is amended by redesignating clause (6) as clause (7) and inserting after clause (5) the following: "(6) the application failed to contain the patent information prescribed by subsection (b); or".

(B) The first sentence of section 505(e) of such Act is amended by redesignating clause (4) as clause (5) and inserting after clause (3) the following: "(4) the patent information prescribed by subsection (c) was not filed within thirty days after the receipt of written notice from the Secretary specifying the failure to file such information; or".

(b)(1) Section 505(a) of such Act is amended by inserting "or (j)" after "subsection (b)".

(2) Section 505(c) of such Act is amended by striking out "this subsection" and inserting in lieu thereof "subsection (b)".

(3) The second sentence of section 505(e) of such Act is amended by inserting "submitted under subsection (b) or (j)" after "an application".

(4) The second sentence of section 505(e) is amended by striking out "(j)" each place it occurs in clause (1) and inserting in lieu thereof "(k)".

(5) Section 505(k)(1) of such Act (as so redesignated) is amended by striking out "pursuant to this section" and inserting in lieu thereof "under subsection (b) or (j)".

(6) Subsections (a) and (b) of section 527 of such Act are each amended by striking out "505(b)" each place it occurs and inserting in lieu thereof "505".

SEC. 103. (a) Section 505(b) of such Act is amended by inserting "(1)" after "(b)", by redesignating clauses (1) through (6) as clauses (A) through (F), respectively, and by adding at the end the following:

"(2) An application submitted under paragraph (1) for a drug for which the investigations described in clause (A) of such paragraph and relied upon by the applicant for approval of the application were not conducted by or for the applicant and for which the applicant has not obtained a right of reference or use from the person by or for whom the investigations were conducted shall also include—

"(A) a certification, in the opinion of the applicant and to the best of his knowledge, with respect to each patent which claims the drug for which such investigations were conducted or which claims a use for such drug for which the applicant is seeking approval under this subsection and for which information is required to be filed under paragraph (1) or subsection (c)—

"(i) that such patent information has not been filed,

"(ii) that such patent has expired,

"(iii) of the date on which such patent will expire, or

"(iv) that such patent is invalid or will not be infringed by the manufacture, use, or sale of the new drug for which the application is submitted; and

"(B) if with respect to the drug for which investigations described in paragraph (1)(A) were conducted information was filed under paragraph (1) or subsection (c) for a method of use patent which does not claim a use for which the applicant is seeking approval under this subsection, a statement that the method of use patend does not claim such a use.

"(3)(A) An applicant who makes a certification described in paragraph (2)(A)(iv) shall include in the application a statement that the applicant will give the notice required by subparagraph (B) to—

"(i) each owner of the patent which is the subject of the certification or the representative of such owner designated to receive such notice, and

"(ii) the holder of the approved application under subsection (b) for the drug which is claimed by the patent or a use of which is claimed by the patent or the representative of such holder designated to receive such notice.

"(B) The notice referred to in subparagraph (A) shall state that an application has been submitted under this subsection for the drug with respect to which the certification is made to obtain approval to engage in the commercial manufacture, use, or sale of the drug before the expiration of the patent referred to in the certification. Such notice shall include a detailed statement of the factual and legal basis of the applicant's opinion that the patent is not valid or will not be infringed.

"(C) If an application is amended to include a certification described in paragraph (2)(A)(iv), the notice required by subparagraph (B) shall be given when the amended application is submitted.".

(b) Section 505(c) of such Act (as amended by section 102(a)(2)) is amended by adding at the end the following:

"(3) The approval of an application filed under subsection (b) which contains a certification required by paragraph (2) of such subsection shall be made effective on the last applicable date determined under the following:

"(A) If the applicant only made a certification described in clause (i) or (ii) of subsection (b)(2)(A) or in both such clauses, the approval may be made effective immediately.

"(B) If the applicant made a certification described in clause (iii) of subsection (b)(2)(A), the approval may be made effective on the date certified under clause (iii).

"(C) If the applicant made a certification described in clause (iv) of subsection (b)(2)(A), the approval shall be made effective immediately unless an action is brought for infringement of a patent which is the subject of the certification before the expiration of forty-five days from the date the notice provided under paragraph (3)(B) is received. If such an action is brought before the expiration of such days, the approval may be made effective upon the expiration of the thirty-month period beginning on the date of the receipt of the notice provided under paragraph (3)(B) or such shorter or longer period as the court may order because either party to the action failed to reasonably cooperate in expediting the action, except that—

"(i) if before the expiration of such period the court decides that such patent is invalid or not infringed, the approval may be made effective on the date of the court decision,

"(ii) if before the expiration of such period the court decides that such patent has been infringed, the approval may be made effective on such date as the court orders under section 271(e)(4)(A) of title 35, United States Code, or

"(iii) if before the expiration of such period the court grants a preliminary injunction prohibiting the applicant from engaging in the commercial manufacture or sale of the drug until the court decides the issues of patent validity and infringement and if the court decides that such patent is not invalid or not infringed, the approval shall be made effective on the date of such court decision.

In such an action, each of the parties shall reasonably cooperate in expediting the action. Until the expiration of forty-five days from the date the notice made under paragraph (3)(B) is received, no action may be brought under section 2201 of title 28, United States Code, for a declaratory judgment with respect to the patent. Any action brought under such section 2201 shall be brought in the judicial district where the defendant has its principal place of business or a regular and established place of business.

"(D)(i) If an application (other than an abbreviated new drug application) submitted under subsection (b) for a drug, no active ingredient (including any ester or salt of the active ingredient) of which has been approved in any other application under subsection (b), was approved during the period beginning January 1, 1982, and ending on the date of the enactment of this subsection, the Secretary may not make the approval of another application for a drug for which the investigations described in clause (A) of subsection (b)(1) and relied upon by the applicant for approval of the application were not conducted by or for the applicant and for which the applicant has not obtained a right of reference or use from the person by or for whom the investi-

gations were conducted effective before the expiration of ten years from the date of the approval of the application previously approved under subsection (b).

"(ii) If an application submitted under subsection (b) for a drug, no active ingredient (including any ester or salt of the active ingredient) of which has been approved in any other application under subsection (b), is approved after the date of the enactment of this clause, no application which refers to the drug for which the subsection (b) application was submitted and for which the investigations described in clause (A) of subsection (b)(1) and relied upon by the applicant for approval of the application were not conducted by or for the applicant and for which the applicant has not obtained a right of reference or use from the person by or for whom the investigations were conducted may be submitted under subsection (b) before the expiration of five years from the date of the approval of the application under subsection (b), except that such an application may be submitted under subsection (b) after the expiration of four years from the date of the approval of the subsection (b) application if it contains a certification of patent invalidity or noninfringement described in clause (iv) of subsection (b)(2)(a). The approval of such an application shall be made effective in accordance with this paragraph except that, if an action for patent infringement is commenced during the one-year period beginning forty-eight months after the date of the approval of the subsection (b) application, the thirty-month period referred to in subparagraph (C) shall be extended by such amount of time (if any) which is required for seven and one-half years to have elapsed from the date of approval of the subsection (b) application.

"(iii) If an application submitted under subsection (b) for a drug, which includes an active ingredient (including any ester or salt of the active ingredient) that has been approved in another application approved under subsection (b), is approved after the date of the enactment of this clause and if such application contains reports of new clinical investigations (other than bioavailability studies) essential to the approval of the application and conducted or sponsored by the applicant, the Secretary may not make the approval of an application submitted under subsection (b) for the conditions of approval of such drug in the approved subsection (b) application effective before the expiration of three years from the date of the approval of the application under subsection (b) if the investigations described in clause (A) of subsection (b)(1) relied upon by the applicant for approval of the application were not conducted by or for the applicant and if the applicant has not obtained a right of reference or use from the person by or for whom the investigations were conducted.

"(iv) If a supplement to an application approved under subsection (b) is approved after the date of enactment of this clause and the supplement contains reports of new clinical investigations (other than bioavailability studies) essential to the approval of the supplement and conducted or sponsored by the person submitting the supplement, the Secretary may not make the approval of an application submitted under subsection (b) for a change approved in the supplement effective before the expiration of three years from the date of the approval of the supplement under subsection (b) if the investigations described in clause (A) of subsection (b)(1) and relied upon by the applicant for approval of the application were not conducted by or for the applicant and if the applicant has not obtained a right of reference or use from the person by or for whom the investigations were conducted.

"(v) If an application (or supplement to an application) submitted under subsection (b) for a drug, which includes an active ingredient (including any ester or salt of the active ingredient) that has been approved in another application under subsection (b), was approved during the period beginning January 1, 1982, and ending on the date of the enactment of this clause, the Secretary may not make the approval of an application submitted under this subsection and for which the investigations described in clause (A) of subsection (b)(1) and relied upon by the applicant for approval of the application were not conducted by or for the applicant and for which the applicant has not obtained a right of reference or use from the person by or for whom the investigations were conducted and which refers to the drug for which the subsection (b) application was submitted effective before the expiration of two years from the date of enactment of this clause.".

SEC. 104. Section 505 of such Act is amended by adding at the end the following:

"(l) Safety and effectiveness data and information which has been submitted in an application under subsection (b) for a drug and which has not previously been disclosed to the public shall be made available to the public, upon request, unless extraordinary circumstances are shown—

"(1) if no work is being or will be undertaken to have the application approved,

"(2) if the Secretary has determined that the application is not approvable and all legal appeals have been exhausted,

"(3) if approval of the application under subsection (c) is withdrawn and all legal appeals have been exhausted,

"(4) if the Secretary has determined that such drug is not a new drug, or

"(5) upon the effective date of the approval of the first application under subsection (j) which refers to such drug or upon the date upon which the approval of an application under subsection (j) which refers to such drug could be made effective is such an application had been submitted.

"(m) For purposes of this section, the term 'patent' means a patent issued by the Patent and Trademark Office of the Department of Commerce.".

SEC. 105. (a) The Secretary of Health and Human Services shall promugate, in accordance with the notice and comment requirements of section 553 of title 5, United States Code, such regulations as may be necessary for the administration of section 505 of the Federal Food, Drug, and Cosmetic Act, as amended by section 101, 102, and 103 of this Act, within one year of the date of enactment of this Act.

(b) During the period beginning sixty days after the date of the enactment of this Act and ending on the date regulations promulgated under subsection (a) take effect, abbreviated new drug applications may be submitted in accordance with the provisions of section 314.2 of title 21 of the Code of Federal Regulations and shall be considered as suitable for any drug which has been approved for safety and effectiveness under section 505(c) of the Federal Food, Drug, and Cosmetic Act before the date of the enactment of this Act. If any such provision is inconsistent with the requirements of section 505(j) of the Federal Food, Drug, and Cosmetic Act, the Secretary shall consider the application under the applicable requirements of such section. The Secretary of Health and Human Services may not approve such an abbreviated new drug application which is filed for a drug which is described in sections 505(c)(3)(D) and 505(j)(4)(D) of the Federal Food, Drug, and Cosmetic Act except in accordance with such section.

SEC. 106. Section 2201 of title 28, United States Code, is amended by inserting "(a)" before "In a case" and by adding at the end the following:

"(b) For limitations on actions brought with respect to drug patents see section 505 of the Federal Food, Drug, and Cosmetic Act.".

Mr. WAXMAN (during the reading). Mr. Chairman, I ask unanimous consent that the amendment be considered as read and printed in the RECORD.

The CHAIRMAN. Is there objection to the request of the gentleman from California?

There was no objection.

Mr. WAXMAN. Mr. Chairman, this amendment makes several changes to title I of the bill to incorporate compromises reached in negotiations between the brand name drug industry and the generic drug industry. While the bill before us has been endorsed by an overwhelming majority of the brand name drug companies as well as the generic drug industry, consumer, senior citizen, and labor groups, several major drugmakers and the Patent and Trademark Office continued to have concerns about some provisions of H.R. 3605.

During the final week of session before the August break, the chairman of the Senate Labor and Human Resources Committee, Senator HATCH, worked tirelessly to address these last remaining concerns. As a result of his diligence and committment to making more low-cost generic drugs available for our citizens, a number of changes to the bill were agreed upon by the brand name and generic drug industries and subsequently passed by the Senate on August 10.

With technical and minor modifications, this amendment adds those changes to the bill before us. Let me describe the changes.

First, the amendment provides a 5-year period of exclusive market life for drugs approved for the first time after enactment of the legislation. This provision will give the drug industry the incentives needed to develop new chemical entities whose therapeutic usefulness is discovered late when little or no patent life remains.

Generic drugmakers that wished to challenge the validity of any patent life remaining on such drugs would not be barred from doing so. Such patent litigation could commence at the expiration of the fourth year of the period and the generic drugmaker could begin marketing after a favorable court decision or 7½ years after approval of the brand name drug, whichever occurs first.

Second, the 10-year period of exclusive market life for drugs approved between 1982 and the date of enactment of the bill is supplemented by affording a 2-year period of exclusive market life to drugs which are not new chemi-

cal entities approved during that same period.

Third, a 3-year period of exclusive market life is afforded to nonnew chemical entities approved after enactment of the bill which have undergone new clinical studies essential to FDA approval. This provision will encourage drugmakers to obtain FDA approval for significant therapeutic uses of previously approved drugs.

Fourth, the period during which a generic drugmaker may not market pending the judicial resolution of a challenge to patent validity is expanded from the 18 months currently in the bill to 30 months. Some of the brand name drug companies felt this change increases the likelihood that such patent, litigation will be concluded before the generic drugmaker begins marketing.

Fifth, the bill clarifies the authority of the Food and Drug Administration [FDA] to reject a petition filed by a generic drugmaker for consideration of a combination product that differs from the approved product of the brand name manufacturer.

Last, the authority of the FDA to disapprove generic copies of brand name drugs when the agency is seeking to remove the brand name drug from the market due to safety or effectiveness concerns is clarified.

While there was some discussion on amending section 104 of the bill dealing with the confidentiality of safety and effectiveness data and information submitted in a new drug application, no change is made in that section by this amendment. With the exception of subsection (l)(5), the provision in section 104 statutorily codifies the current FDA regulation pertaining to disclosure of this type of information. FDA's current approach to release of the data and to its policies regarding the extraordinary circumstances when the data would not be released are explained in the premable to FDA's Freedom of Information Act regulations—39 Federal Register 44602-44642 (December 24, 1974), Section 104 adopts this same approach.

These changes to H.R. 3605 do not upset the fundamental balance of the bill that assures consumers of more low-cost generic drugs when a valid patent expires and the drug industry of sufficient incentive to develop innovative pharmaceutical therapies. I urge my colleagues to support the amendment.

□ 1150

Mr. MADIGAN. Mr. Chairman, I rise in strong support of the amendment offered by the gentleman from California, which takes care of one of the two administration objections to this bill. I understand that their second objection will be addressed in an amendment to be offered later by the gentleman from California.

The amendment now under consideration adopts the compromise proposals agreed to by Senator HATCH and the chief executive officers of the domestic drug companies that previously were not supporting this bill. These changes are fair and reasonable; they do not alter the basic thrust of H.R. 3605, and they do bring the bill in line with the Senate-passed bill, so that this important measure can be quickly signed into law.

I urge my colleagues to support the amendment of the gentleman from California [Mr. WAXMAN].

Mr. KASTENMEIER. Mr. Chairman, I reluctantly rise in opposition to the amendment offered by the gentleman from California to express strong reservations about the amendment.

The bill before us, H.R. 3605, represents a far from perfect compromise which—on balance—furthers the public interest. This amendment, on the other hand, undoes that balance and tilts too heavily toward unwarranted rewards for private economic interests. Moreover, the various changes suggested by this amendment constitute fundamentally wrongheaded public policy. The proposed changes in the bill include four different types of monopoly or exclusive marketing authority. These changes do little to further the interests of consumers, nor do they strengthen our system of intellectual property protection.

The first "minor" change made by this amendment is to protect from generic competition until the fall of 1986 drugs approved between 1982 and today which do not constitute "new chemical entities." In lay terms this means that for the next 2 years no one may obtain approval for a generic substitute for the oral contraceptive Ortho-Novum, produced by Johnson & Johnson. This provision also precludes generic competition in the over-the-counter [OTC] market for two newly introduced pain relievers, Advil, made by American Home Products, and NUPRIN, made by Bristol Myers. The sales of the drugs affected by this minor amendment are in the hundreds of millions of dollars. Precluding competition by generics for these drugs cannot and do not serve the interests of consumers.

The second minor change to the bill being proposed is to grant the Food and Drug Administration authority to bar generic competition for either 5-plus or 3 years, depending on the nature of the drug. The grant of authority to issue the functional equivalent of a monopoly should be reserved to the patent and copyright laws. These changes serve to undermine the integrity of our system of intellectual property law. Furthermore, the basic rationale for this grant of authority to the FDA is that patent protection is insufficient. Thus, under this proposal, the FDA will be able to grant a monopoly to persons for ideas which are not sufficiently unique or useful to constitute a patentable invention. Let me give two quick examples of how bad an idea this will be.

First, under this proposal a drug company whose patent is going to expire could—under some circumstances—conduct short, simple, noninnovative, clinical trials and seek FDA approval for an over-the-counter version of the drug. Under this proposal, even though this change would not affect patent status, the drug company would receive a "reward" of 3 years of exclusive marketing authority.

In a second example, a drug company could seek FDA approval for the use of an unpatentable substance—like a naturally occurring chemical or substances like lithium, vaccines, or blood products—and obtain a right to exclude all others from the market for up to 3 years. The proposal does not guide the FDA in determining who first had the idea—which is the approach used in patent law. Rather, the monopoly is to be granted to whomever the FDA grants approval first. This first-to-file or first-to-decision approach is a radical departure from our current intellectual property law.

The CHAIRMAN. The time of the gentleman from Wisconsin [Mr. KASTENMEIER] has expired.

(By unanimous consent, Mr. KASTENMEIER was allowed to proceed for 2 additional minutes.)

Mr. KASTENMEIER. Finally, with respect to the proposed 5-year rule, let me explain to my colleagues what this will mean with respect to patent litigation. Once this provision is in place, then no one will be able to challenge the validity of a patent for at least 5 years. Thus, we will have two types of patents: those subject to challenge at any time after issuance, and those subject to challenge only after the expiration of 5 years. The net effect of this provision is to give pioneer drug companies super patents—unchallengable patents. In addition, this provision will delay the entry of generic competition for up to 90 months—7½ years—even when the original patent is invalid.

I should also note that these giveaways should not have been necessary. We already had made a compromise by putting in the bill a 10-year rule that serves to protect from generic competition drugs approved between 1982 and the date of enactment for the next 10 years. Thus, we are protecting the following drugs:

Zantac by Glaxo/Roche;
Dolobid by Merck Sharpe & Dohme;
Feldene by Pfizer [1];
Cardizem by Marion [1];
Wytension by Wyeth.

These drugs have a combined estimated market of over a half of a billion dollars—$500 million. Thus, we have already given a significant concession to the drug industry, and I fail to see why we should go farther.

[1] These drugs actually received more favorable treatment in the nature of a 10-year protection—the functional equivalent of patent term extension—than any new drug patented after the date of enactment will receive.

CONCLUSION

The agreement which has passed the U.S. Senate—and which is represented in this proposal—is not in the public interest. This proposal is not the result of thoughtful consideration by committees or by Members of Congress; rather it is the byproduct of a backroom deal between two branches of the drug industry. While there are substantial consumer benefits through the easing of approvals for generic competition, there are some significant, anticonsumer provisions in the amendment before us. I urge defeat of the amendment.

□ 1200

AMENDMENT OFFERED BY MR. SHAW TO THE AMENDMENT OFFERED BY MR. WAXMAN

Mr. SHAW. Mr. Chairman, I offer an amendment to the amendment offered by the gentleman from California [Mr. WAXMAN].

The Clerk read as follows:

Amendment offered by Mr. SHAW to the amendment offered by Mr. WAXMAN: In the proposed section 505(j)(4)(D)(iii) and 505(c)(3)C) of the Federal Food, Drug and Cosmetics Act, strike out "thirty-month" and insert in lieu thereof "eighteen-month".

Mr. SHAW. Mr. Chairman, as I view the debate this morning and the sleepy pace at which it goes on and the discussion of this not being a controversial substitute to the House bill, I think all the Members should take careful note of exactly what we are doing.

I have heard this morning around this floor talk of compromise. The word "compromise" has been used very often. But I think when we are talking about extending patent protection on medicine that we have to be very conscious and very concerned about people who were not involved in this so-called compromise.

First of all, we have to consider who is using these drugs the most. It is the elderly; it is the sick. And anything that we do to extend the life of patents, anything we do to keep other drugs off of the market, is going to have and extraordinary effect upon this segment of our population.

The House bill, as it came to the Committee on the Judiciary and the other committees of Congress, provided that in the event a new application is filed and infringement notification is also filed, that the new drug—which could be a great drug, could be a great thing for the American consumer—will be held off of the market for 18 months. I do not think that that is good law.

But the language that we are now considering is even worse law. It extends this period of time for 30 months. This means that during the period of time that litigation is going on to determine whether this drug is, in fact, an infringement, that those who would compete in this market would be prohibited from doing so for 18 months, and it is even more extraordinary when we extend that to 30 months.

Now, this is automatic. It is automatic. There are no damages provided for in this bill. If the suit was wrongfully brought just to keep the competition off the market, the generic drug company that was manufacturing the other drug or the other drug company which would, in fact, put itself in a competitive position—and competition does, I must say, mean lower costs to the consumer—there are no responsibilities in this bill for any damages that might be incurred.

So an infringement suit can be brought of a very frivolous nature. It does not, in our Federal court proceeding, require any great attorney to let litigation drag on for 30 months, as clogged as our Federal courts are today. I think that the group that we must talk to are the aged and the sick of this country. That is who I think we have to have a primary responsibility for here in this Chamber today.

This amendment does not do all that much, but I think it is an important step forward and it is one that we should certainly support. I would ask my colleagues to simply vote in favor of this amendment and roll that time period back from 30 months to the 18 months as the language is in the House bill.

Mr. KASTENMEIER. Mr. Chairman, will the gentleman from Florida yield?

Mr. SHAW. I would be glad to yield to the chairman, the gentleman from Wisconsin.

Mr. KASTENMEIER. I thank the gentleman for yielding.

Mr. Chairman, I am pleased to join the gentleman in support of this amendment. I think it is an excellent idea. I think it does get us back to where we were before.

As the gentleman has so well explained, it is certainly in the public interest.

Mr. SHAW. I thank the gentleman for his support, and also the leadership that he has given in the Committee on the Judiciary in getting this House bill before us today.

Mr. WAXMAN. Mr. Chairman, I rise in reluctant but nevertheless opposition to the amendment offered by the gentleman from Florida.

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

Mr. WAXMAN. Mr. Chairman, I rise in opposition to the amendment because the change from 18 months to 30 months was a change agreed upon as part of a package to bring along all of the groups that were interested in this legislation.

The facts of life are that a generic drug manufacturer will await, as a practical matter, until the decision of a court on a patent challenge before that manufacturer markets a generic drug. That is the information they have given us as to their practice. We would expect the litigation to be resolved and, once it is resolved, it is determinative of the issue.

What the 18-month or 30-month issue deals with is, should not the litigation be resolved, at what point would we allow the generic manufacturer to go on the market with the generic product anyway. The 30-month period is one that gave further assurance to the brand-name drug manufacturer that the generic drug manufacturer would not put his competitor on that market until that court decision came through.

So as a practical matter, if we accept what the generic drug manufacturers tell us is their practice, that they will await a court decision as to whether that patent is valid or not, then we are not talking about, in any significant way, reducing the number of generic drugs that will be available to the public.

I would have prefered the 18-month to the 30-month period because I do not want to extend that option any further than is necessary. As a matter of fact, I would have preferred that the whole patent infringement law stay the way it is now on the books, without any special rules for drug manufacturers, in order to prevent someone from marketing another competitive product. After all, under the patent law, if someone markets a competitive product, they can go to court and sue for an injunction, or they can sue for treble damages for infringment of that patent. As far as I am concerned, that is sufficient protection for the original manufacturer of a product who has that product under patent protection.

But on balance, what we have is a total bill that I think is very good. It provides low-cost, generic drugs for millions of Americans, saving maybe a billion dollars over a several-year period. There is going to be a significant savings to people who purchase drugs. Twenty percent of the people who buy drugs in this country are elderly. Medicare does not pay for drugs. Many people are under the misapprehension that medicare does. So that is coming out of the pockets of the elderly and obviously the sick.

So on balance this is a good bill, and that provision brought everybody along and, therefore, I would reluctantly resist the gentleman's amendment.

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

Mr. WAXMAN. I would be pleased to yield to the gentleman from Florida.

Mr. SHAW. I thank the gentleman for yielding.

Mr. Chairman, I know that the gentleman, as the chairman, would be opposing this particular amendment reluctantly. I do realize that balance is trying to be reached, but what the Members should be very much aware of, the balance being taking some of the bad with the good.

□ 1210

This is an opportunity to extract some of the bad, so I think we can even get a better balance. What we are talking about, when we are talking about bringing people on board and bringing them along, is trying to stop obstructionism within this House and within the rules by which we do business. I understand that. But I have not seen anything of such a consequence come through this House this week, nor do I expect it will, and I think all the Members have plenty of time to sit here and work on this important piece of legislation.

The gentleman brought up the question of medicare and medicaid. This is also an opportunity for us as Members of this Congress to do some cost containment within the medicare program. This is an extraordinarily important program to the elderly citizens of this country, and this is an opportunity for us to do something constructive which is going to send the message out to the elderly people that we are on their side and in this particular instance we are for lower cost on drugs. And also this is going to have a direct effect on our own budget, which we are very painfully aware of, but it does not in any way take anything away from anybody except perhaps some profits by the big name drug companies, and I think they have plenty of that.

Mr. Chairman, I thank the gentleman for yielding.

The CHAIRMAN. The time of the gentleman from California [Mr. WAXMAN] has expired.

(By unanimous consent, Mr. WAXMAN was allowed to proceed for 2 additional minutes.)

Mr. WAXMAN. Mr. Chairman, I appreciate what the gentleman has said and, of course, what he has said is the significance of this legislation, which he has pointed out so ably. This legislation will do more to contain the cost of elderly care than perhaps anything else this Congress has passed, because it will bring about lower priced generic alternatives to brand-name drugs once the patent has expired or if there is no valid patent and the courts decide that there is no valid patent in order to give that monopoly protection.

A patent is a monopoly, and when anyone holds a monopoly, that person has the ability or that company has the ability to charge the highest price because there is no one else in competition, and as a matter of public policy we, under the patent law, give that protection to the person who has put money into research and development for an innovative and new product.

But at some point public policy calls for the free market system competition which will bring about the result of a lower price for the consumer. That is the purpose of the legislation.

This particular amendment deals with a very narrow area of when a patent might be challenged and at what point the challenger can market the product that he wishes to market in competition, and as a practical matter generic drug manufacturers will not market a product until the court has decided that they are free to do so without infringing the original patent.

I therefore think that adopting this amendment will not mean more generics on the market for the benefit of the consumers, and as a political matter in dealing with this legislation it would shake the overall compromise that has been signed off on by the original drug manufacturers, the Pharmaceutical Manufacturers Association, the generic drug manufacturers, and the consumers and the elderly, because on balance this is a good bill.

Therefore, Mr. Chairman, we should defeat this amendment and go with the bill.

Mr. MOORHEAD. Mr. Chairman, I move to strike the requisite number of words, and I rise in strong support of the Waxman amendment and against the Shaw perfecting amendment.

We have struggled for a long time with this legislation, and most of the things that are in this bill, together with the amendments that the gentleman from California [Mr. WAXMAN] will offer today, are the result of much effort and work over a long period of time and which resulted in compromises between the various industries that are involved, the people that will be affected, the senior citizens of our country, the people who manufacture generics, and the people whose patents need to be protected to guarantee that they can get a recovery on the investment that they have made.

Surely this bill in this form, as it is being amended today by the gentleman from California [Mr. WAXMAN], will speed the marketing by generic drugs following patent expiration. If we start fooling around with this formula that has been worked on for long and arduous negotiating periods that have involved Members of Congress, committee chairmen, members of the committees, and so forth, we will end up without a bill that will help our senior citizens, one that will help the generic drug manufacturers, and at the same time protect those people who have invested millions of dollars in new drugs that are needed by all of the citizens of America that would not be produced unless there were some minimum protection for them after they got the drugs on the market.

For that reason, Mr. Chairman, I strongly support the amendment offered by the gentleman from California [Mr. WAXMAN], and I oppose the amendment offered by the gentleman from Florida [Mr. SHAW].

Mr. SHAW. Mr. Chairman, we keep talking about the balance and we keep talking about the parties to this particular compromise. We are the parties, we are the people who work and labor right here in this Chamber, and we are the ones to make the decisions, not any members of any particular industry. It is going to be up to each Member of this Congress when we get to a vote—and I intend to ask for a recorded vote on this particular item—to decide their exact vote.

I do not know of anyone who was in that room when this compromise was struck. I certainly was not. I was in the Judiciary Committee when the House bill came through, and we worked on what we thought was a good balance at that particular time.

I agree with the other speakers, this bill has a lot of good things in it, and I intend to support it on final passage, I do believe. But I think this is a most important amendment, and when we talk about balance, I think our primary consideration has to be the people, the consumers, and particularly the elderly, the sick, and the infirmed. These are the types of people we have to be concerned about today.

Mr. Chairman, I thank the gentleman for yielding.

□ 1220

Mr. MADIGAN. I appreciate the gentleman's position and his remarks. I am sure he understands that compromise is the essence of any political ativity and a compromise is what we have here and the senior citizens of America are the real beneficiaries of this compromise.

I would hate to see it picked apart and destroyed. I would hope this amendment would be defeated.

Mr. KASTENMEIER. Mr. Chairman, I move to strike the requisite number of words. I rise in support of the amendment.

Mr. Chairman, I will be very brief, but I did want to comment about some of the suggestions by my friend, the gentleman from California [Mr. MOORHEAD] and others that this bill has been carefully worked out. As a matter of fact, the care that has been taken was with respect to the bill that appears on the floor, the Waxman bill, H.R. 3605, as reported by two committees. There was no care taken with respect to the backroom deal in the Senate involving the chief executive officer of one of the dissenting drug companies and a lobbyist of one of the generic groups. That is really what is being imposed upon this body today.

There is no reason we should not take to conference or to the Senate the original H.R. 3605. If the deal worked out over there has any validity at all, it could, in part, be accepted in conference; but as the gentleman from Florida [Mr. SHAW] has pointed out in this argument, which I support, what we do here is limit the access of the patent law to contest, to challenge a patent, pursuant to conditions of FDA approval for a period of years. That is not necessary and at the very least we should do what the gentleman from Florida suggests, go back to the 18-month period of time.

I would also say that while the gentleman from California [Mr. WAXMAN] may be correct, that consumers and the elderly did support his carefully worked out version, I do not believe there is any evidence that they support the Waxman amendment offered here this morning, which was worked out on a 24-hour basis in the Senate 4 weeks ago.

So I would hope the House would stand on its own feet and approve its version of the bill and if there are any changes to be made, let them be made in an orderly fashion.

Mr. FISH. Mr. Chairman, I move to strike the requisite number of words.

Mr. Chairman, just briefly, as the ranking minority member of the Judiciary Committee, I want to speak briefly in support of what my colleague, the gentleman from California [Mr. MOORHEAD] the ranking member of the subcommittee involved, and the gentleman from Illinois [Mr. MADIGAN], speaking on behalf of the minority for the Commerce Committee, said that we do support this compromise legislation which will be presented to us through amendments offered by the gentleman from California [Mr. WAXMAN].

The compromise has two admirable goals: First, to provide renewed incentives for pharmaceutical innovation by restoring some of the patent life lost during periods of Federal premarket regulatory review; and second, give the generic drug industry the ability to bring generic copies of off-patent drugs to market as soon as the patent expires. The consumer is the ultimate benefactor of this legislation because they will receive cheaper drugs today and better drugs tomorrow.

This is important legislation, it is important to the consumer, especially the elderly. It has the support of the pharmaceutical industry, the generic drug industry, the AFL-CIO and a number of individual unions, the American Association of Retired Persons and the National Council of Senior Citizens, and I urge a favorable vote for its enactment.

Mr. KINDNESS. Mr. Chairman, I move to strike the requisite number of words.

Mr. Chairman, I will not take the 5 minutes, but I think it is important for us to realize that not only the series of amendments that are offered as a substitute for title I, but also the bill itself before us, H.R. 3605, is the result of a great deal of negotiation and compromise and adjustment and an attempt at consensus between various interested parties and groups.

I have stated previously in debate relating to this bill that I do not think you get good legislation that way. I still believe that is the case; however, this is no time to say in this total process that this one step of negotiation is the wrong step. If it is wrong now, it was wrong at the beginning, it was wrong for H.R. 3605 to be a negotiated bill and to be brought to this floor in that form. Let us not say just one step is wrong.

Now, we can say we have done something in this process that has brought us to a point where there ought to be agreement and there ought to be an end to the controversy and there ought to be some balance.

Oh, we can say let us start all over in the next Congress, and perhaps that is the better course; but if we are going to act on a bill today or if there is going to be legislation finalized along with the action of the other body, the gentleman from California [Mr. WAXMAN] has offered the way for that course to be pursued and to be completed in a reasonable manner.

So I would urge that the amendment of the gentleman from Florida be defeated and I would urge that the substitute for title I offered by the gentleman from California [Mr. WAXMAN] be adopted, and that we put an end to the negotiations.

If it does not work out in this Congress, hopefully next time we will do it by the legislative process rather than by the negotiating process.

Mr. SHAW. Mr. Chairman, will the gentleman yield to me?

Mr. MOORHEAD. Yes, I yield to the gentleman from Florida.

Mr. SHAW. Mr. Chairman, I would like to just pick up on one item that the gentleman did bring up. He is talking about protection. This is protectionism, this type of provision within the law itself. It is already there to a certain degree, and what we are being asked to do is to extend that.

As the gentleman from California [Mr. WAXMAN] pointed out, the remedies are already in the law, triple damages. How much are we going to give them? This absolutely smothers competition, and it guarantees an absolute monopoly in a particular area that might not even be an infringement. This is wrong.

Mr. Chairman, this is what I am trying to get to, and this is what I am trying to lessen with this amendment.

Mr. MOORHEAD. Mr. Chairman, all patents protect. They create a monopoly. We try to encourage innovation. We try to encourage the development of new products, and to do that we protect products.

But this bill as it is being amended will provide for the generic drug manufacturers and provide senior citizens their drugs more rapidly than they would otherwise get them except for those instances in which a patent is expiring before the drug ever gets on the market. We give them 5 years in which to recover their investment. But for most drugs that are manufactured, the generics will be able to get them and get them on the market and be able to provide drugs for the senior citizens that are reasonably priced for the American people.

Mr. Chairman, I do not think that we want to take away the balance that is in this legislation, which is what the gentleman's amendment would do.

Mr. MADIGAN. Mr. Chairman, I move to strike the requisite number of words, and I rise in opposition to the Shaw amendment.

I wish to associate myself with the remarks of the two gentleman from California [Messrs. MOORHEAD and WAXMAN]. I think what the gentleman from California has just said is absolutely correct.

While it is true that the adoption of the Shaw amendment might make this bill a little bit better for senior citizens, the fact of the matter is that the senior citizens are the principal beneficiaries of the bill to begin with. They are the people we have been trying to help through this whole process, but by trying to make it a little bit better for them, we lose all of the other parties to the compromise that have enabled us to get this far and we insure that this bill thus would never become law.

So I think the two gentleman from California have been absolutely on target when they said that what we have done is in the best interests of the senior citizens. They want this bill, we want this bill, but we cannot tear it apart now by trying to make it a little bit better here and a little bit better there, because if we do that, we are going to lose the bill.

Mr. SHAW. Mr. Chairman, will the gentleman yield for one short moment?

Mr. MADIGAN. I am happy to yield to the gentleman from Florida.

Mr. GEKAS. Mr. Chairman, I move to strike the requisite number of words.

Mr. Chairman, over the last 18 months, I have found myself almost automatically opposing everything that the gentleman from California [Mr. WAXMAN] would propose almost viscerally because of our different philosophies.

Now, I am confused today, because I think I agree with him on this particular issue. It seems to me, and this is what I need some clarification on, and I will ask the gentleman from Illinois to state it for me—I talked at side bar with the gentleman from Florida whose amendment we are going to be considering. If indeed we have arrived at a position where the gentleman from California is now offering an amendment that is the consensus of agreement that brings into play the agreement that the administration and senior citizens and the major drug companies and of the regulators, then it seems to me that we rank-and-file people are not privy to all the information that is absolutely necessary to make an independent judgment that gives us a basis upon which to cast a final vote.

Is that indeed the case, this gigantic compromise?

I yield to the gentleman from Illinois.

Mr. MADIGAN. Mr. Chairman, I thank the gentleman for yielding.

The administration has two concerns about the bill. One of their two concerns is addressed in the amendment offered by the gentleman from California [Mr. WAXMAN]. He then later in the process will offer a second amendment which addresses the administration's second concern and then enables the administration to be supportive of the bill.

The amendment being considered now which addresses one of two administration concerns represents a compromise between all the parties the gentleman described in his statement.

What we have in supporting the Waxman amendment is one-half of what we need for administration support and the compromise that has brought us to this point where we have senior citizens, drug companies, Members of the other body, and everybody in unison in support of what the gentleman from California has asked us to consider.

Mr. GEKAS. In recapturing my time, Mr. Chairman, I would further yield to the gentleman from Illinois to answer one other question.

How would the adoption of the Shaw amendment do serious damage to this compromise if indeed it only affects the 18-month time period extending it to 30 months? Is that a serious blow to the compromise which we are discussing here?

I yield to the gentleman from Illinois.

Mr. MADIGAN. Well, I thank the gentleman for yielding.

What we have done under the leadership of Senator HATCH and Chairman WAXMAN and others is that we have tried to get a compromise that would represent the majority of the things sought by the majority of the people who have been interested in this legislation.

□ 1230

Now, if we are to begin the process by adopting this amendment, and then this amendment, and then this amendment over here—as there is more than one amendment to be considered, each takes away part of this compromise. So the adoption of the Shaw amendment, should that be the case, would be the first stone pulled out of the foundation, and there are other stones that will be attempted to be pulled out of the foundation, and then the whole structure is going to collapse.

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

Mr. GEKAS. I yield to the gentleman from Florida.

Mr. SHAW. I thank the gentleman for yielding.

I think it is important and I would like to repeat this particular point: I did not pull this amendment out of the air. This is the amendment that is presently in the House bill. This is the language that is presently in the House bill and it goes back to this language—that is all it does. So this is not anything new or innovative or that is unheard of. It was considered by the committees of the House of Representatives and passed, and it was done in open hearings, not in back rooms, and it is, I think, a much better language and should be supported.

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

Mr. GEKAS. I yield to the gentleman from California with whom I seem to be agreeing.

Mr. WAXMAN. Well, it is a pleasure that the gentleman agrees with me. I would hope that in the future the gentleman would distrust his visceral reaction which would lead him into disagreement with my position.

Mr. GEKAS. I will try—I will try.

Mr. WAXMAN. I thank the gentleman.

The original 18 months, just for historical footnote, was a number of months that was arrived at after negotiation, not in the legislative hearings but between the various industry groups as they tried to resolve competing concerns.

The generic drug manufacturers—first of all, this bill is a bill dealing primarily with getting generic drugs on the market when the patent expires. The conceptualization of the bill is to give more time and more incentives for research and development.

The CHAIRMAN. The time of the gentleman from Pennsylvania [Mr. GEKAS] has expired.

(On request of Mr. WAXMAN and by unanimous consent, Mr. GEKAS was allowed to proceed for 2 additional minutes.)

Mr. WAXMAN. Mr. Chairman, will the gentleman yield further?

Mr. GEKAS. I yield to the gentleman from California.

Mr. WAXMAN. I thank the gentleman for yielding.

Mr. Chairman, the whole conceptuality of this bill is to give more time for the firm developing the patented drug, to give them a further incentive for research and development. There is a public good in that. The other side of it is to give the opportunity for competition in generic drugs to be on the market after that patent has expired.

This issue is a side issue. That is a side issue of when there is an invalid patent. The pharmaceutical manufacturers, the brand-name manufacturers were concerned that the generic manufacturers would come in and say that the patent was invalid and immediately go out in the market and compete, and they would be at some disadvantage. There were negotiations back and forth.

As far as I was concerned, the present patent law ought to be operative and they ought to go to court and try to enforce their patents. But instead of leaving the law as it is, it was agreed upon to have a period of time by which there most likely would have been a court adjudication of the patent in question.

As a practical matter, the generic drug manufacturers have told us they wait for a court decision before they will market a drug. But this is a side issue to the overall importance of this bill. But it is a significant issue in terms of emotion.

I must tell you that while we may want the legislative process to be only Congressmen and Senators discussing the issues on a certain academic, intellectual level, there is a practical level by which people deal in day-to-day life. And the pharmaceutical manufacturers had an enormous amount of distrust with the generic manufacturers, the feeling that they may challenge a lot of patents that were quite valid. And the distrust ran the other way as well; the generic manufacturers said, "All they are trying to do is to keep us off the market and keep us from pressing our case."

The CHAIRMAN. The time of the gentleman from Pennsylvania [Mr. GEKAS] has again expired.

(By unanimous consent, Mr. GEKAS was allowed to proceed for 2 additional minutes.)

Mr. WAXMAN. Mr. Chairman, will the gentleman yield further?

Mr. GEKAS. I yield further to the gentleman from California.

Mr. WAXMAN. The 18-month figure was a compromise. It was a compromise that brought onboard the Pharmaceutical Manufacturers Association along with the generic drug groups.

The change from 18 months to 30 months was a change that brought on the dissident groups within the PMA and has brought us to a package now that we can say with confidence is opposed by no one and backed by all of the groups concerned because their definition of reality has been redefined by virtue of this process having taken place. So I would make that clarification to the gentleman. I appreciate the significance of the legislative process, but let us not elevate procedure over substance.

What we have here is substantively a very good bill in the public interest. The public will benefit twice; by the further incentive for research and development for new, innovative drugs and by the immediate reduction in drug prices when a generic is on the market as a competitor.

That is a very worthwhile objective for this Congress to accomplish.

Mr. GEKAS. I thank the gentleman.

Recapturing my time, Mr. Chairman, I just wish to say that I reluctantly disagree with my colleague from Florida [Mr. SHAW] on this particular issue and I reluctantly agree with the gentleman from California [Mr. WAXMAN] and will support his amendment.

I thank the gentleman for his explanation.

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

Mr. CHAIRMAN. The question is on the amendment offered by the gentleman from Florida [Mr. SHAW] to the amendment offered by the gentleman from California [Mr. WAXMAN].

The question was taken; and the Chairman announced that the noes appeared to have it.

Mr. SHAW. Mr. Chairman, I demand a recorded vote, and pending that, I make the point of order that a quorum is not present.

The CHAIRMAN. Evidently a quorum is not present. The Chair announces that pursuant to clause 2, rule XXIII, he will reduce to a minimum of 5 minutes the period of time within which a vote by electronic device, if ordered, will be taken on the pending question following the quorum call. Members will record their presence by electronic device.

The call was taken by electronic device.

The following Members responded to their names:

[Roll No. 374]

Albosta	Davis	Hansen (UT)
Anderson	de la Garza	Hartnett
Andrews (NC)	Dellums	Hatcher
Andrews (TX)	Derrick	Hawkins
Annunzio	DeWine	Hayes
Anthony	Dickinson	Hefner
Applegate	Dicks	Hertel
AuCoin	Dixon	Hightower
Badham	Donnelly	Hiler
Barnes	Dorgan	Hillis
Bartlett	Downey	Holt
Bateman	Dreier	Hopkins
Bates	Duncan	Howard
Bedell	Durbin	Hoyer
Bennett	Dwyer	Hubbard
Bereuter	Dymally	Huckaby
Berman	Dyson	Hughes
Biaggi	Eckart	Hunter
Billirakis	Edgar	Hutto
Boehlert	Edwards (AL)	Hyde
Boland	Edwards (CA)	Ireland
Boner	Edwards (OK)	Jacobs
Bonior	Emerson	Jeffords
Borski	English	Jenkins
Bosco	Erdreich	Johnson
Boxer	Erlenborn	Jones (NC)
Britt	Evans (IA)	Jones (OK)
Brooks	Evans (IL)	Jones (TN)
Broomfield	Fascell	Kaptur
Brown (CO)	Fazio	Kasich
Broyhill	Feighan	Kastenmeier
Bryant	Fiedler	Kazen
Burton (CA)	Fields	Kemp
Burton (IN)	Fish	Kennelly
Byron	Foglietta	Kildee
Campbell	Ford (MI)	Kindness
Carney	Ford (TN)	Kleczka
Carper	Frank	Kogovsek
Carr	Franklin	Kolter
Chandler	Frenzel	Kostmayer
Chappie	Frost	Kramer
Clarke	Garcia	LaFalce
Clay	Gaydos	Lagomarsino
Clinger	Gejdenson	Lantos
Coats	Gekas	Latta
Coelho	Gephardt	Leath
Coleman (MO)	Gibbons	Lehman (CA)
Coleman (TX)	Gilman	Lehman (FL)
Conable	Gingrich	Leland
Conte	Glickman	Lent
Conyers	Gonzalez	Levin
Cooper	Goodling	Levine
Coughlin	Gore	Levitas
Courter	Gramm	Lewis (CA)
Coyne	Gray	Lipinski
Craig	Green	Livingston
Crane, Daniel	Guarini	Lloyd
Crane, Philip	Gunderson	Loeffler
Crockett	Hall (OH)	Long (LA)
Daniel	Hall, Ralph	Long (MD)
Dannemeyer	Hall, Sam	Lott
Darden	Hamilton	Lowery (CA)
Daschle	Hammerschmidt	Lowry (WA)
Daub	Hance	Lujan
Luken	Parris	Smith, Denny
Lundine	Patman	Snowe
Lungren	Patterson	Snyder
Mack	Paul	Solarz
MacKay	Pease	Solomon
Madigan	Penny	Spence
Markey	Pepper	Spratt
Marlenee	Petri	St Germain
Marriott	Pickle	Staggers
Martin (IL)	Porter	Stangeland
Martin (NY)	Price	Stenholm
Martinez	Pritchard	Stokes
Mavroules	Pursell	Stratton
Mazzoli	Quillen	Studds
McCain	Rahall	Sundquist
McCandless	Ratchford	Swift
McCloskey	Ray	Synar
McCollum	Regula	Tallon
McEwen	Reid	Tauke
McGrath	Richardson	Thomas (CA)
McHugh	Ridge	Thomas (GA)
McKernan	Rinaldo	Torricelli
McKinney	Ritter	Traxler
McNulty	Robinson	Udall
Mica	Rodino	Valentine
Michel	Roe	Vander Jagt
Mikulski	Roemer	Vento
Miller (CA)	Rogers	Volkmer
Miller (OH)	Rose	Walgren
Mineta	Roth	Walker
Minish	Roukema	Watkins
Mitchell	Rowland	Waxman
Moakley	Roybal	Weaver
Molinari	Russo	Weber
Mollohan	Sabo	Weiss
Montgomery	Savage	Wheat
Moody	Sawyer	Whitehurst
Moore	Schaefer	Whitley
Moorhead	Scheuer	Whittaker
Morrison (CT)	Schneider	Whitten
Morrison (WA)	Schroeder	Williams (MT)
Murphy	Schumer	Williams (OH)
Murtha	Selberling	Wilson
Myers	Sensenbrenner	Wirth
Natcher	Sharp	Wise
Nichols	Shaw	Wolf
Nielson	Shelby	Wolpe
Nowak	Shumway	Wortley
O'Brien	Sikorski	Wyden
Oakar	Siljander	Wylie
Oberstar	Sisisky	Yates
Obey	Skelton	Yatron
Olin	Slattery	Young (AK)
Ortiz	Smith (FL)	Young (FL)
Oxley	Smith (IA)	Young (MO)
Packard	Smith (NE)	Zschau
Panetta	Smith (NJ)	

□ 1250

The CHAIRMAN. Three hundred and sixty-two Members have answered to their names, a quorum is present, and the Committee will resume its business.

RECORDED VOTE

The CHAIRMAN. The pending business is the demand of the gentleman from Florida [Mr. SHAW] for a recorded vote.

A recorded vote was ordered.

The CHAIRMAN. The Chair will announce again that this is a 5-minute vote.

The vote was taken by electronic device, and there were—ayes 66, noes 304, answered "present" 1, not voting 61, as follows:

[Roll No. 375]

AYES—66

Applegate	Fascell	Jacobs
Badham	Foglietta	Jones (OK)
Billirakis	Frank	Kastenmeier
Bonior	Garcia	Kildee
Boxer	Glickman	Kleczka
Brown (CO)	Gonzalez	Kogovsek
Coelho	Gore	Kramer
Conyers	Guarini	Lehman (FL)
Davis	Hall, Sam	Long (MD)
Dellums	Hammerschmidt	Lowry (WA)
Durbin	Hertel	Mack
Eckart	Hunter	MacKay
Edwards (CA)	Ireland	Markey
McCollum	Rahall	Smith (IA)
McKinney	Roemer	Snyder
Minish	Roth	St Germain
Moody	Russo	Stratton
Morrison (CT)	Schroeder	Vento
Oberstar	Selberling	Volkmer
Obey	Shaw	Weaver
Pepper	Slattery	Weiss
Petri	Smith (FL)	Young (FL)

NOES—304

Albosta	Fish	McHugh
Anderson	Ford (MI)	McKernan
Andrews (NC)	Ford (TN)	McNulty
Andrews (TX)	Franklin	Mica
Annunzio	Frenzel	Michel
Anthony	Frost	Mikulski
Archer	Gaydos	Miller (CA)
AuCoin	Gejdenson	Miller (OH)
Barnes	Gekas	Mineta
Bartlett	Gephardt	Mitchell
Bateman	Gibbons	Moakley
Bates	Gilman	Molinari
Bedell	Gingrich	Mollohan
Bennett	Goodling	Montgomery
Bereuter	Gramm	Moore
Berman	Gray	Moorhead
Biaggi	Green	Morrison (WA)
Boehlert	Gunderson	Mrazek
Boland	Hall (OH)	Murphy
Boner	Hall, Ralph	Murtha
Borski	Hamilton	Myers
Bosco	Hance	Natcher
Breaux	Hansen (UT)	Nichols
Britt	Hartnett	Nielson
Brooks	Hatcher	Nowak
Broomfield	Hayes	O'Brien
Brown (CA)	Hefner	Oakar
Broyhill	Hightower	Olin
Bryant	Hiler	Ortiz
Burton (CA)	Hillis	Ottinger
Burton (IN)	Holt	Oxley
Byron	Hopkins	Packard
Campbell	Howard	Panetta
Carney	Hoyer	Parris
Carper	Hubbard	Patman
Carr	Huckaby	Patterson
Chandler	Hughes	Paul
Chappie	Hutto	Pease
Clarke	Hyde	Penny
Clay	Jeffords	Pickle
Clinger	Jenkins	Porter
Coats	Johnson	Price
Coleman (MO)	Jones (NC)	Pritchard
Coleman (TX)	Jones (TN)	Pursell
Collins	Kaptur	Quillen
Conable	Kasich	Ratchford
Conte	Kazen	Ray
Cooper	Kemp	Regula
Coughlin	Kennelly	Reid
Courter	Kindness	Richardson
Coyne	Kolter	Ridge
Craig	Kostmayer	Rinaldo
Crane, Daniel	LaFalce	Ritter
Crane, Philip	Lagomarsino	Robinson
Crockett	Lantos	Rodino
D'Amours	Latta	Roe
Daniel	Leath	Rogers
Dannemeyer	Lehman (CA)	Rose
Darden	Leland	Roukema
Daschle	Lent	Rowland
Daub	Levin	Roybal
Derrick	Levine	Sabo
DeWine	Levitas	Savage
Dickinson	Lewis (CA)	Sawyer
Dicks	Lipinski	Schaefer
Dingell	Livingston	Scheuer
Dixon	Lloyd	Schneider
Donnelly	Loeffler	Schumer
Dorgan	Long (LA)	Sensenbrenner
Downey	Lott	Sharp
Dreier	Lowery (CA)	Shelby
Duncan	Lujan	Shumway
Dwyer	Luken	Shuster
Dymally	Lundine	Sikorski
Dyson	Lungren	Siljander
Edgar	Madigan	Sisisky
Edwards (AL)	Marlenee	Skeen
Edwards (OK)	Marriott	Skelton
Emerson	Martin (IL)	Smith (NE)
English	Martin (NY)	Smith (NJ)
Erdreich	Martinez	Smith, Denny
Erlenborn	Mavroules	Snowe
Evans (IA)	Mazzoli	Solarz
Evans (IL)	McCain	Solomon
Fazio	McCandless	Spence
Feighan	McCloskey	Spratt
Fiedler	McEwen	Staggers
Fields	McGrath	Stangeland

Stenholm	Vander Jagt	Wirth
Stokes	Walgren	Wise
Studds	Walker	Wolf
Sundquist	Watkins	Wolpe
Swift	Waxman	Wortley
Synar	Weber	Wyden
Tallon	Wheat	Wylie
Tauke	Whitehurst	Yates
Thomas (CA)	Whitley	Yatron
Thomas (GA)	Whittaker	Young (AK)
Torricelli	Whitten	Young (MO)
Traxler	Williams (MT)	Zschau
Udall	Williams (OH)	
Valentine	Wilson	

ANSWERED "PRESENT"—1

de la Garza

NOT VOTING—61

Ackerman	Foley	Pashayan
Addabbo	Fowler	Rangel
Akaka	Fuqua	Roberts
Alexander	Gradison	Rostenkowski
Aspin	Gregg	Rudd
Barnard	Hall (IN)	Schulze
Bellenson	Hansen (ID)	Shannon
Bethune	Harkin	Simon
Bevill	Harrison	Smith, Robert
Bliley	Hawkins	Stark
Boggs	Heftel	Stump
Bonker	Horton	Tauzin
Boucher	Leach	Taylor
Chappell	Lewis (FL)	Torres
Cheney	Martin (NC)	Towns
Corcoran	Matsui	Vandergriff
Dowdy	McCurdy	Vucanovich
Early	McDade	Winn
Ferraro	Neal	Wright
Flippo	Nelson	
Florio	Owens	

The Clerk announced the following pair:

On this vote:

Mr. Nelson for, with Mr. Rangel against.

Mr. WILSON and Mr. BURTON of Indiana changed their votes from "aye" to "no."

Messrs. WEAVER, LOWRY of Washington, and ECKART, Mrs. BOXER, Messrs. DAVIS, LONG of Maryland and COELHO, Mrs. SCHROEDER, and Mr. KOGOVSEK changed their votes from "no" to "aye."

So the amendment to the amendment was rejected.

The result of the vote was announced as above recorded.

□ 1300

The CHAIRMAN. Are there further amendments to the Waxman amendment?

AMENDMENT OFFERED BY MR. QUILLEN TO THE AMENDMENT OFFERED BY MR. WAXMAN

Mr. QUILLEN. Mr. Chairman, I offer an amendment.

The Clerk read as follows:

Amendment offered by Mr. QUILLEN to the amendment offered by Mr. WAXMAN: In the proposed section 505(j)(4)(D) (ii), (iii), and (v), strike out "for a drug" and insert in lieu thereof "for a drug which is subject to section 503(b)" and in the proposed section 505(j)(4)(D)(iv) is amended by inserting after "change approved in the supplement" the following: "for a drug subject to section 503(b)".

Mr. QUILLEN. Mr. Chairman, I am offering an amendment to the substitute being offered by the gentleman from California [Mr. WAXMAN]. The amendment would limit the application of the bill to prescription drugs only. If the amendment is adopted, over-the-counter drugs would not be affected by the bill's provisions. Congress has debated legislation affecting the drug industry for the past 3½ years. In the last Congress, legislation to restore lost patent protection to drugs was narrowly defeated. That legislation was considered in response to concerns by prescription drug companies that part of their patent protection was lost while drugs were being reviewed by the Food and Drug Administration.

A compromise was developed in this Congress that granted limited patent restoration while at the same time speeding the approval process for generic competitors. Throughout all of this discussion, the debate has been about the prescription drug industry. Extensive hearings have been held in the House Judiciary Committee as well as the Energy and Commerce Committee. The legislation came before the Rules Committee, on which I serve, recently.

Throughout all of this debate, however, no consideration has been given to these issues as applied to over-the-counter drugs. In the last-minute compromise that passed the other body just before the recess, language was inserted to grant a period of market protection outside of the patent system by building in a statutory delay before the Food and Drug Administration could approve generic versions of any drug; prescription or over-the-counter.

This amendment is necessary to avoid sweeping over-the-counter drugs into the provisions of an enormously complex bill without the benefit of any hearings or extensive discussion of this issue. For this reason, I strongly urge my colleagues on both sides of the aisle to support the amendment so that we can revisit the over-the-counter drug issue at a time when it can be given the attention that it deserves.

As a Member of Congress who has devoted much of his time to opposing unnecessary restraints on small business, I am reluctant to vote for a bill that would have such a dramatic and unprecedented effect on the entire drug industry without having the benefit of hearings and informed discussions of its impact on over-the-counter drug companies in general, and small companies in particular.

Mr. Chairman, I have a letter here from Chattem Drug Co. of Chattanooga, TN, dated September 5, 1985, stating:

It has come to our attention that the future of the small over-the-counter pharmaceutical companies of the United States has been placed in jeopardy by language in H.R. 3506, which is scheduled for floor action Thursday. The language originated in a last-minute compromise that produced S. 2926.

□ 1310

The letter goes on to state opposition to the inclusion of over-the-counter drugs, and in closing says:

Circumstances have limited opportunities to respond because no hearings were held, no opportunity for the small drug companies to make an input.

And the views stated by Chattem are shared by Combe, Inc., Schmid Laboratories, Inc., the Mentholatum Co., Goody's Manufacturing Corp., MK Laboratories, Inc., and others.

Mr. Chairman, I urge the approval of this amendment because we could go back to a hearing process and determine in actuality whether or not the provisions of the compromise are really needed.

Mrs. LLOYD. Mr. Chairman, will the gentleman yield?

Mr. QUILLEN. I yield to the gentlewoman from Tennessee.

(Mrs. LLOYD asked and was given permission to revise and extend her remarks.)

Mrs. LLOYD. I thank the gentleman for yielding. Mr. Chairman, I rise in strong support for the amendment offered by my colleague from Tennessee to exempt over-the-counter drugs from the terms of this bill and limit it instead to prescription drugs. As has been mentioned, no hearings, no formal discussion of the inclusion of OTC drugs in this bill were held by House committees. I have been concerned for some time that small, over-the-counter manufacturers, like Chattem, have been completely left out during consideration of this compromise. I don't think we should now be including them in the scope of this legislation.

This bill accords an additional 3 years of protection to the large drug companies, a period of time they can use to establish a strong market foothold. That's a tremendous disadvantage for smaller firms, such as Chattem, Combe, Inc., Schmid Laboratories, Inc., the Mentholatum Co., Goody's Manufacturing Corp., and MK Laboratories in the over-the-counter industry who may have limited advertising budgets.

Passage of this bill will clearly benefit consumers. But I don't think we want to include in it language restricting the ability of the smaller business to freely compete. Their presence in this market is of benefit to consumers as well. We should not, through a reluctance to fully debate, impose unfair, unreasonable, monopolistic limits to their operations.

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

Mr. QUILLEN. I yield to the gentleman from Tennessee.

Mr. DUNCAN. I thank the gentleman for yielding.

Mr. Chairman, I rise in support of the amendment offered by the gentleman from Tennessee [Mr. QUILLEN]. It is a good amendment and I urge all of my colleagues to vote for approval of the amendment as stated.

Mr. QUILLEN. I thank the gentleman.

Mr. KASTENMEIER. Mr. Chairman, will the gentleman from Tennessee yield?

Mr. QUILLEN. I would be happy to yield to the gentleman from Wisconsin.

Mr. KASTENMEIER. I thank the gentleman for yielding.

Mr. Chairman, I want to compliment the gentleman on his amendment. Obviously, in the original versions neither the Committee on Energy and Commerce nor the Committee on the Judiciary contemplated a monopoly grant for over-the-counter drugs and the gentleman is quite right to raise this as an issue.

I hope the gentleman's amendment succeeds.

Mr. QUILLEN. I thank the gentleman for his contribution.

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

Mr. QUILLEN. I would be happy to yield to the gentleman from Tennessee.

Mr. GORE. I thank the gentleman for yielding.

Mr. Chairman, I intend to seek my own time on this amendment, but I just want the Members of this body to understand that this is not just a routine amendment that is going to be debated briefly and then passed by and then never heard from again. This is an extremely important matter.

My colleague, with whom I am proud and privileged to serve, has an extremely important point to make here and I hope that my colleagues will listen to his argument.

The CHAIRMAN. The time of the gentleman from Tennessee [Mr. QUILLEN] has expired.

(On request of Mr. GORE and by unanimous consent, Mr. QUILLEN was allowed to proceed for 2 additional minutes.)

Mr. GORE. If the gentleman will yield further, what happened here is that a compromise was reached between consumer groups and senior citizens' groups and others on the one hand, and the pharmaceutical industry on the other hand, including the large companies and the generic companies, and a pretty sensible balance was struck.

I was one of those who worked along with Chairman WAXMAN in trying to put this original thing together, and he has done a fabulous job on it. But what happened then is that even though the industry supported the compromise, a few companies within the industry wanted a little more. They wanted some extra provisions, even though the industry as a whole had signed off on it, and they convinced the other body to add some other provisions. Then they let it be known that they would kill the bill if they did not get their way.

The bill came back over here and now some modifications have been made to those new provisions, but essentially they are being offered in the substitute offered by the gentleman from California.

My colleague from Tennessee quite sensibly is saying, "Look, there have been no hearings held on this. This is not what all these groups agreed to. This is not in the public interest."

Yes; it is true that if this amendment passed, then the compromise would have to be revisited. It would be a little more difficult, but they would accept this amendment because it is in the public interest. Let us argue it out.

I support the amendment offered by my colleague, and I am going to seek my own time to speak a little bit longer on it, but I wanted to lend my support on this occasion.

Mr. QUILLEN. I thank the gentleman.

Mr. Chairman, I would hope that the gentleman from California [Mr. WAXMAN] would accept this amendment. It is a good amendment, and I cannot imagine the gentleman from California agreeing to a compromise that neither the Committee on the Judiciary nor the House Committee on Energy and Commerce has held hearings on. No mention of this was made in the Committee on Rules when the rule was requested.

The CHAIRMAN. The time of the gentleman from Tennessee [Mr. QUILLEN] has again expired.

(By unanimous consent, Mr. QUILLEN was allowed to proceed for 1 additional minute.)

Mr. QUILLEN. Then to bring it up without the drug companies really knowing what the situation is, and they were no cognizant of the fact before a day or two ago of what language was going into the compromise or whether or not the compromise would be accepted in the House. I think it is not becoming to this body to pass legislation in this way.

Mr. Chairman, I urge the adoption of the amendment.

Mr. WAXMAN. Mr. Chairman, I rise in opposition to the amendment.

Mr. Chairman and my colleagues, I admire the tenacity of the Tennessee delegation in pursuing this amendment. The leading force behind this amendment is evidently an over-the-counter firm in their State, and I appreciate the fact that they can have concerns about the legislation.

For the history of this legislation, let me indicate that we were dealing primarily with prescription drugs and the Proprietary Association which represents the over-the-counter drug manufacturers came to us and said, "Now, wait a second. If we put money into the research and development of a new drug that would be sold over the counter, why should we not be protected?"

I indicated that there has never been an over-the-counter drug that met that classification. Over-the-counter drugs primarily are drugs that previously had been prescription drugs and after a long period of time, when the patents had expired and the record of that drug usage was clear that it was in the public interest and there would be no harm done to sell it over the counter rather than by prescription, then the over-the-counter manufacturer went forward and produced that product.

But at the insistence of the Proprietary Association, we agreed to put them in the bill. So the legislation applies to the over-the-counter drugs.

I do not think they are going to be disadvantaged by the compromise that was worked out that is before us today. The only time an over-the-counter product will receive additional protection is when there is a switch from a prescription drug status to an over-the-counter status, and there were human clinical trials to justify the FDA approving that new drug application.

Under those circumstances, the 3-year provision of the legislation would go into effect. The 3-year protection, in effect, provides that a product that is not a new chemical entity would be protected for 3 years after the FDA approval because there were essential clinical trials submitted to FDA, and only when clinical trials were submitted. Most likely an over-the-counter drug is not going to have a clinical trial period in order to get FDA approval and, therefore, this 3-year rule would not apply, but when there has been an investment by an over-the-counter firm to go through those clinical trials, to get FDA approval, then the argument that the Proprietary Association made to us that they ought to be protected, it seems to me, is a valid one. They ought to be protected because they have made their investment and they would be protected under this legislation for 3 years. This protection is fair, because the manufacturer had to spend a substantial amount of money to conduct those tests. The manufacturer deserves the same period to recoup that investment. If a switch to OTC is made without new studies, then the OTC product would not receive protection from competition.

Therefore, I must reluctantly—and I say reluctantly because of the enormous admiration I have for the gentleman from Tennessee and his colleagues also from Tennessee—oppose this amendment and argue that we ought to leave this compromise that has been worked out in place.

□ 1320

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

Mr. WAXMAN. I am happy to yield to the gentleman from Tennessee.

Mr. QUILLEN. Mr. Chairman, I have here, I will say to the gentleman from California, a confidential active member insert from the Board to which the gentleman refers as supporting this compromise. This is the Proprietary Association. Let me read it to the gentleman.

PA board members reaffirm position on patent term legislation.

Both the executive committee and the board of directors have overwhelmingly reaffirmed the Proprietary Association's

policy of not becoming actively involved in current negotiations.

Now, the gentleman says that they agreed and have worked out the negotiation. I do not understand, because somebody must have been speaking from the Proprietary Association without the authority of the board or the executive committee because it clearly states this.

The CHAIRMAN. The time of the gentleman from California [Mr. WAXMAN] has expired.

(By unanimous consent, Mr. WAXMAN was allowed to proceed for 2 additional minutes.)

Mr. WAXMAN. Mr. Chairman, I will reclaim my time to respond.

The Proprietary Association wanted to be included in this legislation so they would get the protection for their patent should they receive a patent for one of their products, and on that basis, at the request of the association, we put them in the bill, but they were not involved as participants in the overall working out of this bill because it did not affect them so directly.

The Proprietary Association is not asking for the Quillen amendment. There is only one company asking for the Quillen amendment, a company in the State of Tennessee, and they think they are going to be disadvantaged by this compromise. I disagree with their interpretation.

Mr. QUILLEN. Mr. Chairman, will the gentleman yield on that point?

Mr. WAXMAN. I yield to the gentleman from Tennessee.

Mr. QUILLEN. Mr. Chairman, I read there is my testimony that there are five companies, including Mentholatum and Chattem Drug. I turn the list over, and I see there are five drug companies that are interested in this amendment. And there were others, but others did not know about it.

Mr. Alex Guerry and Mr. Jolly of Chattem Drug are members of the board of directors of the association, and they did not know anything about it. They have repeatedly told me that the Proprietary Association was taking no stand on it.

Mr. WAXMAN. Mr. Chairman, it is my understanding that the Proprietary Association has not come to us with this amendment. This amendment was generated by some representatives of at least one company, maybe more, but I only know of one company in the State of Tennessee that feels that they may be in some way disadvantaged by the changes that have been proposed from the Senate version of the bill which provides for this 3-year protection. But I disagree with them. As I read the bill, I do not think they are disadvantaged, and I think if an over-the-counter drug company puts in the money for research, they ought to be protected for 3 years.

The CHAIRMAN. The time of the gentleman from California [Mr. WAXMAN] has again expired.

(By unanimous consent, Mr. WAXMAN was allowed to proceed for 5 additional minutes.)

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

Mr. WAXMAN. I yield to the gentleman from Illinois.

Mr. MADIGAN. Mr. Chairman, I thank the chairman of the subcommittee for yielding.

I understand, having been a party to this, that these people came to us and asked us to put them in the bill, No. 1, and that they asked to be put in the bill because there is a possibility of their making a considerable investment into the processes that would lead to the development and approval, of a new over-the-counter drug.

Mr. WAXMAN. The gentleman is correct.

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

Mr. WAXMAN. The trade association asked to be included in the legislation, and we did that.

Mr. MADIGAN. For the reasons I have just stated, is that correct?

Mr. WAXMAN. That is correct.

Mr. MADIGAN. Now, I am given to understand, and I ask the gentleman if he has the same understanding, that one new over-the-counter drug, an aspirin substitute, has been developed, and under the terms of this bill, because of the development expense that has been incurred, the company would have an exclusive marketing period for that product; is that correct?

Mr. WAXMAN. Yes; that is correct.

Mr. MADIGAN. And now I understand that there is a company in Tennessee that does not want that company to have the exclusive marketing period for the product that they have invested the research dollars in. The company in Tennessee wants to come along piggyback and compete immediately on this new over-the-counter product even though the first company is the company that spent the research and development dollars.

Does the gentleman have an understanding that is anything similar to that?

Mr. WAXMAN. I have the same understanding that the gentleman has.

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

Mr. WAXMAN. I yield to the gentleman from Tennessee.

Mr. QUILLEN. Mr. Chairman, I have asked the gentleman to yield so I may respond.

The emphasis has been placed on one company from Tennessee. Let me read what I read a moment ago.

The views of the company from Tennessee, Chattem Drug, "are shared by Combe, Inc., Schmid Laboratories, Inc., the Mentholatum Co., Goody's Manufacturing Co., MK Laboratories, Inc., and others."

Now, the gentleman says it is one company in Tennessee. I am proud of that company, and I am glad that they contacted me and talked about this amendment. They are reliable and aboveboard, and they do not want to piggyback on anybody's back. They are leaders in their field, and they do not want to be squeezed by a larger company. So by reference, let us not have this get out of hand.

Mr. WAXMAN. Mr. Chairman, the only comment I would make is that the gentleman may be correct about those other companies. I do not know one way or the other. The only company that has contacted us is Chattem Drug in the State of Tennessee. They may have supporters from other companies as well.

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

Mr. WAXMAN. I am pleased to yield to my colleague, the gentleman from Tennessee.

Mr. GORE. Mr. Chairman, I want to clear up my colleague's statements about the Proprietary Association. Let me state my understanding of what has happened, and the gentleman can clarify it if he feels it is mistaken.

It is my understanding that the Proprietary Association has not taken any position in favor of the substitute language that the gentleman is trying to put into the bill, nor has it taken a position in favor of the Quillen amendment. It has officially decided to be neutral on this entire question.

Now, my colleague said a moment ago——

Mr. WAXMAN. No, let me clarify that position.

Mr. GORE. All right.

Mr. WAXMAN. By and large, the gentleman is correct, with one addition. The Proprietary Association said to us that if they were not included in the bill, they would not be neutral; they would be opposed to the bill.

Mr. GORE. All right.

Mr. WAXMAN. But once we put them in the bill, then they were satisfied. That is not to say the real issues are those to be decided by the generic and pharmaceutical manufacturers; they are incidental to those issues.

Mr. GORE. All right. That is the statement about which there is some controversy that I want to pursue. My understanding is that it was not the Proprietary Association at all which made the statement to the gentleman that they would withdraw support for the bill unless we put this substitute language in, and in fact the association did not act on this but, instead, one person within the association came and spoke with the gentleman and his staff and communicated his views about it, and there is some great controversy about whether he is purporting to speak for the association or not.

Mr. WAXMAN. No, let me clarify it. I was not saying the Proprietary Association wanted to be included in the coverage of the bill with these amendments. They wanted to be included in the coverage of the bill originally, and it was the head of the association that

came to see me, and we agreed to put them in.

The CHAIRMAN. The time of the gentleman from California [Mr. WAXMAN] has again expired.

(By unanimous consent, Mr. WAXMAN was allowed to proceed for 1 additional minute.)

Mr. WAXMAN. Mr. Chairman, the only other time we have had contact by an over-the-counter drug manufacturer was not on behalf of the association but on behalf of only one drug manufacturer in the State of Tennessee, and that related to this one issue of the 3-year rule. That individual said he would like to see a change, but he did not represent, nor could he, the association, although he did indicate to us that he is a member of the board of directors. But he did not claim to be representing the association's position; it was only what he thought was in his best interest.

Mr. GORE. Mr. Chairman, I move to strike the requisite number of words, and I rise in support of the amendment.

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

Mr. GORE. Mr. Chairman, let me try to put this in perspective, if I can.

First of all, it is true that there is a Tennessee company that has a great interest in the outcome of this legislation and this amendment. But it is not true that that is the principal reason for this controversy. As my colleague, the gentleman from Tennessee, stated, there are many other companies involved, and much more importantly than that, the public interest is involved and the interests of consumers and senior citizens are involved.

□ 1330

This entire effort to rewrite the new drug approval procedures and this whole law has been a very difficult and complex effort to strike a balance between the interests of consumers and generic drug companies, on the one hand, which is the interest of having more competition from generic drugs in order to drive drug prices down. That is one interest that is involved here.

The second interest is that we give enough compensation and incentive to the innovators of new drugs to invest the money and develop new drugs.

Now, where do you draw that line? How do you strike that balance? Years ago they said we will have 14 years for patent protection. Well, that 14 years was eroded a little bit by the time necessary for the FDA to approve drugs and then there were proposals to extend the patent period and that is how this controversy began.

I stood with my colleague, the gentleman from California, 2 years ago here in the well of this House speaking against one effort to strike that balance, which he and I and some others felt went too far in taking away from the consumer interests and giving too much incentive and too much encouragement to the innovators of new drugs when they really did not need as much as we felt was given them in that bill. It was a well-intentioned bill and there was a legitimate difference of opinion on it.

Well, we fought that bill and managed to stop that bill, just barely.

Well, in this Congress another effort began to strike a compromise between the consumer interests and the major drug manufacturers' interests to give them incentive and yet stimulate more competition and drive prices down.

OK. That effort was led by my colleague, the gentleman from California, and to put this whole dispute into perspective, let me say very clearly for my colleagues on both sides of the aisle that the gentleman from California [Mr. WAXMAN], the gentleman from Illinois [Mr. MADIGAN], the gentleman from Oklahoma [Mr. SYNAR], and others have worked tirelessly to get what I felt was a tremendous compromise, the biggest change in the Nation's drug laws since the Kefauver amendments of 1962. It is an excellent package, but—and here is the big but—after that compromise was arrived at, then a minority within the pharmaceutical industry said, "Well, there is not enough in it for us. We want more. We want to tilt it away from the consumer a little bit more. We don't want quite so much competition from generic drugs. We don't want to drive the prices down quite so low. We want more protection."

They found champions in the other body.

My colleague, the gentleman from California, the chairman of the subcommittee, would not give them the time of day. He said, "No, you are asking for too much. You are asking for too much from the consumers and senior citizens," and he would not put it into the bill and I admire him for it. His motives here today are perfectly genuine, but let me outline them so that we all clearly understand what is involved.

Members of the other body put in these additional provisions to tilt it away from the consumer interests and more toward the large drug manufacturers and they made it known that they would kill the bill if they did not get their way.

All right. At this point you have this huge effort which has gone on for 2 years to get a compromise which is in the public interest. Overall, you know, this bill needs to pass. It is a good bill, but here we have a situation where the whole endeavor, 2 years worth, is in jeopardy because a minority of the pharmaceutical industry is stamping its feet and saying, "We are going to kill it."

The CHAIRMAN. The time of the gentleman from Tennessee has expired.

(By unanimous consent, Mr. GORE was allowed to proceed for 5 additional minutes.)

Mr. GORE. Because a minority within the industry is stamping their feet and saying, "We will kill the bill unless you add this additional language."

After the compromise, after the industry accepted the compromise, a minority within the industry was able to get the other body to put these extra provisions in extending it to over-the-counter drugs, putting in this 3-year rule and the 2-year rule and the rest.

All right. We have a decision to make here in this body. Do we want to automatically accept what the other body has done to placate the minority of companies that disagreed with the original compromise for fear that if we do not the whole endeavor may be jeopardized?

Now, it is a legitimate question. I helped in the early days to give birth to this compromise and I certainly understand and appreciate the fact that we do not want to risk this whole endeavor being destroyed or lost because of this dispute.

I would argue to you though, my colleagues, that we do not have to automatically accept what the other body has done. We can say, "Look, we think you went a little bit too far away from the consumer interests, away from the generic companies, away from the small companies, a little bit too far away from competition and driving prices down. We would like to give it one more shot. Let us see if we cannot pass this package, which is a good package overall, without these extra provisions."

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

Mr. GORE. I will in just a moment.

My colleague said they would not be able to get this provision unless they went to the expense to get new clinical trials. My colleague has no commitment from the industry whether they will accept even that qualification. They may still stamp their feet and insist upon the original Senate version. There is no agreement from the industry that they will accept that.

Second, there is no way to enforce this provision, because the information upon which the new clinical trials are based is confidential and those who wish to challenge it cannot get access to it.

So I would argue very strongly, particularly in light of the fact that the industry and the other body has not agreed to even the refinements my colleague, the gentleman from California, is suggesting, there will have to be further discussions with them in any event. Let us have those further discussions on our terms. Let us have the compromise take place from a good sound House position and what they manage to get in over there in the other body, rather than going toward what is a bad position in the other body and then having a compromise that is worse off from the consumer point of view.

Now I will be happy to yield to my colleague.

Mr. WAXMAN. Mr. Chairman, I thank my friend for yielding to me, because I want to put this in a different perspective. I think the gentleman is painting a picture in which this amendment fits in a much more significant place than it deserves.

We live in a world where there are competing interests. I originally introduced a bill only for the promotion of generic drugs so that consumers could have lower prices. That was the point that I was pushing; but we compromised with the pharmaceutical manufacturers and they said, "Wait a minute. We put in the money for research and development to bring about these innovations. If we did not put in that money, there would be nothing for generics to copy and we ought to be protected."

We tried to balance out those interests. That has been the whole course of the negotiations on this legislation.

It is accurate to say that there were changes brought about in the legislation in the Senate which were more to the liking of the pharmaceutical manufacturers.

Mr. GORE. Because a minority within the industry wanted a little more than the industry as a whole and wanted those changes. Is that not correct?

Mr. WAXMAN. There was a dissident group of manufacturers who were insisting on further concessions.

Mr. GORE. And this was to satisfy them.

Mr. WAXMAN. Will the gentleman yield to me? It was not an effort to satisfy them that resulted in this OTC company in Tennessee being disadvantaged. That is giving this amendment too much stature. That was not on the table in the discussions.

Mr. GORE. Well, reclaiming my time——

Mr. WAXMAN. Then I will have to seek my own time, because the gentleman is not yielding.

Mr. GORE. Well, I will yield right back to the gentleman.

Mr. WAXMAN. I will give the gentleman my real motivations when I have a chance to talk.

Mr. GORE. Well, I apologize to my colleague. I yield further.

Mr. WAXMAN. Well, I thank the gentleman for yielding further, because I do want to have a chance to match the statement the gentleman made. We do not have an enormous amount of disagreement on the general overall picture with this legislation, but we do disagree on this particular amendment and this particular question that deals with the interest of a particular company primarily in the State of Tennessee and maybe with other companies as well. The Senate approved a rule which established a 3-year protection for a non-new chemical entity where there were clinical tests.

The CHAIRMAN. The time of the gentleman from Tennessee has expired.

(By unanimous consent, Mr. GORE was allowed to proceed for 2 additional minutes.)

Mr. GORE. I yield to the gentleman from California.

Mr. WAXMAN. The bill came over to us with some question about whether an over-the-counter manufacturer would be disadvantaged.

We clarified the language, which by the way everybody has agreed to that is involved in the negotiations, so that the 3-year provision will apply only when a substantial investment is made in new clinical trials.

I must disagree with my friend, the gentleman from Tennessee. If an over-the-counter company developed a drug product or changed a drug product which is of enough significance that new clinical tests are a prerequisite to FDA approval, I think it should be protected.

□ 1340

It would be fine to say that the consumer could get the same drug at a lower price if there were generics of the new drug. But there would not be a new drug to copy if the first company did not put in the money to develop it. What we are saying is if they put the money in to develop it, they ought to have a 3-year protection. We have narrowed it to make sure that it is a significant-enough change so that the 3-year rule will apply only when new clinical tests are essential to getting FDA approval and when there is an investment of some magnitude.

So I disagree. I think this is a provision that we ought to support. I understand the gentleman's [Mr. GORE] concern for the public interest and the Tennessee company's concerns as well, but I think we ought to on balance reject this amendment.

Mr. GORE. If I may reclaim my time, has the gentleman [Mr. WAXMAN] gotten an agreement from those who supported the original language which he is substituting into this bill, has he gotten an agreement from the industry and from the sponsors of that language in the other body that they will accept his requirement that new clinical trials have to be involved?

Mr. WAXMAN. Yes, we have an agreement that they will accept this clarification of the 3-year rule which we are putting in the House bill.

The CHAIRMAN. The time of the gentleman [Mr. GORE] has again expired.

(By unanimous consent, Mr. GORE was allowed to proceed for 1 additional minute.)

Mr. GORE. I will not use a full minute, Mr. Chairman. I simply wanted to conclude by urging my colleagues to support the amendment. I am utterly convinced that the public interest is in favor of passing this amendment and going forward with the negotiations one more time and not letting the dissident companies who form a minority have the last word in this matter and squeeze out an additional concession from the consumers in this country.

But I wanted to conclude by putting it again in perspective by saying that I think my colleagues who have managed this bill and who have written this bill overall have done a fantastic job and are eminently serving the public interest with a monumental effort to reform our Nation's drug laws. I think this bill overall is definitely in the public interest and I strongly support it.

I would urge your support of this amendment.

Mr. MADIGAN. Mr. Chairman, I move to strike the requisite number of words and I rise in opposition to the amendment.

Mr. Chairman, if I may have the attention of the chairman of the subcommittee [Mr. WAXMAN], the manager of the bill, I should like to ask him a couple of questions. I thank the gentleman for giving me his attention.

I think one of the things that is important that we address before we vote on this amendment is this issue that has been raised about large drug companies versus small drug companies and something being in this compromise fashioned by the gentleman [Mr. WAXMAN] and others that somehow benefits large companies at the expense of small companies.

That has been suggested now I think three times in the debate. But I have been involved in the process of helping develop this bill and this compromise and I do not know of any provision in the bill anywhere that treats a large company differently than a small company.

Can the gentleman [Mr. WAXMAN] tell me of any provision like that?

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

Mr. MADIGAN. I yield to the gentleman from California.

Mr. WAXMAN. I thank the gentleman for yielding.

Mr. Chairman, I do want to point out that I think that when that distinction has been made that it is a flare of rhetoric as part of trying to bootstrap a position that ought to be argued solely on the merits of that position.

This protection for 3 years will apply for any company, big or small, that puts in the money as an investment to develop a product that will have to be approved by FDA and requires clinical tests, which means it is not just some minor change in a chemical entity that has already previously been approved, but a change that is significant enough to require clinical tests. Whether the company is big or small, supported the original agreement or came on board later, it does not make any differences. The principle is that we are going to protect their invest-

ment for 3 years, and I think that is reasonable.

We were very careful in drafting this to make it narrow enough so that we are only protecting some change that is significant enough to require clinical tests and not some very minor change that would allow a company to come in and claim that there is some reason they ought to be protected on and on and on and on and on.

So I would suggest that when we hear the discussion of big companies or companies that were excessively greedy, and I do not disagree with my colleague, Mr. GORE's, characterization of some of those dissident companies that were fighting for further changes in this bill; they were fighting for their economic self-interest. And I would also go along with the characterization that he gave them as to their standards, as to what they saw as their interests, irrespective of the public interest.

But this has nothing to do with that. This has to do with the issue of whether we give protection to over-the-counter drugs when an investment has been made to get a drug approved just as it would be for an ordinary pharmaceutical by any pharmaceutical manufacturer, big or large, rich or poor, if there are any poor ones.

Mr. MADIGAN. As a matter of fact, the whole problem with the dissident manufacturers, as they have been described here, dealt more with prescription drugs and patent terms. The over-the-counter thing was not involved in that controversy at all that I recall.

I am directing that a question to the chairman of the subcommittee.

Mr. WAXMAN. Except to the extent that the over-the-counter drug group, the trade association, the proprietary association, wanted to be included in a protection of any patents that they may have. And although it is very rare that they have patented products that would be extended, we are providing for them to be treated the same as the pharmaceutical companies when that rare occasion comes about.

Mr. MADIGAN. Just in summary and to come back to my original question so that this will be clear in everybody's mind, it is 3 years in the bill, it is 3 years to a large company, it is 3 years to a small company, it is 3 years to a middle-size company, it is 3 years whether the company is in Tennessee or New York or Minnesota or wherever they might be located; is that correct?

Mr. WAXMAN. That is correct.

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

Mr. MADIGAN. Yes; I yield to the gentleman from Tennessee.

Mr. GORE. I thank the gentleman for yielding.

I appreciate my colleague yielding.

Mr. Chairman, I would submit that the distinction between large and small is not merely a rhetorical flare. Although there are some small companies that are innovators and research-intensive and though there are many large companies, certainly, that produce generic drugs, by and large it is the case that the research-intensive companies are much larger and they have a set of interests that need to be balanced in this bill and those companies that are more likely to come in and produce generics when the patent period ends, although large companies are in that part of the industry, by and large they are more likely to be smaller companies. And I think you can see a clear distinction.

Now, as for there being no large companies instigating the original change, in the language of the other body, which led to this controversy, the American Home Products Co. can hardly be described as a mom and pop operation. They are the ones that are responsible for this being put in the bill.

Mr. MADIGAN. Well, I think the gentleman, if we just extrapolate what the gentleman has said, he has made the point which I suggested in the beginning of the discussion on this amendment because he is suggesting that the large companies do the research, the small companies do the generic business, over the counter, and the gentleman does not want the large companies to have the 3-year exclusive marketing to recover their investment; the gentleman wants the small company to be able to come in on them immediately.

Mr. SKELTON. Mr. Chairman, I move to strike the requisite number of words, and I rise in support of H.R. 3065.

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

Mr. SKELTON. Mr. Chairman, I rise today in support of H.R. 3065. I cosponsored H.R. 3065 because I believe that increasing the availability of generic drugs through expedited approval process embodied in the bill is a logical means of showing the rate of increase in the cost of health care. Most importantly, making generic drugs more available offers some relief to the millions of older Americans whose budgets are strained because medicare does not cover the cost of outpatient drugs. Currently, 17 percent of the out-of-pocket payments made by the elderly for health care are devoted to paying for drugs. Giving seniors the option of purchasing lower-priced generic drugs is imperative.

The approval process included in H.R. 3065 assures that, while generic drugs will be made more quickly available, the quality and effectiveness of those drugs will not be reduced. Moreover, H.R. 3065 offers incentives to drug manufacturers to continue to develop new drugs by extending the period in which the developing manufacturer can enjoy exclusive marketing rights.

Mr. KINDNESS. Mr. Chairman, I move to strike the requisite number of words and I rise in opposition to the amendment.

Mr. Chairman, I rise in opposition to the amendment, not in opposition to our esteemed colleague from Tennessee but in opposition to his amendment. I think it is interesting, Mr. Chairman, how in debate sometimes we see the different perspectives exhibited, those different perspectives represented by those of us who serve here in this House of Representatives and sometimes we may get things a little out of focus.

The gentleman from Illinois [Mr. MADIGAN] I think has helped to bring things back into focus very nicely but I think there is one other aspect of this whole matter that has gotten a little out of focus, at least from what I understand to be the case.

That is I have never known generic drug manufacturers to be clothed quite so heavily in the cloak of consumerism and protection of senior citizens as has been the case in the discussion of this bill.

□ 1350

They are making money off of those people. Right? They are making money off of those people just as surely as the innovators who invent drugs.

Now, the question is, How much money are they going to make? Are they going to make more money because we say to the innovators who invent the drugs, "No, you only have a little bit of protection here"?

"Patent? Well, forget about patents. We are going to do this kind of outside of the patent law."

"The regulatory process is going to limit your proprietary rights and we are going to work those around in such a manner as is necessary to fulfill a public policy, whatever we decided it is from time to time."

Today we are trying to decide that the public policy is somewhere in the area that balances in a negotiated compromise between all these parties that are concerned. But do not forget the consumer generally is going to paying for all of this.

Now, what is the least expensive way for the consumer to pay for it? Is it to say to the over-the-counter drug people, "well, you don't live under these same rules that are applicable to prescription drugs." In the event that there is some innovation in over-the-counter drugs, we should be treating that innovation and its costly process just the same as though it was a prescription drug, it seems to me. If it is an advantage to the public to have that drug available, it ought to be available on the same terms as a prescription drug. We ought not to say, "well, some people can make more profit out of it than the innovators can make and therefore discourage innovation in the public interest."

That is what we are really down to here. Are we going to discourage inno-

vation in this over-the-counter drug market—and there is not much of it now. Now we say there are small companies. Well OK. Many of them are small, but what they make their living from is a kind of business that is profitable. So let us not feel sorry for them to any greater extent than we feel sorry for anyone else who is providing drugs, whether over-the-counter prescription, to the American public. It is our role to determine what is fair in the law.

Mr. QUILLEN. Mr. Chairman, will the gentleman yeild?

Mr. KINDNESS. I yield to the gentleman from Tennessee.

Mr. QUILLEN. I thank the gentleman for yielding.

The gentleman has raised some points that I think could be developed in his committee and in the Commerce Committee, if hearings were held.

The point is that no hearings, no discussion on the inclusion of over-the-counter drugs into this measure has ever taken place in the House of Representatives. Therefore, what we are doing is bying by piggyback what the Senate has done. I do not think it is right for this body to do that. I think we have competent committees that could hold hearings and develop the facts, and if they turn out the way the gentleman is stating, then let us bring it to the floor of the House. But let us not bring it to the floor under an assumption that we are doing the right thing by latching onto something because we think that is the only way we are going to get a measure.

The CHAIRMAN pro tempore. The time of the gentleman from Ohio [Mr. KINDNESS] has expired.

(By unanimous consent, Mr. KINDNESS was allowed to proceed for 2 additional minutes.)

Mr. KINDNESS. Mr. Chairman, I want to thank the gentleman from Tennessee for his observations which are quite correct in a sense, but we have to remember that this bill, as it was reported by the committee, was not subject to hearings either, as I understand it, in the Energy and Commerce Committee. It was the result of a lot of work that followed hearings.

Now, in those hearings there was not a direction of attention to over-the-counter drugs. I understand that. But the principles that apply to drugs that are supposed to be available on the market to help people in their illnesses, those principles ought to be the same, whether the drug is sold only with a prescription or without a prescription. There is no basis for differentiating on that basis alone.

If the FDA has to approve in order for the drug to be marketed and if there is the expense involved, the investment you might call it, in getting the testing done and the data together for the approval, that company that does it, it seems to me, ought to be protected. It does not matter a whit whether it is prescription or not prescription.

The gentleman's point sounds substantial, but when you back off and take a look at it, it is really not a matter of substance. There is really no difference between a prescription drug and a nonprescription drug except that we treat it differently in some aspects of the law.

Mr. QUILLEN. If the gentleman will yield further, we held a hearing in the Rules Committee at which this inclusion was never discussed, never mentioned. The small drug companies, which, to some degree, have been criticized—and I certainly do not—I think they are very responsible and very honorable. They need to be heard. They did not know about the compromise. Although they are members of the board of the proprietary association, they did not know about it.

The CHAIRMAN pro tempore. The time of the gentleman from Ohio [Mr. KINDNESS] has again expired.

(At the request of Mr. QUILLEN and by unanimous consent, Mr. KINDNESS was allowed to proceed for 2 additional minutes.)

Mr. QUILLEN. I know that the gentleman from Ohio always advocates complete and thorough hearings on every matter that comes before the House and I know the gentleman from California would like to have hearings on all matters. But when you come before us and say, "Here, now, accept this pig in a poke that the Senate has worked out," without these companies having an opportunity for an input, I think, we are doing an injustice.

Mr. KINDNESS. I thank the gentleman for that observation which is essentially correct about the whole bill. But if the bill is a negotiated bill, as it appears to have been, we are at that stage where we are getting down to the final form of it, I think, and I would urge the defeat of the amendment. Basically, I think we would find that the bill with the additional amendments to be offered by the gentleman from California [Mr. WAXMAN] to be pretty much acceptable.

Mr. KASTENMEIER. Mr. Chairman, I move to strike the requisite number of words and I rise in support of the amendment.

Mr. Chairman, I did want to underline the point made by the gentleman from Tennessee [Mr. QUILLEN] that indeed there have not been hearings on this question and, in fact, would underline the statement made by the gentleman from Tennessee [Mr. GORE], who pointed out in his wisdom the gentleman from California rejected this approach formerly.

Apparently the only mention of this general issue before the Subcommittee on Health and Environment, chaired by Mr. WAXMAN, was by Dr. Novich, Deputy Commissioner of the Food and Drug Administration who said:

> Should there be a lengthier pre-eligibility period before ANDAs are permitted to avoid disincentives to drug innovation? This is a controversial issue on which many people have expressed strong views, and we believe it is a legitimate subject for debate. Those who oppose establishing a pre-eligibility period to preserve incentives for drug innovation argue that Congress has established a patent system for the specific purpose of encouraging invention and that FDA should not impose requirements designed to achieve the same objective.

So when the gentleman from Ohio [Mr. KINDNESS] talks about innovation, it is not a patentable innovation. We are not talking about prescription drugs for which patents are obtained. We are talking about investments that any business enterprise might make prior to putting a product on the market.

□ 1400

We do not reward all products that are the product of investment and research with protective monopoly devices such as that included in the Waxman amendment. Indeed, we ought to reject the Waxman amendment.

I think it has been pointed out even the proprietary industry itself is badly split on the 3-year rule which was added in the Senate. At least we know that this is a controversial item for consumers, and I would hope that we could indeed reject the additional device found in the Waxman amendment to protect a product which is not a new chemical entity, and which may be off patent or be an item for which no patent could be obtained.

Mr. Chairman, I hope we agree to the Quillen amendment.

Mr. BOEHLERT. Mr. Chairman, as I considered the proposed amendment, I asked myself some important questions dealing with consumer interests, particularly those of our senior citizens since the impact of any action no doubt will be greatest on this group.

The first question I asked was this: Isn't it in the consumers' interest, particularly our elderly consumers, to have new, improved drugs brought to the market?

The answer, of course, is yes.

Then I asked: Isn't it in the consumers' interest, particularly our elderly consumers, to encourage research and development that hopefully will produce new, improved drugs which can be brought to the market?

Here, too, my answer was yes.

Then, I said to myself, isn't it fair to provide some measure of protection for a company, large or small, which makes a substantial investment to develop the new and improved drugs we all want to see available to the public?

My answer to all three of these questions was the same. Yes. Therefore, I have logically and objectively concluded that the pending amendment is contrary to a whole range of interests, the most important of which is that of the consumers, particularly our elderly.

I urge rejection of the pending amendment and in the process wish to commend both the chairman of the subcommittee [Mr. WAXMAN] and the

ranking member [Mr. MADIGAN] for their responsible leadership on this issue. We're in agreement.

Mr. ROWLAND. Mr. Chairman, I rise in support of the Waxman amendment to H.R. 3605. I commend the chairman of the Health Subcommittee and members of the Energy and Commerce Committee in helping to fashion a compromise between all the interested parties so that we can pass a bill that will provide for the greater availability of generic substitutes to the public. The greater presence of generic drugs, will provide needed relief, especially to the elderly. Our senior citizens, many of whom are on fixed incomes, are the major users of prescription drugs, and few receive any assistance to help pay for this medication. As a former family physician and one who is extremely interested in containing health care costs, I believe this compromise is an important step in addressing the skyrocketing cost of health care.

The CHAIRMAN pro tempore (Mr. BENNETT). The question is on the amendment offered by the gentleman from Tennessee [Mr. QUILLEN] to the amendment offered by the gentleman from California [Mr. WAXMAN].

The question was taken; and on a division (demanded by Mr. WAXMAN) there were—ayes 4, noes 13.

RECORDED VOTE

Mr. QUILLEN. Mr. Chairman, I demand a recorded vote.

A recorded vote was ordered.

The vote was taken by electronic device, and there were—ayes 24, noes 347, answered "present" 1, not voting 60, as follows:

[Roll No. 376]

AYES—24

Albosta	Latta	Petri
Cooper	Lehman (FL)	Quillen
Duncan	Lloyd	Sawyer
Gore	McKinney	Seiberling
Hammerschmidt	Moody	Skelton
Jeffords	Morrison (CT)	Vander Jagt
Jones (NC)	Nichols	Vento
Kastenmeier	Obey	Yates

NOES—347

Anderson	Broomfield	Crane, Daniel
Andrews (NC)	Brown (CA)	Crane, Philip
Andrews (TX)	Brown (CO)	Crockett
Annunzio	Broyhill	D'Amours
Anthony	Bryant	Daniel
Applegate	Burton (CA)	Dannemeyer
Archer	Burton (IN)	Darden
AuCoin	Byron	Daschle
Badham	Campbell	Daub
Barnes	Carney	Davis
Bartlett	Carper	de la Garza
Bateman	Carr	Dellums
Bates	Chandler	Derrick
Bedell	Chappell	DeWine
Bennett	Chappie	Dickinson
Bereuter	Cheney	Dicks
Berman	Clarke	Dingell
Biaggi	Clay	Dixon
Bilirakis	Clinger	Donnelly
Boehlert	Coats	Dorgan
Boggs	Coelho	Downey
Boland	Coleman (MO)	Dreier
Boner	Coleman (TX)	Durbin
Bonior	Collins	Dwyer
Borski	Conte	Dymally
Bosco	Conyers	Dyson
Boxer	Coughlin	Eckart
Breaux	Courter	Edgar
Britt	Coyne	Edwards (AL)
Brooks	Craig	Edwards (CA)
Edwards (OK)	Levine	Rodino
Emerson	Levitas	Roe
English	Lipinski	Roemer
Erdreich	Livingston	Rogers
Erlenborn	Loeffler	Rose
Evans (IA)	Long (LA)	Roth
Evans (IL)	Long (MD)	Roukema
Fascell	Lott	Rowland
Fazio	Lowery (CA)	Roybal
Feighan	Lowry (WA)	Russo
Fiedler	Lujan	Sabo
Fields	Luken	Savage
Fish	Lundine	Schaefer
Foglietta	Lungren	Scheuer
Ford (MI)	Mack	Schneider
Ford (TN)	MacKay	Schroeder
Fowler	Madigan	Schumer
Frank	Markey	Sensenbrenner
Franklin	Marlenee	Sharp
Frenzel	Marriott	Shaw
Frost	Martin (IL)	Shelby
Garcia	Martin (NY)	Shumway
Gaydos	Martinez	Shuster
Gejdenson	Mavroules	Sikorski
Gekas	Mazzoli	Siljander
Gephardt	McCain	Sisisky
Gibbons	McCandless	Skeen
Gilman	McCloskey	Slattery
Gingrich	McCollum	Smith (FL)
Glickman	McEwen	Smith (IA)
Goodling	McGrath	Smith (NE)
Gramm	McHugh	Smith (NJ)
Gray	McKernan	Smith, Denny
Green	McNulty	Snowe
Guarini	Mica	Snyder
Gunderson	Michel	Solarz
Hall (OH)	Mikulski	Solomon
Hall, Ralph	Miller (OH)	Spence
Hall, Sam	Mineta	Spratt
Hamilton	Minish	St Germain
Hance	Mitchell	Staggers
Hansen (UT)	Moakley	Stangeland
Hartnett	Molinari	Stenholm
Hatcher	Mollohan	Stokes
Hawkins	Montgomery	Stratton
Hayes	Moore	Studds
Hefner	Moorhead	Sundquist
Hertel	Morrison (WA)	Swift
Hightower	Mrazek	Synar
Hiler	Murphy	Tallon
Hillis	Murtha	Tauke
Holt	Myers	Thomas (CA)
Hopkins	Natcher	Thomas (GA)
Howard	Nielson	Torricelli
Hoyer	Nowak	Traxler
Hubbard	O'Brien	Udall
Huckaby	Oakar	Valentine
Hughes	Oberstar	Volkmer
Hunter	Olin	Walgren
Hutto	Ortiz	Walker
Hyde	Ottinger	Watkins
Ireland	Oxley	Waxman
Jacobs	Packard	Weaver
Jenkins	Panetta	Weber
Johnson	Parris	Weiss
Jones (OK)	Patman	Wheat
Jones (TN)	Patterson	Whitehurst
Kaptur	Paul	Whitley
Kasich	Pease	Whittaker
Kazen	Penny	Whitten
Kemp	Pepper	Williams (MT)
Kennelly	Pickle	Williams (OH)
Kildee	Porter	Wilson
Kindness	Price	Wirth
Kleczka	Pritchard	Wise
Kogovsek	Pursell	Wolf
Kolter	Rahall	Wolpe
Kostmayer	Ratchford	Wortley
Kramer	Ray	Wyden
LaFalce	Regula	Wylie
Lagomarsino	Reid	Yatron
Lantos	Richardson	Young (AK)
Leath	Ridge	Young (FL)
Lehman (CA)	Rinaldo	Young (MO)
Leland	Ritter	Zschau
Levin	Robinson	

ANSWERED "PRESENT"—1

Gonzalez

NOT VOTING—60

Ackerman	Bevill	Ferraro
Addabbo	Bliley	Flippo
Akaka	Bonker	Florio
Alexander	Boucher	Foley
Aspin	Conable	Fuqua
Barnard	Corcoran	Gradison
Bellenson	Dowdy	Gregg
Bethune	Early	Hall (IN)
Hansen (ID)	McDade	Simon
Harkin	Miller (CA)	Smith, Robert
Harrison	Neal	Stark
Heftel	Nelson	Stump
Horton	Owens	Tauzin
Leach	Pashayan	Taylor
Lent	Rangel	Torres
Lewis (CA)	Roberts	Towns
Lewis (FL)	Rostenkowski	Vandergriff
Martin (NC)	Rudd	Vucanovich
Matsui	Schulze	Winn
McCurdy	Shannon	Wright

□ 1410

Mr. BENNETT and Mr. KOGOVSEK changed their votes from "aye" to "no."

Mr. YATES and Mr. LEHMAN of Florida changed their votes from "no" to "aye."

So the amendment to the amendment was rejected.

The result of the vote was announced as above recorded.

The CHAIRMAN. Are there any other amendments to the Waxman amendment?

If not, the question is on the amendment offered by the gentleman from California [Mr. WAXMAN].

The amendment was agreed to.

The CHAIRMAN. The Clerk will designate title II.

The Clerk read as follows:

TITLE II—PATENT EXTENSION

SEC. 201. (a) Title 35 of the United States Code is amended by adding the following new section immediately after section 155A:

"§ 156. Extension of patent term

"(a) The term of a patent which claims a product, a method of using a product, or a method of manufacturing a product shall be extended in accordance with this section from the original expiration date of the patent if—

"(1) the term of the patent has not expired before an application is submitted under subsection (d) for its extension;

"(2) the term of the patent has never been extended;

"(3) an application for extension is submitted by the owner of record of the patent or its agent and in accordance with the requirements of subsection (d);

"(4)(A) in the case of a patent which claims the product or a method of using the product—

"(i) the product is not claimed in another patent having an earlier issuance date or which was previously extended, and

"(ii) the product and the use approved for the product in the applicable regulatory review period are not identically disclosed or described in another patent having an earlier issuance date or which was previously extended; or

"(B) in the case of a patent which claims the product, the product is also claimed in a patent which has an earlier issuance date or which was previously extended and which does not identically disclose or describe the product and—

"(i) the holder of the patent to be extended has never been and will not become the holder of the patent which has an earlier issuance date or which was previously extended, and

"(ii) the holder of the patent which has an earlier issuance date or which was previously extended has never been and will not become the holder of the patent to be extended;

"(5)(A) in the case of a patent which claims a method of manufacturing the product which does not primarily use recombi-

nant DNA technology in the manufacture of the product—

"(i) no other patent has been issued which claims the product or a method of using the product and no other patent which claims a method of using the product may be issued for any known therapeutic purposes; and

"(ii) no other method of manufacturing the product which does not primarily use recombinant DNA technology in the manufacture of the product is claimed in a patent having an earlier issuance date;

"(B) in the case of a patent which claims a method of manufacturing the product which primarily uses recombinant DNA technology in the manufacture of the product—

"(i) the holder of the patent for the method of manufacturing the product (I) is not the holder of a patent claiming the product or a method of using the product, (II) is not owned or controlled by a holder of a patent claiming the product or a method of using the product or by a person who owns or controls a holder of such a patent, and (III) does not own or control the holder of such a patent or a person who owns or controls a holder of such patent; and

"(ii) no other method of manufacturing the product primarily using recombinant DNA technology is claimed in a patent having an earlier issuance.

"(6) the product has been subject to a regulatory review period before its commercial marketing or use;

"(7)(A) except as provided in subparagraph (B), the permission for the commercial marketing or use of the product after such regulatory review period is the first permitted commercial marketing or use of the product under the provision of law under which such regulatory review period occurred; or

"(B) in the case of a patent which claims a method of manufacturing the product which primarily uses recombinant DNA technology in the manufacture of the product, the permission for the commercial marketing or use of the product after such regulatory review period is the first permitted commercial marketing or use of a product manufactured under the process claimed in the patent; and

"(8) the patent does not claim another product or a method of using or manufacturing another product which product received permission for commercial marketing or use under such provision of law before the filing of an application for extension.

The product referred to in paragraphs (4), (5), (6), and (7) is hereinafter in this section referred to as the 'approved product'. For purposes of paragraph (4)(B) (5)(B), the holder of a patent is any person who is the owner of record of the patent or is the exclusive licensee of the owner of record of the patent.

"(b) The rights derived from any patent the term of which is extended under this section shall during the period during which the patent is extended—

"(1) in the case of a patent which claims a product, be limited to any use approved for the approved product before the expiration of the term of the patent under the provision of law under which the applicable regulatory review occurred;

"(2) in the case of a patent which claims a method of using a product, be limited to any use claimed by the patent and approved for the approved product before the expiration of the term of the patent under the provision of law under which the applicable regulatory review occurred; and

"(3) in the case of a patent which claims a method of manufacturing a product, be limited to the method of manufacturing as used to make the approved product.

"(c) The term of a patent eligible for extension under subsection (a) shall be extended by the time equal to the regulatory review period for the approved product which period occurs after the date the patent is issued, except that—

"(1) each period of the regulatory review period shall be reduced by any period determined under subsection (d)(2)(B) during which the applicant for the patent extension did not act with due diligence during such period of the regulatory review period;

"(2) after any reduction required by paragraph (1), the period of extension shall include only one-half of the time remaining in the periods described in paragraphs (1)(B)(i), (2)(B)(i), and (3)(B)(i) of subsection (g); and

"(3) if the period remaining in the term of a patent after the date of the approval of the approved product under the provision of law under which such regulatory review occurred when added to the regulatory review period as revised under paragraphs (1) and (2) exceeds fourteen years, the period of extension shall be reduced so that the total of both such periods does not exceed fourteen years.

"(d)(1) To obtain an extension of the term of a patent under this section, the owner of record of the patent or its agent shall submit an application to the Commissioner. Such an application may only be submitted within the sixty-day period beginning on the date the product received permission under the provision of law under which the applicable regulatory review period occurred for commercial marketing or use. The application shall contain—

"(A) the identity of the approved product;

"(B) the identity of the patent for which an extension is being sought and the identification of each claim of such patent which claims the approved product or a method of using or manufacturing the approved product;

"(C) the identity of every other patent known to the patent owner which claims or identically discloses or describes the approved product or a method of using or manufacturing the approved product;

"(D) the identity of all other products which have received permission under the provision of law under which the applicable regulatory review period occurred for commercial marketing or use and which are claimed in any of the patent identified in subparagraph (C);

"(E) information to enable the Commissioner to determine under subsections (a) and (b) the eligibility of a patent for extension and the rights that will be derived from the extension and information to enable the Commissoner and the Secretary of Health and Human Services or the Secretary of Agriculture to determine the period of the extension under subsection (g);

"(F) a brief description of the activities undertaken by the applicant during the applicable regulatory review period with respect to the approved product and the significant dates applicable to such activities; and

"(G) such patent or other information as the Commissioner may require.

"(2)(A) Within sixty days of the submittal of an application for extension of the term of a patent under paragraph (1), the Commissioner shall notify—

"(i) the Secretary of Agriculture if the patent claims a drug product or a method of using or manufacturing a drug product and the drug product is subject to the Virus Serum Toxin Act, and

"(ii) the Secretary of Health and Human Services if the patent claims any other drug product, a medical device, or a food additive or color additive or a method of using or manufacturing such a product, device, or additive and if the product, device, and additive are subject to the Federal Food, Drug, and Cosmetic Act,

of the extension application and shall submit to the Secretary who is so notified a copy of the application. Not later than thirty days after the receipt of an application from the Commissioner, the Secretary receiving the application shall review the dates contained in the application pursuant to paragraph (1)(E) and determine the applicable regulatory review period, shall notify the Commissioner of the determination, and shall publish in the Federal Register a notice of such determination.

"(B(i) If a petition is submitted to the Secretary making the determination under paragraph (A), not later than one hundred and eighty days after the publication of the determination under subparagraph (A), upon which it may reasonably be determined that the applicant did not act with due diligence during the applicable regulatory review period, the Secretary making the determination shall, in accordance with regulations promulgated by such Secretary determine if the applicant acted with due diligence during the applicable regulatory review period. The Secretary shall make such determination not later than ninety days after the receipt of such a petition. The Secretary of Health and Human Services may not delegate the authority to make the determination prescribed by this subparagraph to an office below the Office of the Commissioner of Food and Drugs.

"(ii) The Secretary making a determination under clause (i) shall notify the Commissioner of the determination and shall publish in the Federal Register a notice of such determination together with the factual and legal basis for such determination. Any interested person may request, within the sixty day period beginning on the publication of a determination, the Secretary making the determination to hold an informal hearing on the determination. If such a request is made within such period, such Secretary shall hold such hearing not later than thirty days after the date of the request, or at the request of the person making the request, not later than sixty days after such date. The Secretary who is holding the hearing shall provide notice of the hearing to the owner of the patent involved and to any interested person and provide the owner and any interested person an opportunity to participate in the hearing. Within thirty days after the completion of the hearing, such Secretary shall affirm or revise the determination which was the subject of the hearing and notify the Commissioner of any revision of the determination and shall publish any such revision in the Federal Register.

"(3) For purposes of paragraph (2)(B), the term 'due diligence' means that degree of attention, continuous directed effort, and timeliness as may reasonably be expected from, and are ordinarily exercised by, a person during a regulatory review period.

"(4) An application for the extension of the term of a patent is subject to the disclosure requirements prescribed by the Commissioner.

"(e)(1) A determination that a patent is eligible for extension may be made by the Commissioner solely on the basis of the information contained in the application for the extension. If the Commissioner determines that a patent is eligible for extension under subseciton (a) and that the requirements of subsection (d) have been complied with, the Commissioner shall issue to the

applicant for the extension of the term of the patent a certificate of extension, under seal, for the period prescribed by subsection (c). Such certificate shall be recorded in the official file of the patent and shall be considered as part of the original patent.

"(2) If the term of a patent for which an application has been submitted under subsection (d) would expire before a determination is made under paragraph (1) respecting the application, the Commissioner shall extend, until such determination is made, the term of the patent for periods of up to one year if he determines that the patent is eligible for extension.

"(f) For purposes of this section:

"(1) The term 'product' means:

"(A) A drug product.

"(B) Any medical device, food additive, or color additive subject to regulation under the Federal Food, Drug, and Cosmetic Act.

"(2) The term 'drug product' means the active ingredient of a new drug, antibiotic drug, new animal drug, or human or veterinary biological product (as those terms are used in the Federal Food, Drug, and Cosmetic Act, the Public Health Service Act, and the Virus Serum Toxin Act including any salt or ester of the active ingredient, as a single entity or in combination with another active ingredient.

"(3) The term 'major health or environmental effects test' means a test which is reasonably related to the evaluation of the health or environmental effects of a product, which requires at least six months to conduct, and the data from which is submitted to receive permission for commercial marketing or use. Periods of analysis or evaluation of test results are not to be included in determining if the conduct of a test required at least six months.

"(4)(A) Any reference to section 351 is a reference to section 351 of the Public Health Service Act.

"(B) Any reference to section 503, 505, 507, 512, or 515 is a reference to section 503, 505, 507, 512, or 515 of the Federal Food, Drug, and Cosmetic Act.

"(C) Any reference to the Virus Serum Toxin Act is a reference to the Act of March 4, 1913 (21 U.S.C. 151-158).

"(5) The term 'informal hearing' has the meaning prescribed for such term by section 201(y) of the Federal Food, Drug, and Cosmetic Act.

"(6) The term 'patent' means a patent issued by the United States Patent and Trademark Office.

"(g) For purposes of this section, the term 'regulatory review period' has the following meanings:

"(1)(A) In the case of a product which is a drug product, the term means the period described in subparagraph (B) to which the limitation described in paragraph (4) applies.

"(B) The regulatory review period for a drug product is the sum of—

"(i) the period beginning on the date—

"(I) an exemption under subsection (i) of section 505, subsection (d) of section 507, or subsection (i) of section 512, or

"(II) the authority to prepare an experimental drug product under the Virus Serum Toxin Act,

became effective for the approved drug product and ending on the date an application was initially submitted for such drug product under section 351, 505, 507, or 512 or the Virus Serum Toxin Act, and

"(ii) the period beginning on the date the application was initially submitted for the approved drug product under section 351, subsection (b) of such section 505, section 507, section 512, or the Virus Serum Toxin Act and ending on the date such application was approved under such section or Act.

"(2)(A) In the case of a product which is a food additive or color additive, the term means the period described in subparagraph (B) to which the limitation described in paragraph (4) applies.

"(B) The regulatory review period for a food or color additive is the sum of—

"(i) the period beginning on the date a major health or environmental effects test on the additive was initiated and ending on the date a petition was initially submitted with respect to the product under the Federal Food, Drug, and Cosmetic Act requesting the issuance of a regulation for use of the product, and

"(ii) the period beginning on the date a petition was initially submitted with respect to the product under the Federal Food, Drug, and Cosmetic Act requesting the issuance of a regulation for use of the product, and ending on the date such regulation became effective or, if objections were filed to such regulation, ending on the date such objections were resolved and commercial marketing was permitted or, if commercial marketing was permitted and later revoked pending further proceedings as a result of such objections, ending on the date such proceedings were finally resolved and commercial marketing was permitted.

"(3)(A) In the case of a product which is a medical device, the terms means the period described in subparagraph (B) to which the limitation described in paragraph (4) applies.

"(B) The regulatory review period for a medical device is the sum of—

"(i) the period beginning on the date a clinical investigation on humans involving the device was begun and ending on the date an application was initially submitted with respect to the device under section 515, and

"(ii) the period beginning on the date an application was initially submitted with respect to the device under section 515 and ending on the date such application was approved under such Act or the period beginning on the date a notice of completion of a product development protocol was initially submitted under section 515(f)(5) and ending on the date the protocol was declared completed under section 515(f)(6).

"(4) A period determined under any of the preceding paragraphs is subject to the following limitations:

"(A) If the patient involved was issued after the date of the enactment of this section, the period of extension determined on the basis of the regulatory review period determined under any such paragraph may not exceed five years.

"(B) If the patent involved was issued before the date of the enactment of this section and—

"(i) no request for an exemption described in paragraph (1)(B) was submitted,

"(ii) no request was submitted for the preparation of an experimental drug product described in paragraph (1)(B),

"(iii) no major health or environmental effects test described in paragraph (2) was initiated and no petition for a regulation or application for registration described in such paragraph was submitted, or

"(iv) no clinical investigation described in paragraph (3) was begun or product development protocol described in such paragraph was submitted,

before such date for the approved product the period of extension determined on the basis of the regulatory review period determined under any such paragraph may not exceed five years.

"(C) If the patent involved was issued before the date of the enactment of this section and if an action described in subparagraph (B) was taken before the date of the enactment of this section with respect to the approved product and the commercial marketing or use of the product has not been approved before such date, the period of extension determined on the basis of the regulatory review period determined under such paragraph may not exceed two years.

"(h) The Commissioner may establish such fees as the Commissioner determines appropriate to cover the costs to the Office of receiving and acting upon applications under this section.".

(b) The analysis for chapter 14 of title 35 of the United States Code is amended by adding at the end thereof the following:

"156. Extension of patent term.".

SEC. 202. Section 271 of title 35, United States Code is amended by adding at the end the following:

"(e)(1) It shall not be an act of infringement to make, use, or sell a patented invention solely for uses reasonably related to the development and submission of information under a Federal law which regulates the manufacture, use, or sale of drugs.

"(2) It shall be an act of infringement to submit an application under section 505(j) of the Federal Food, Drug, and Cosmetic Act or described in section 505(b)(2) of such Act for a drug claimed in a patent or the use of which is claimed in a patent, if the purpose of such submission is to obtain approval under such Act to engage in the commercial manufacture, use, or sale of a drug claimed in a patent or the use of which is claimed in a patent before the expiration of such patent.

"(3) In any action for patent infringement brought under this section, no injunctive or other relief may be granted which would prohibit the making, using, or selling of a patented invention under paragraph (1).

"(4) For an act of infringement described in paragraph (2)—

"(A) the court shall order the effective date of any approval of the drug involved in the infringement to be a date which is not earlier than the date of the expiration of the patent which has been infringed,

"(B) injunctive relief may be granted against an infringer to prevent the commercial manufacture, use, or sale of an approved drug, and

"(C) damages or other monetary relief may be awarded against an infringer only if there has been commercial manufacture, use, or sale of an approved drug.

The remedies prescribed by subparagraphs (A), (B), and (C) are the only remedies which may be granted by a court for an act of infringement described in paragraph (2), except that a court may award attorney fees under section 285.".

SEC. 203. Section 282 of title 35, United States Code, is amended by adding at the end the following:

"Invalidity of the extension of a patent term or any portion thereof under section 156 of this title because of the material failure—

"(1) by the applicant for the extension, or

"(2) by the Commissioner,

to comply with the requirements of such section shall be a defense in any action involving the infringement of a patent during the period of the extension of its term and shall be pleaded. A due diligence determination under section 156(d)(2) is not subject to review in such an action.".

□ 1420

JUDICIARY COMMITTEE AMENDMENTS TO TITLE II

The CHAIRMAN. The Clerk will report the amendments by the Committee on the Judiciary to title II.

The Clerk read as follows:

Committee amendments to title II:

Page 38, line 2, strike out "or the Secretary of Agriculture".

Page 38, strike out lines 13, through 24, and insert in lieu thereof the following:

"(1), the Commissioner shall notify the Secretary of Health and Human Services if the patent claims any human drug product, a medical device, or a food additive or color additive or a method of using or manufacturing such a product, device, or additive and if the product, device, and additive are subject to the Federal Food, Drug, and Cosmetic Act.

Page 39, line 9, strike out "who is so notified".

Page 39, line 11, strike out "receiving the application".

Page 39, lines 18 and 23, strike out "making the determination".

Page 39, line 24, stike out "such" and insert in lieu thereof "the".

Page 40, beginning in line 3 strike out "of Health and Human Services".

Page 40, beginning in line 7 strike out "making a determination under clause (i)".

Page 40, line 13, stike out "making the determination".

Page 40, lines 15 and 23, strike out "such" and insert in lieu thereof "the".

Page 40, beginning in line 18 strike out "who is holding the hearing".

Page 42, line 6, strike out "drug product" and insert in lieu thereof "human drug product".

Page 42, line 10, strike out "drug product" and insert in lieu thereof "human drug product".

Page 42, beginning in line 11, strike out "new animal" and all that follows through line 15 and insert in lieu thereof the following: "or human biological product (as those terms are used in the Federal Food, Drug, and Cosmetic Act and the Public Health Service Act)".

Page 43, lines 7 and 8, strike out "512,".

Page 43, strike out lines 10 through 12.

Page 43, lines 21 and 24, insert "human" before "drug".

Page 44, strike out lines 1 through 12, and insert in lieu thereof the following:

"(i) the period beginning on the date an exemption under subsection (i) of section 505 or under subsection (d) of section 507 became effective for the approved human drug product and ending on the date an application was initially submitted for such drug product under section 351, 505, or 507, and

Page 44, strike out lines 23 through 25 and lines 1 and 2 on page 45 and insert in lieu thereof the following: "human drug product under section 351, subsection (b) of section 505, or section 507 and ending on the date such application was approved under such section."

Page 47, strike out lines 14 through 16 and redesignate clauses (iii) and (iv) as clauses (i) and (iii), respectively.

Page 48, line 25, insert after "patented invention" the following: "(other than a new animal drug or veterinary biological product (as those terms are used in the Federal Food, Drug, Cosmetic Act and the Act of March 4, 1913))".

Mr. KASTENMEIER (during the reading). Mr. Chairman, I ask unanimous consent that the committee amendments be considered as read and printed in the RECORD.

Mr. CHAIRMAN. Is there objection to the request of the gentleman from Wisconsin?

There was no objection.

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

Mr. KASTENMEIER. I will be very brief, Mr. Chairman.

I rise in support of the Judiciary Committee amendments.

The amendment deletes authority for patent term extension for animal drugs, because these substances are dealt with in another bill recently ordered reported by the Committee on the Judiciary, H.R. 6034.

I know of no opposition to these amendments and I would hope that the Committee of the Whole could vote for the amendments.

The CHAIRMAN. The question is on the Judiciary Committee amendments to title II.

The Judiciary Committee amendments to title II were agreed to.

AMENDMENT OFFERED BY MR. WAXMAN

Mr. WAXMAN. Mr. Chairman, I offer an amendment.

The Clerk read as follows:

Amendment offered by Mr. WAXMAN: Page 31, strike out line 7 and all that follows through line 2 on page 51 and insert in lieu thereof the following:

TITLE II—PATENT EXTENSION

SEC. 201. (a) Title 35 of the United States Code is amended by adding the following new section immediately after section 155A:

"§ 156. Extension of patent term

"(a) The term of a patent which claims a product, a method of using a product, or a method of manufacturing a product shall be extended in accordance with this section from the original expiration date of the patent if—

"(1) the term of the patent has not expired before an application is submitted under subsection (d) for its extension;

"(2) the term of the patent has never been extended;

"(3) an application for extension is submitted by the owner of record of the patent or its agent and in accordance with the requirements of subsection (d);

"(4) the product has been subject to a regulatory review period before its commercial marketing or use;

"(5)(A) except as provided in subparagraph (B), the permission for the commercial marketing or use of the product after such regulatory review period is the first permitted commercial marketing or use of the product under the provision of law under which such regulatory review period occurred; or

"(B) in the case of a patent which claims a method of manufacturing the product which primarily uses recombinant DNA technology in the manufacture of the product, the permission for the commercial marketing or use of the product after such regulatory review period is the first permitted commercial marketing or use of a product manufactured under the process claimed in the patent.

The product referred to in paragraphs (4) and (5) is hereinafter in this section referred to as the 'approved product'.

"(b) The rights derived from any patent the term of which is extended under this section shall during the period during which the patent is extended—

"(1) in the case of a patent which claims a product, be limited to any use approved for the approved product before the expiration of the term of the patent under the provision of law under which the applicable regulatory review occurred;

"(2) in the case of a patent which claims a method of using a product, be limited to any use claimed by the patent and approved for the approved product before the expiration of the term of the patent under the provision of law under which the applicable regulatory review occurred; and

"(3) in the case of a patent which claims a method of manufacturing a product, be limited to the method of manufacturing as used to make the approved product.

"(c) The term of a patent eligible for extension under subsection (a) shall be extended by the time equal to the regulatory review period for the approved product which period occurs after the date the patent is issued, except that—

"(1) each period of the regulatory review period shall be reduced by any period determined under subsection (d)(2)(B) during which the applicant for the patent extension did not act with due diligence during such period of the regulatory review period;

"(2) after any reduction required by paragraph (1), the period of extension shall include only one-half of the time remaining in the periods described in paragraphs (1)(B)(i), (2)(B)(i), and (3)(B)(i) of subsection (g);

"(3) if the period remaining in the term of a patent after the date of the approval of the approved product under the provision of law under which such regulatory review occurred when added to the regulatory review period as revised under paragraphs (1) and (2) exceeds fourteen years, the period of extension shall be reduced so that the total of both such periods does not exceed fourteen years; and

"(4) in no event shall more than one patent be extended for the same regulatory review period for any product.

"(d)(1) To obtain an extension of the term of a patent under this section, the owner of record of the patent or its agent shall submit an application to the Commissioner. Such an application may only be submitted within the sixty-day period beginning on the date the product received permission under the provision of law under which the applicable regulatory review period occured for commercial marketing or use. The application shall contain—

"(A) the identity of the approved product and the Federal stature under which regulatory review occurred;

"(B) the identity of the patent for which an extension is being sought and the identity of each claim of such patent which claims the approved product or a method of using or manufacturing the approved product;

"(C) information to enable the Commissioner to determine under subsections (a) and (b) the eligibility of a patent for extension and the rights that will be derived from the extension and information to enable the Commissioner and the Secretary of Health and Human Services to determine the period of the extension under subsection (g);

"(D) a brief description of the activities undertaken by the applicant during the applicable regulatory review period with respect to the approved product and the significant dates applicable to such activities; and

"(E) such patent or other information as the Commissioner may require.

"(2)(A) Within sixty days of the submittal of an application for extension of the term of a patent under paragraph (1), the Commissioner shall notify the Secretary of Health and Human Services if the patent claims any human drug product, a medical device, or a food additive or color additive or a method of using or manufacturing such a

product, device, or additive and if the product, device, and additive are subject to the Federal Food, Drug, and Cosmetic Act, of the extension application and shall submit to the Secretary a copy of the application. Not later than 30 days after the receipt of an application from the Commissioner, the Secretary shall review the dates contained in the application pursuant to paragraph (1)(C) and determine the applicable regulatory review period, shall notify the Commissioner of the determination, and shall publish in the Federal Register a notice of such determination.

"(B)(i) If a petition is submitted to the Secretary under subparagraph (A), not later than one hundred and eighty days after the publication of the determination under subparagraph (A), upon which it may reasonably be determined that the applicant did not act with due diligence during the applicable regulatory review period, the Secretary shall, in accordance with regulations promulgated by the Secretary determine if the applicant acted with due diligence during the applicable regulatory review period. The Secretary shall make such determination not later than 90 days after the receipt of such a petition. The Secretary may not delegate the authority to make the determination prescribed by this subparagraph to an office below the Office of the Commissioner of Food and Drugs.

"(ii) The Secretary shall notify the Commissioner of the determination and shall publish in the Federal Register a notice of such determination together with the factual and legal basis for such determination. Any interested person may request, within the 60 day period beginning on the publication of a determination, the Secretary to hold an informal hearing on the determination. If such a request is made within such period, the Secretary shall hold such hearing not later than thirty days after the date of the request, or at the request of the person making the request, not later than sixty days after such date. The Secretary shall provide notice of the hearing to the owner of the patent involved and to any interested person and provide the owner and any interested person an opportunity to participate in the hearing. Within thirty days after the completion of the hearing, the Secretary shall affirm or revise the determination which was the subject of the hearing and notify the Commissioner of any revision of the determination and shall publish any such revision in the Federal Register.

"(3) For purposes of paragraph (2)(B), the term 'due diligence' means that degree of attention, continuous direct effort, and timeliness as may reasonably be expected from, and are ordinarily exercised by, a person during a regulatory review period.

"(4) An application for the extension of the term of a patent is subject to the disclosure requirements prescribed by the Commissioner.

"(e)(1) A determination that a patent is eligible for extension may be made by the Commissioner solely on the basis of the representations contained in the application for the extension. If the Commissioner determines that a patent is eligible for extension under subsection (a) and that the requirements of subsection (d) have been complied with, the Commissioner shall issue to the applicant for the extension of the term of the patent a certificate of extension, under seal, for the period prescribed by subsection (c). Such certificate shall be recorded in the official file of the patent and shall be considered as part of the original patent.

"(2) If the term of a patent for which an application has been submitted under subsection (d) would expire before a certificate of extension is issued or denied under paragraph (1) respecting the application, the Commissioner shall extend, until such determination is made, the term of the patent for periods of up to one year if he determines that the patent is eligible for extension.

"(f) For purposes of this section:

"(1) The term 'product' means:

"(A) A human drug product.

"(B) Any medical device, food additive, or color additive subject to regulation under the Federal Food, Drug, and Cosmetic Act.

"(2) The term 'human drug product' means the active ingredient of a new drug, antibiotic drug, or human biological product (as those terms are used in the Federal Food, Drug, and Cosmetic Act and the Public Health Service Act) including any salt or ester of the active ingredient, as a single entity or in combination with another active ingredient.

"(3) The term 'major health or environmental effects test' means a test which is reasonably related to the evaluation of the health or environmental effects of a product, which requires at least six months to conduct, and the data from which is submitted to receive permission for commercial marketing or use. Periods of analysis or evaluation of test results are not to be included in determining if the conduct of a test required at least six months.

"(4)(A) Any reference to section 351 is a reference to section 351 of the Public Health Service Act.

"(B) Any reference to section 503, 505, 507, or 515 is a reference to section 503, 505, 507, or 515 of the Federal Food, Drug, and Cosmetic Act.

"(5) The term 'informal hearing' has the meaning prescribed for such term by section 201(y) of the Federal Food, Drug, and Cosmetic Act.

"(6) The term 'patent' means a patent issued by the United States Patent and Trademark Office.

"(g) For purposes of this section, the term 'regulatory review period' has the following meanings:

"(1)(A) In the case of a product which is a human drug product, the term means the period described in subparagraph (B) to which the limitation described in paragraph (4) applies.

"(B) The regulatory review period for a human drug product is the sum of—

"(i) the period beginning on the date an exemption under subsection (i) of section 505 or subsection (d) of section 507 became effective for the approved human drug product and ending on the date an application was initially submitted for such drug product under section 351, 505, or 507; and

"(ii) the period beginning on the date the application was initially submitted for the approved human drug product under section 351, subsection (b) of section 505, or section 507 and ending on the date such application was approved under such section.

"(2)(A) In the case of a product which is a food additive or color additive, the term means the period described in subparagraph (B) to which the limitation described in paragraph (4) applies.

"(B) The regulatory review period for a food or color additive is the sum of—

"(i) the period beginning on the date a major health or environmental effects test on the additive was initiated and ending on the date a petition was initially submitted with respect to the product under the Federal Food, Drug, and Cosmetic Act requesting the issuance of a regulation for use of the product, and

"(ii) the period beginning on the date a petition was initially submitted with respect to the product under the Federal Food, Drug, and Cosmetic Act requesting the issuance of a regulation for use of the product, and ending on the date such regulation became effective or, if objections were filed to such regulation, ending on the date such objections were resolved and commercial marketing was permitted or, if commercial marketing was permitted and later revoked pending further proceedings as a result of such objections, ending on the date such proceedings were finally resolved and commercial marketing was permitted.

"(3)(A) In the case of a product which is a medical device, the term means the period described in subparagraph (B) to which the limitation described in paragraph (4) applies.

"(B) The regulatory review period for a medical device is the sum of—

"(i) the period beginning on the date a clinical investigation on humans involving the device was begun and ending on the date an application was initially submitted with respect to the device under section 515, and

"(ii) the period beginning on the date an application was initially submitted with respect to the device under section 515 and ending on the date such application was approved under such Act or the period beginning on the date a notice of completion of a product development protocol was initially submitted under section 515(f)(5) and ending on the date the protocol was declared completed under section 515(f)(6).

"(4) A period determined under any of the preceding paragraphs is subject to the following limitations:

"(A) If the patent involved was issued after the date of the enactment of this section, the period of extension determined on the basis of the regulatory review period determined under any such paragraph may not exceed five years.

"(B) If the patent involved was issued before the date of the enactment of this section and—

"(i) no request for an exemption described in paragraph (1)(B) was submitted,

"(ii) no major health or environmenal effects test described in paragraph (2) was initiated and no petition for a regulation or application for registration described in such pargraph was submitted, or

"(iii) no clinical investigation described in paragraph (3) was begun or product development protocol described in such paragraph was submitted.

before such date for the approved product the period of extension determined on the basis of the regulatory review period determined under any such paragraph may not exceed five years.

"(C) If the patent involved was issued before the date of the enactment of this section and if an action described in subparagraph (B) was taken before the date of the enactment of this section with respect to the approved product and the commercial marketing or use of the product has not been approved before such date, the period of extension determined on the basis of the regulatory review period determined under such paragraph may not exceed two years.

"(h) The Commissioner may establish such fees as the Commissioner determines appropriate to cover the costs to the Office of receiving and acting upon applications under this section.".

"(b) The analysis for chapter 14 of title 35 of the United States Code is amended by adding at the end thereof the following:

"156. Extension of patent term.".

SEC. 202. Section 271 of title 35, United States Code is amended by adding at the end the following:

"(e)(1) It shall not be an act of infringement to make, use, or sell a patented invention (other than a new animal drug or veterinary biological product (as those terms are used in the Federal Food, Drug, and Cosmetic Act and the Act of March 4, 1913)) solely for uses reasonably related to the development and submission of information under a Federal law which regulates the manufacture, use, or sale of drugs.

"(2) It shall be an act of infringement to submit an application under section 505(j) of the Federal Food, Drug, and Cosmetic Act or described in section 505 (b)(2) of such Act for a drug claimed in a patent or the use of which is claimed in a patent, if the purpose of such submission is to obtain approval under such Act to engage in the commercial manufacture, use, or sale of a drug claimed in a patent or the use of which is claimed in a patent before the expiration of such patent.

"(3) In any action for patent infringement brought under this section, no injunctive or other relief may be granted which would prohibit the making, using, or selling of a patented invention under paragraph (1).

"(4) For an act of infringement described in paragraph (2)—

"(A) the court shall order the effective date of any approval of the drug involved in the infringement to be a date which is not earlier than the date of the expiration of the patent which has been infringed,

"(B) injunctive relief may be granted against an infringer to prevent the commercial manufacture, use, or sale of an approved drug, and

"(C) damages or other monetary relief may be awarded against an infringer only if there has been commercial manufacture, use, or sale of an approved drug.

The remedies prescribed by subparagraphs (A), (B), and (C) are the only remedies which may be granted by a court for an act of infringement described in paragraph (2), except that a court may award attorney fees under section 285.".

SEC. 203. Section 282 of title 35, United States Code, is amended by adding at the end the following:

"Invalidity of the extension of a patent term or any portion thereof under section 156 of this title because of the material failure—

"(1) by the applicant for the extension, or

"(2) by the Commissioner,

to comply with the requirements of such section shall be a defense in any action involving the infringement of a patent during the period of the extension of its term and shall be pleaded. A due diligence determination under section 156(d)(2) is not subject to review in such an action.".

Mr. WAXMAN [during the reading]. Mr. Chairman, I ask unanimous consent that the amendment be considered as read and printed in the RECORD.

The CHAIRMAN. Is there objection to the request of the gentleman from California?

There was no objection.

Mr. WAXMAN. Mr. Chairman, my amendment to title II is the same as the text of title II of the Senate-passed bill. This amendment would make one significant change to title II of the bill before us.

The one change involves the rules about which patents can be extended. Under this amendment, the patent-holder would be allowed to select the patent to be extended. Under the bill, the first issued patent would have automatically been extended. The rules in the bill which establish the length of patent extension and which allow only one patent per drug to be extended are not changed.

I believe this amendment is acceptable because it gives the patent-holder the flexibility to select the most important patent for extension, but it does not undercut the two most important rules. They are that only one patent can be extended per drug and only for up to 14 years.

This amendment also addresses an issue raised by the Patent and Trademark Office (PTO). The PTO expressed concern that the bill may require it to verify information submitted in an application for patent extension. The amendment clarifies that the PTO may rely upon representations made by a patentowner in its application.

This is a good amendment and I urge all Members to support it.

Mr. MADIGAN. Mr. Chairman, I rise in support of the amendment.

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

Mr. MADIGAN. Mr. Chairman, this change referred to by the chairman of the subcommittee is the one requested by the Patent Office, and with this change enables the administration to be supportive of not only this amendment but of the bill, and I would urge that all my colleagues support the amendment.

The CHAIRMAN. The question is on the amendment offered by the gentleman from California [Mr. WAXMAN].

The amendment was agreed to.

AMENDMENT OFFERED BY MR. DERRICK

Mr. DERRICK. Mr Chairman, I offer an amendment.

The Clerk read as follows:

Amendment offered by Mr. DERRICK: Insert at the end the following:

TITLE III—AMENDMENTS TO THE TEXTILE FIBER PRODUCTS IDENTIFICATION ACT AND THE WOOL PRODUCTS LABELING ACT OF 1939

SEC. 301. Subsection (b) of section 4 of the Textile Fiber Products Identification Act (15 U.S.C. 70b) is amended by adding at the end thereof the following new paragraph:

"(5) If it is a textile fiber product processed or manufactured in the United States, it be so identified.".

SEC. 302. Subsection (e) of section 4 of the Textile Fiber Products Identification Act (15 U.S.C. 70b) is amended to read as follows:

"(e) For purposes of this Act, in addition to the textile fiber products contained therein, a package of textile fiber products intended for sale to the ultimate consumer shall be misbranded unless such package has affixed to it a stamp, tag, label, or other means of identification bearing the information required by subsection (b), with respect to such contained textile fiber products, or is transparent to the extent it allows for the clear reading of the stamp, tag, label, or other means of identification on the textile fiber product, or in the case of hosiery items, this section shall not be construed as requiring the affixing of a stamp, tag, label, or other means of identification to each hosiery product contained in a package if (1) such hosiery products are intended for sale to the ultimate consumer in such package, (2) such package has affixed to it a stamp, tag, label, or other means of identification bearing, with respect to the hosiery products contained therein, the information required by subsection (b), and (3) the information on the stamp, tag, label, or other means of identification affixed to such package is equally applicable with respect to each textile fiber product contained therein.".

SEC. 303. Section 4 of the Textile Fiber Products Identification Act (15 U.S.C. 70b) is amended by adding at the end thereof the following new subsections:

"(i) For the purposes of this Act, a textile fiber product shall be considered to be falsely or deceptively advertised in any mail order catalog or mail order promotional material which is used in the direct sale or direct offering for sale of such textile fiber product, unless such textile fiber product description states in a clear and conspicuous manner that such textile fiber product is processed or manufactured in the United States of America, or imported, or both.

"(j) For purposes of this Act, any textile fiber product shall be misbranded if a stamp, tag, label, or other identification conforming to the requirements of this section is not on or affixed to the collar of such product if such product contains a collar, or if such product does not contain a collar, in the most conspicuous place on the inner side of such product, unless it is on or affixed on the outer side of such product, or in the case of hosiery items on the outer side of such product or package.".

SEC. 304. Paragraph (2) of section 4(a) of the Wool Products Labeling Act of 1939 (15 U.S.C. 68b(1)) is amended by adding at the end thereof the following new subparagraphs:

"(5) If it is an imported wool product without the name of the country where processed or manufactured.

"(6) If it is wool product processed or manufactured in the United States, it shall be so identified.".

SEC. 305. Section 4 of the Wool Products Labeling Act of 1939 (15 U.S.C. 68b) is amended by adding at the end thereof the following new subsections:

"(e) For the purposes of this Act, a wool product shall be considered to be falsely or deceptively advertised in any mail order catalog or mail order promotional material which is used in the direct sale or direct offering for sale of such wool product, unless such wool product description states in a clear and conspicuous manner that such wool product is processed or manufactured in the United States of America, or imported, or both.

"(f) For purposes of this Act, any wool product shall be misbranded if a stamp, tag, label, or other identification conforming to the requirements of this section is not on or affixed to the collar of such product if such product contains a collar, or if such product does not contain a collar in the most conspicuous place on the inner side of such product, unless it is on or affixed on the outer side of such product or in the case of hosiery items, on the outer side of such product or package.".

SEC. 306. Section 5 of the Wool Products Labeling Act of 1939 (15 U.S.C. 68c) is amended—

(1) by striking out "Any person" in the first paragraph and inserting in lieu thereof "(a) Any person",

(2) by striking out "Any person" in the second paragraph and inserting in lieu thereof "(b) Any person", and

(3) by inserting after subsection (b) (as designated by this section) the following new subsection:

"(c) For the purposes of subsections (a) and (b) of this section, any package of wool products intended for sale to the ultimate consumer shall also be considered a wool product and shall have affixed to it a stamp, tag, label, or other means of identification bearing the information required by section 4, with respect to the wool products contained therein, unless such package of wool products is transparent to the extent that it allows for the clear reading of the stamp, tag, label, or other means of identification affixed to the wool product, or in the case of hosiery items this section shall not be construed as requiring the affixing of a stamp, tag, label, or other means of identification to each hosiery product contained in a package if (1) such hosiery products are intended for sale to the ultimate consumer in such package, (2) such package has affixed to it a stamp, tag, label, or other means of identification bearing, with respect to the hosiery products contained therein, the information required by subsection (4), and (3) the information on the stamp, tag, label, or other means of identification affixed to such package is equally applicable with respect to each hosiery product contained therein.".

SEC. 307. The amendments made by this title shall be effective ninety days after the date of enactment of this Act.

Mr. DERRICK (during the reading). Mr. Chairman, I ask unanimous consent that the amendment be considered as read and printed in the RECORD.

The CHAIRMAN. Is there objection to the request of the gentleman from South Carolina?

There was no objection.

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

[Mr. DERRICK addressed the Committee. His remarks will appear hereafter in the Extensions of Remarks.]

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

Mr. DERRICK. I yield to the gentleman from North Carolina.

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

Mr. HEFNER. Mr. Chairman, I rise in strong support of this amendment.

Mr. BROYHILL. Mr. Chairman, I rise in support of the amendment.

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

Mr. BROYHILL. Mr. Chairman, I rise in strong support of the amendment that has been offered here by the gentleman from South Carolina [Mr. DERRICK].

He has stated the many problems that are confronting the textile and apparel industry. Certainly they are serious problems. We have seen the textile and apparel imports increasing substantially just in the past 12 months.

What this amendment is about, however, really goes, it seems to me, to a question of what are fair trade practices. Studies have shown that the consumers of U.S. textile and apparel products would prefer American-made products if they know where those products are made. Unfortunately, there is presently in existence in the law no provision or regulation requiring that American-made products be labeled as such. Of course, the public has a tendency to assume that a product is domestically produced unless that product is labeled as coming from a foreign country. But that is not always the case.

What this legislation is designed to do is to give consumers the information they have a right to know and need in order to make informed purchasing decisions.

Now, the amendment that is offered by the gentleman from South Carolina is based on H.R. 5638, a bill that I introduced on May 10, 1984. It has been cosponsored by some 79 of my colleagues. What the amendment offered by the gentleman from South Carolina would do simply is to require that the textile and apparel products be labeled as made in the United States if they are produced domestically, and as I have said, this would assist consumers in making consumer decisions.

Also, the amendment would correct certain ambiguities and strengthen provisions in our present laws. At the present time the Federal Trade Commission has issued regulations to carry out the Textile Fiber Products Identification Act, and those regulations currently provide that all imported textile products bear a country-of-origin label. This requirement is not in the law itself. Many textile and apparel products are not in compliance as they enter this country. Oftentimes the label are placed in inconspicuous places, and it makes enforcement a major problem.

In addition, the amendment offered by the gentleman from South Carolina requires that the bulk container, as well as the individual textile product, be labeled as to country of origin. Frequently we have found in the marketplace that the bulk shipments into the United States are labeled correctly, but on entry and on placement in the shelves, retail shelves, the goods are broken up and packages are broken up, and by the time the product reaches the shelf no label exists.

Finally, the amendment would require that the descriptive material for textile and wool products in catalogs and in mail-order promotional literature must contain an appropriate disclosure of where they were made. Here also American consumers have the right to know what they are buying, and this amendment will assure that they have the information they need to make well-informed choices.

So, Mr. Chairman, as I have stated earlier, this amendment is a good first step toward correcting an imbalance in the law. It provides American consumers with the information they need with respect to the products that they are about to purchase. I urge my colleagues to join with us in voting for this amendment.

Mr. JENKINS. Mr. Chairman, I move to strike the requisite number of words.

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

Mr. JENKINS. Mr. Chairman, today I rise in strong support of the Derrick amendment on textile labeling. current law does not address the oversights that this proposal seeks to remedy. I am also opposed to any amendments that will alter its intent. Please bear in mind that this legislation has progressed through a House subcommittee and full committee without a dissenting vote, It has passed the full Senate without a dissenting vote. There would not appear to be a need to make changes on what has unanimously been agreed to in the legislative process.

A few of the most important features of this proposal should be noted. First, under this proposal, all U.S.-made textile products would be required to contain a label noting that they are made in the United States; and all labels—both foreign and domestic—must be conspicuously placed. consumer surveys have indicated that the American consumer, if given a chance, would like to purchase American-made textile products over their foreign counterparts. However, there are presently no clear-cut ways that the consumer can determine whether a garment is manufactured in the United States or not. The absence of any origin label generally causes the consumer to automatically assume that a product is domestically produced, but such is often not the case. Although there are laws that require that foreign-made textile products be labeled as such, there are various ways the American consumer can be deceived by labels placed in such an inconspicuous manner that few ever detect them. This provision would help provide information that the consumer desires.

A second and most important feature of this proposal is a requirement that mail-order catalog offerings indicate whether a textile product is imported or made in the United States. The Federal Trade Commission has maintained in numerous advisory opinions issued that country of origin information should be included in all mail order catalogs and promotional materials, so that the consumer may determine where a textile product originated at the point of purchase. The Federal Trade Commission has based its determination on the fact that when a consumer orders textile products, he or she does not have an opportunity, generally, to inspect the merchandise before making payment.

It should also be noted here that a number of mail order catalog companies already disclose such information, and do not consider this item-by-item

type of disclosure as overly burdensome or costly in the least. In response to the mail-order catalog industry's contention that this requirement is costly, I understand that they have provided no data to prove their contention, despite persistent requests for this data from the subcommittee which conducted hearings on this matter.

It should also be pointed out that, in addition to the bill being a consumer information proposal, it requires absolutely no Federal expenditure in order to be enacted.

This proposal comes at a time when the domestic industry is seriously hurting from unfair foreign competition. The textile industry has had to deal in a practical manner with the consequences of a 44-percent year-to-date import increase in textiles and apparel. Hundreds of thousands of job opportunities are being displaced annually due to the phenomenal import surge the industry has witnessed in recent years. I've received stacks of letters from textile workers in my district who have either been laid off or are living in constant fear of losing their jobs to imports. They have asked me to suport this labeling proposal. A large coalition known as AFTAC, which is comprised of textile and apparel manufacturers, natural fiber and man-made fiber producers, and two labor unions, has asked me to support this proposal. Let me just name some of the 21 organizations which are members of AFTAC [the American Fiber, Textile, Apparel Coalition] so you may see the broad support that this proposal enjoys: the American Apparel Manufacturers Association, the American Textile Manufacturers Institute, the International Ladies' Garment Workers Union, the Amalgamated Clothing and Textile Workers Union, the National Cotton Council, The National Wool Growers Association, the Man-Made Fiber Producers Association, and the Northern Textile Association.

I once again urge all my fellow colleagues to join me in my support of this proposal by voting down any amendments that would weaken its intent.

□ 1440

Mr. BROYHILL. Mr. Chairman, would the gentleman yield?

Mr. JENKINS. I would be happy to yield.

Mr. BROYHILL. Mr. Chairman, as one example of what the bill would do, and I hold it in my hand here, a textile product, it is a pair of work gloves, a 100-percent cotton work gloves. These came in a bulk shipments and on the bulk container it was marked from the country of origin. Well, what happened was that the retailer broke these up and put them on the retail shelf and there is absolutely no indication of the country of origin. That is just one of the simple amendments that is included in the gentleman's amendment to assure that when the bulk shipment is broken up that the individual garment or the individual item itself be appropriately marked.

I just wanted to show that to the Members and to indicate this which we have found out there in the market place.

Mr. JENKINS. I thank my colleague for pointing that out. This is a good example of what is occurring today.

I do urge that all my colleagues support this very needed amendment.

Mr. CAMPBELL. Mr. Chairman, I move to strike the requisite number of words.

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

Mr. CAMPBELL. Mr. Chairman, I rise in support of the textile labeling amendment offered by my colleague, the gentleman from South Carolina [Mr. DERRICK]. This amendment is based on H.R. 5638, of which I was an original cosponsor.

To me this is a straightforward piece of legislation that simply gives American consumers a choice, an option to support American workers and American industry by buying U.S. made textile and apparel goods. I cannot find anything wrong with that.

American consumers have become increasingly aware of the desirability of buying American. The overall trade deficit has skyrocketed in this country, fueled in no small part by the growing textile-apparel trade deficit. Consumers cannot help but be aware of the detrimental effect the trade imbalance has on American jobs. Night after night on the evening news Americans see workers, not only in textile and apparel, but in other areas who have been put out of work because their jobs have been taken by imports. They cannot help but become sensitized to their plight.

Moreover, studies have shown that given the option, consumers perfer to buy American. Yet it is often difficult for them to make an informed choice, and that is what this legislation is all about.

Current law in this area is easily evaded. While there is a requirement that imported goods be marked as to country of origin, the fact is that these labels are often placed in inconspicuous places or are missing entirely on the individual items, as was just pointed out by the gentleman from North Carolina [Mr. BROYHILL]. By requiring that the label in each item be attached to the most conspicuous space on the inner side of the foreign-made product, this amendment would insure that consumers know exactly what they are buying. By also requiring American-made goods to be so labeled, which is not necessarily done today, we could also insure that the consumer knows what the choice is.

Mr. Chairman, the suggestion that this very simple, very straightforward measure could be construed as an unfair trade barrier is frankly somewhat ludicrous and I think if it is made, it should be rejected. It is not a trade barrier. It is merely letting people make an informed choice.

I would also like to say a word about some efforts that have been suggested to delete from the textile labeling amendment the requirement that catalog items be identified as U.S.-made or imported. This is a vital section of the legislation inasmuch as it represents the only way that we can give consumers a choice, since they do not have an opportunity to inspect catalog-ordered merchandise prior to their purchasing it and getting it home.

Now, this obviously is not an onerous requirement, since many catalogs, a Sears catalog I was just looking at had it in it, where it was made; so it is not an onerous requirement. I think that it also should be pointed out, Mr. Chairman, that the catalog language reflects a compromise achieved in the Senate with the input of the catalog and mail order industry.

This is a good bill. This is a good piece of legislation. This is a good amendment to the bill. By adopting this amendment today, we are doing American consumers a service by recognizing their right to choose. We are doing a vital American industry a service by giving them the opportunity to promote American quality and workmanship.

By adopting this legislation, we could join with the industry in the goal of making it as easy as possible for Americans to find U.S.-made textiles and apparel when they go shopping.

I do not know whether you have been shopping lately and tried to look through to see if you could find where something was made or not, but if you have not, go try it and you will see the need for this.

Quite frankly, Mr. Chairman, I believe the American consumer will come through for the American worker under these circumnstances.

In closing, I would just like to reiterate something that my colleague, the gentleman from South Carolina [Mr. DERRICK] said earlier. The textile industry is an employer of some 2 million people in this country. It is an entry level industry. It employs more women and minorities than any other industry in this country and they are being put out of work simply because the American consumer in many instances does not know whether they are buying an American-made product or a foreign-made product.

Does it not make sense just to let them choose for themselves? I trust the American people. Give them the information and I think they will make the right decision. That is what this bill does.

Mr. NICHOLS. Mr. Chairman, I move to strike the requisite number of words.

Mr. Chairman, I rise this afternoon to support the amendment of Congressman BUTLER DERRICK to H.R. 3605.

This amendment, known as the "Anticounterfeiting, Textile Fiber and Wool Products Identification Act," contains two very important provisions:

No. 1, all United States made textile products would be required to show an origin label.

Second, all mail order catalogs would be required to indicate whether a textile product is imported or made in the United States of America. The Federal Trade Commission on numerous occasions has maintained opinions that such information should be disclosed in all mail order catalogs and promotional materials.

Mr. Chairman, I represent a district in Alabama which I proudly claim is perhaps the second largest textile apparel district in the country. I must tell you that the unemployment in my home county of Talladega in Alabama for the month of June exceeded 15 percent. We are in bad shape down there in textiles.

Last week I discussed in my weekly column the seriousness of the growth of textile imports in this country. Let me give you some figures. In 1983 textile and apparel imports increased by 25 percent over the figures for 1982, contributing to a textile apparel fiber trade deficit of some $10.6 billion, 15 percent of the Nation's total trade deficit.

The bottom line is that these increases in imports in 1983 represent the loss of some 140,000 American jobs. In the first 4 months of this year, textile apparel imports were up 49 percent over the same period last year.

The amendment now pending will help correct the problem our Nation faces and allow American consumers to know where the products they purchase are made, so that they can make an informed decision.

I urge my colleagues to oppose all weakening amendments, so that the American public can make an informed decision on the textile products which they purchase.

Mr. ROGERS. Mr. Chairman, I move to strike the requisite number of words.

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

□ 1450

Mr. ROGERS. Mr. Chairman, I rise in support of the amendment of the gentlemen from South Carolina because I believe we must take some action to protect our own textile industry from the devastation it is suffering not as a result of free trade but of unfair foreign imports.

I was a cosponsor of H.R. 5638, which has been incorporated into this amendment. I supported that legislation because it strengthened provisions of current law which require textile products to be labeled as to country or origin.

In my own district, thousands of people depend on the textile industry for their livelihood. Our people work for little more than minimum wage, but they seldom complain, and are proud to have their jobs. The factories in my district have increased their productivity and quality in response to foreign imports—and their product is equal to or above any foreign made textile.

And yet, I can take you there today and we can walk through many of those plants that are now dusty and idle because of unfair foreign imports.

I am often amazed at the lackluster enforcement of our trade laws, especially labeling and quota regulations. Some of our trading partners who ship millions of square yards of textile and apparel products to this country each year have devised ingenious ways to bypass our laws and regulations. And, what is even more astounding is their reaction when we take steps to properly enforce our existing trade laws—they threaten retaliation by boycotting other American products which are legally exported to their countries.

Each month of 1984 has produced record import levels of textile and apparel imports. In July 1984, the highest monthly import level ever was reached—with over 1 billion square yards—an increase of 76 percent over the previous July 1983 figures. And, probably when August and September figures are available, new records will be set.

Now I realize that some of the enormous trade imbalance we are presently experiencing is due to our own healthy economy and the strong American dollar.

But I also know that our American textile workers deserve an opportunity to compete fairly in the market place—and this amendment will provide them with this opportunity. The American consumer should have the right to know where the garment he is purchasing is made. And, our customs officials who are charged with enforcing our quota laws should not have to tear an article of clothing apart just to find the country of origin label. It should be prominently displayed—conspicously and packaged in a way which will allow the label to be read through the package.

This amendment is critical to the textile and apparel industry, and to the job security of the hundreds of thousands of Americans in those entry level jobs who work in those factories. Please help us stop this mass exodus of our jobs overseas.

I ask that you support this amendment and that you oppose any weakening amendments to it.

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

Mr. BRITT. Mr. Chairman, I move to strike the requisite number of words and I rise in strong support of the amendment.

Mr. Chairman, I rise to express my strong support for the textile labeling amendment.

This is a consumer amendment. American consumers want to buy quality apparel made in the United States. Conspicuous country-of-origin labels will give American consumers the opportunity to distinguish domestic and foreign goods—an opportunity that they are now denied. This amendment will ensure that the consumer has the chance to make an informed choice.

The provisions of this amendment are eminently fair. They require not only labels on foreign-made goods, but also on those made in the United States. In addition, they extend to the fast-growing mail-order trade, requiring identification of country of origin in catalog and other advertising.

The provisions are reasonable in their scope. For example, in the early versions of this legislation, concerns were raised that labels cannot easily be affixed to hosiery items. These concerns have been addressed in the amendment by language requiring only package labeling, not affixed labeling, for hosiery.

This amendment has the strong support of textile manufacturers and textile labor groups. This industry has suffered greatly from subsidized foreign imports. At the same time, many foreign markets are closed to American exports by unconscionable tariff structures. In the first 6 months of 1984, the textile and apparel trade deficit reached the unprecedented level of $7.4 billion.

Imports of textiles and apparal are up nearly 50 percent over 1983, a record year. In July textile and apparal imports exceeded 1 billion square yards for the first time. This translates into thousands and thousands of American jobs.

Last week I spent a morning working at a textile plant in my district. I worked through the entire manufacturing process from threading the warper to grading the final product, the cloth. I learned firsthand of the skill of American textile workers and the quality of their product and I was directly confronted with their fears and uncertainties in the face of the rising tide of imported goods. This amendment is not a complete solution to the textile import problem but it is a good start.

This is a consumer amendment. This is a fair amendment and I urge its adoption by the House.

Mr. HEFNER. Mr. Chairman, I move to strike the requisite number of words and I rise in support of the amendment.

Mr. Chairman, I would like to engage Mr. DERRICK in a brief colloquy, just a couple of questions.

This in my opinion is legislation that has been needed for an industry that has been devastated. I would like to ask a couple of questions because some of the people are laboring under the

allusion that this is going to be a costly amendment to the taxpayers.

Is there any cost involved to the taxpayers of this country through this amendment?

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

Mr. HEFNER. I yield to the gentleman.

Mr. DERRICK. I thank the gentleman for yielding.

Mr. Chairman, there may be some little cost involved, just from an inspection matter at customs, but that is all, very minimal.

Mr. HEFNER. This is basically an amendment that is supported, as I understand it, and it has been worked on very hard, it is supported not only by the business community, by labor organizations, but it is truly an overall consumer bill.

Mr. DERRICK. This is one of the best patriotic amendments that we can have on the floor of this House. It is supported by business it is supported by labor, it is supported by your textile workers. But all we are doing is giving people an opportunity to make a choice.

I think there is one thing we ought to understand, that this in no way restricts imports. What this does is give the people of this country an opportunity to make the decision on the facts of whether they want to buy goods made in this country or goods that were made overseas.

Mr. HEFNER. Mr. Chairman, I think it is very worthwhile legislation and I would urge my colleagues to support it because I believe that given the choice, the consumers of this country, certainly out of compassion for their coworkers in the textile industry, given the choice, they would choose products that were made in this country.

Many times you go in to buy apparel or whatever and you have difficulty finding where it is made, the origin of the garment, or whatever, and even when you find out some of the countries you cannot even pronounce the names, you have no idea where they are coming from, countries you never heard of.

So I commend Mr. DERRICK and Mr. BROYHILL for bringing this legislation to the floor. For the constituents of my District it is something that we fought for for a long while and I am just happy it has finally come to fruition. I urge all of my colleagues to vote for this fair and important amendment.

Mrs. LLOYD. Mr. Chairman, I move to strike the requisite number of words.

(Mrs. LLOYD asked and was given permission to revise and extend her remarks.)

Mrs. LLOYD. Mr. Chairman, I rise in strong support of this amendment brought to the floor by our colleague from South Carolina [Mr. DERRICK] and commend the work of the gentleman from North Carolina [Mr. BROYHILL].

I think this is one of the most important consumer amendments this body is going to consider this late in the session because it is truly an American amendment.

I know the frustrations of the consumer who wants, and makes an honest effort, to buy American-made products but who is deprived of the information necessary to make that choice. On several occasions I have gone into a store and tried to buy an American-made blouse or skirt and not been able to identify the country of origin. This amendment does not impose any unfair restriction on domestic or foreign manufacturers but clarifies and strengthens current textile and apparel labeling laws.

Besides helping consumers make informed purchases, this amendment is also important to our textile industry, one of the Nation's oldest. I'm proud of the contribution this industry has made to the growth of my district and the jobs it has provided. The American textile workers deserve our support at this critical time through the Derrick amendment. There is another very relevant issue that is touched on by this amendment. As my colleague has pointed out, a sizable percentage of textile workers are women. Many of them have been unemployed as a result of jobs lost in the domestic textile industry due to imports.

I have no statistics, but I do know of the women in my district who have worked in this industry and who have lost their jobs in recent years. They are often the family's second wage earner, they don't have the flexibility of the specific training to relocate with other industries in other sectors of the country. Or they may be the head of household and bear sole responsibility for the support of their children. This industry has given them the opportunity to supplement their family income or to provide on their own for their dependents. It's vitally important to them that these jobs remain in the Third District and in this country.

So this is a fair amendment, it benefits this country, its consumers and its workers and I urge all of my colleagues to support it.

AMENDMENTS OFFERED BY MR. BROYHILL TO THE AMENDMENT OFFERED BY MR. DERRICK

Mr. BROYHILL. Mr. Chairman, I offer amendments to the amendment offered by the gentleman from South Carolina [Mr. DERRICK].

The Clerk read as follows:

Amendments offered by Mr. BROYHILL: In the subsection (j) proposed to be added by section 303 strike out "collar of such product if such product contains a collar, or if such product does not contain a collar" and insert in lieu thereof "inside center of the neck midway between the shoulder seams or, if such product does not contain a neck".

In the proposed section 304 strike out "(15 U.S.C. 68b(1))" and insert in lieu thereof "(15 U.S.C. 68b(a)(2))", strike out "subparagraphs" and insert in lieu thereof "subparagraph", strike out the proposed paragraphs (5) and (6) and insert in lieu thereof the following:

"(D) the name of the country where processed or manufactured.".

In the subsection (e) proposed to be added by section 305 strike out "catalog or mail order".

In the subsection (f) proposed to be added by section 305 strike out "collar of such product if such product contains a collar, or if such product does not contain a collar in the most conspicuous place on the inner side of such product, unless it is on or affixed on the outer side of such product or in the case of hosiery items, on the outer side of such product or package" and insert in lieu thereof "inside center of the neck midway between the shoulder seams or, if such product does not contain a neck, in the most conspicuous place on the inner side of such product, unless it is on or affixed on the outer side of such product or in the case of hosiery items, on the outer side of such product or package".

Mr. BROYHILL. (during the reading). Mr. Chairman, I ask unanimous consent that the amendments be considered as read and printed in the RECORD.

The CHAIRMAN. Is there objection to the request of the gentleman from North Carolina?

There was no objection.

Mr. BROYHILL. Mr. Chairman, I ask unanimous consent that the amendments be considered en bloc.

The CHAIRMAN. Is there objection to the request of the gentleman from North Carolina?

There was no objection.

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

Mr. BROYHILL. I yield to the gentleman from South Carolina.

Mr. DERRICK. I thank the gentleman for yielding.

Mr. Chairman, I just want to say that I certainly have no objection to the amendments. As a matter of fact, I support them and hope that the House will allow them to be accepted.

Mr. BROYHILL. I thank the gentleman.

Mr. Chairman, I rise to offer amendments en bloc to the amendment offered by the gentleman from South Carolina.

My amendments would simply make technical corrections to the amendment.

The gentleman's amendment is based on H.R. 5638, the Textile Fiber and Wool Products Identification Improvement Act, a bill which I introduced in the House on May 10, 1984.

Since that bill was introduced, the Committee on Energy and Commerce, on which I serve as the ranking minority member, has held hearings on the bill and has ordered reported to the House the Textile labeling provisions as title II of H.R. 5929, the Anticounterfeiting and Textile Fiber and Wool Products Identification Improvement Act.

My amendments would simply conform the language in the Derrick amendment to the language contained in H.R. 5929 as ordered reported to

the House. This is also the same language which was contained in S. 1538, which passed the Senate on June 29, 1984.

I urge my colleagues to adopt these amendments.

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

Mr. BROYHILL. I yield to the gentleman from Minnesota.

Mr. FRENZEL. I thank the gentleman for yielding.

Mr. Chairman, as some Members know, I am opposed to the Derrick amendment. However, the Broyhill amendment to it is, in my judgment, what the mover has suggested, an amendment to make it conform to the Senate bill which does not do any substantive damage. Therefore, I have no objection to the amendment.

Mr. BROYHILL. I thank the gentleman.

The CHAIRMAN. The question is on the amendments offered by the gentleman from North Carolina [Mr. BROYHILL] to the amendment offered by the gentleman from South Carolina [Mr. DERRICK].

The amendments to the amendment were agreed to.

Mr. FRANK. Mr. Chairman, I move to strike the requisite number of words.

Mr. Chairman, I rise in support of the amendment offered by my friends from South Carolina and in some wonderment that we are even debating something that I would have thought would have been so noncontroversial as to have been simply adopted as easily as the amendments of the gentleman from North Carolina.

We confront some difficult issues in the area of imports versus domestic products. There are difficult tradeoffs that have to be made as we try to respond to the legitimate economic concerns of American workers and as we try and protect them against unfair subsidies and we try and balance that off against the undoubted consumer advantage that comes in when less expensive products are brought in here.

None of those difficult issues that are involved when we debate free trade versus the degree of protection are at issue today. This is simply a matter of choice for the American consumer. It says if you want to take into account the fact that these products were made in America you can do so. If you do not want to, you do not have to. We are not proposing that those who buy imported goods have that stamped on their foreheads. We are not proposing that people who buy imported goods have to carry separate shopping bags that say, "I have imports in this bag."

What we are saying is that those American consumers who wish to give some preference in their buying decision to the fact that things were made in America, either because they think that may be a better assurance of quality or because they want to be supportive of domestic economics, or for whatever other reason, that they be allowed to do so.

We have a situation now where the consumers have to, with regard to a very important issue to many of them, buy in the dark. They cannot know in many cases where the product was made.

As to those to whom there is no issue, then this is not a problem. This is not going to force itself on anybody. It does not, as was clarified in the colloquy between the gentleman from North Carolina and the gentleman from South Carolina, require any governmental cost. It will impose the most minimal of costs on people who are in the business of selling.

I understand there may be some amendments later to erode and weaken this. They will come from those who probably do not support the whole concept, but understandably do not want to take it on head-on similar to trying to take a piece out of it here and a piece out of it there. I would say to them I have a lot of sympathy with those of my friends who have day after day tried to defend the principle of free trade. I recognize that there are difficult issues there.

But if you undermine and oppose an effort like this, if we are obstructed in trying to simply deal with the labeling question, then the pressures for greater restrictions are going to grow.

I would say to those who most strongly believe in free trade and who are opposed to various measures that will restrict the flow of goods ought to be among the strongest supporters of this labeling because it is one way—it is experimental, we are not sure how it will work—to give the consumers the kind of choice that may lessen some of the pressure for those other things.

The arguments against various forms of protection and restrictions have been cloaked in consumer preference and they have some legitimacy, although I do not always agree with them. That very argument here says that we should support the amendment offered by the gentleman from South Carolina.

There is everything to be said in terms of the argument about free trade and its opposition in favor of this amendment. It is a reasonable effort to try to keep us from having to make some of the more difficult choices.

I hope that the amendment is adopted and I hope that subsequent efforts which we may have to weaken it are rejected.

Mr. KINDNESS. Mr. Chairman, I move to strike the requisite number of words, and I rise in support of the amendment and I wish to associate myself with the remarks of the gentleman from Massachusetts [Mr. FRANK], who just spoke.

I think it is important for us to realize in addition, however, that this is a tested concept, a tried and true concept. Labeling has worked I am sure as in the case of the automobile industry. Now when you get those labels right out there on the back and the sides and sometimes the front of the automobile where it says Datsun, people quit buying those Japanese cars, I guess. Up front it has that Mercedes symbol on the radiator of the car. People know that is a foreign car, so they do not buy that. It solves all those problems just to have that labeling. So we know that it works, I assume.

It will work in the case of textiles and apparel. I suppose.

If it does not, at least we will have left things in the context of the free exercise of choice by American consumers. That is the important point.

No; I do not think that the labeling is going to keep people from buying foreign-made goods, textile or apparel goods. No this probably will not do all that much good all by itself.

But it will afford people, like many in this room and many others who have a particular interest or concern, the opportunity to be informed consumers and say, "I'll pay more for U.S. goods." That is what it will come down to. "I'll pay more for U.S. goods in order to have them."

Now, we all know that is really what we are talking about here. We are not being honest about it up to now, but that is really what is involved. We have a problem that really relates much more to the value of the dollar today and the value of the dollar today is so high in relation to other currencies because, in essence, we cannot learn how to control Federal spending. Interest rates will be high as long as the threat of renewed inflation resulting from Federal deficits continues. Foreign money will come into the United States and be invested here because it is attractive to do so. That will keep interest rates up, that will keep our dollar attractive and too high in value in relation to other currencies. We will have a tough time selling anything we make in this country in other countries. Other countries will have an easier time selling their goods in the United States.

Until we get hold of that problem we are not going to solve any of this concern about people losing their jobs because of foreign competition. We can compete if we have fair conditions. We have done it for decades in textiles and apparel and in other lines of manufacture.

Now, I do support, in all honesty, this amendment. I believe it is desirable. But I am saying we are only touching the surface in the barest way here.

□ 1510

We ought to be honest with ourselves and say we are creating the problem of people losing their jobs to foreign competition, because we do not control spending in this Congress.

I yield to the gentleman from South Carolina.

Mr. CAMPBELL. I appreciate the gentleman yielding, and I certainly agree with him that we have a problem with the strength of the dollar and because of the imbalance between our currency and other currencies. This bill in no way will address that problem. It is not a panacea. We all know that.

However, I think that the importance of the amendment may rest in faith in the American people. I heard a story that was told me as true, and I am not sure whether it was or not, but it made a lot of sense. The person who told it was from North Carolina and was from a small town there. A textile mill had gone out of business and the manager of the department store in the town, a small town, wrote a letter to the superintendent of the mill and said, "You have ruined this town; you have put my store out of business by shutting your plant down. How could you do that?"

And the superintendent of the mill went down to the department store and went through and could not determine that there were any American-made products in that department store. He wrote the store manager back and said, "No; I did not put you out of business; you put us both out of business."

The question must be asked. Would those textile workers in that textile town truly have bought foreign goods and put themselves out of business had they had the opportunity to choose otherwise? That is what we are giving them, that opportunity.

Mr. KINDNESS. I thank the gentleman. I think that is quite right. And oftentimes the case would be that the U.S. consumer would say, "I will pay for U.S. goods in order to make sure that our economy will remain strong." And I, along with many others, would do that.

Mr. RITTER. Mr. Chairman, I rise in support of the amendment. I, too, understand that this amendment is not a panacea to the textile and apparel import problem. But it is a step in the right direction.

In my district, the Lehigh Valley of Pennyslvania, both the cities of Allentown, PA, and Bethlehem, PA, have organized rallies and programs around buy-American. In Bethlehem, PA, just last week there was a major Think-American/Buy-American rally at one of our high school football stadiums.

People are ready to think American and Buy American. But one of the problems is, if you go and look at the labels on apparel you do not know, in many cases, whether it is American or not. People have come up to me and have asked, "How do you know whether it is a U.S.-made goods or not? There are so many pieces of apparel that I have looked at where I cannot tell whether it is an import or is not." This legislation makes it easier for the consumers to find out.

Mr. Chairman. There is a rising tide of a kind of national interest and an interest in promoting our own products which will help in the sales and in the marketing, the purchase, and then in the production and jobs relating to the apparel and textile industry.

While many important points have been made, there is one other crucial point that this amendment seeks to address; that is that the burgeoning sales in catalogs, in direct mail, in telecommunications and phone order sales, are areas will be covered by the amendment. We are all familiar with the enormous amount of marketing and sales that have taken place in these new arenas of American trade and commerce.

What this amendment does is require that a label—imported or made in the U.S.A.—be placed in ads in a catalog or in a telephone message, as well as require a similar label for a garment in a store. That is essential, given the increasing volume of goods that are sold outside of traditional stores.

I support this amendment and urge my colleagues to do the same.

AMENDMENT OFFERED BY MR. FRENZEL TO THE AMENDMENT OFFERED BY MR. DERRICK, AS AMENDED

Mr. FRENZEL. Mr. Chairman I offer an amendment to the amendment.

The Clerk read as follows:

Amendment offered by Mr. FRENZEL to the amendment offered by Mr. DERRICK, as amended: On page 2 of the amendment, delete lines 16-24. On page 3 of the amendment delete lines 21 through line 3 of page 4.

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

Mr. FRENZEL. Mr. Chairman, some of the Members who heard the scheduled debate on this bill will recall that I very strongly opposed this amendment.

I opposed the rule which allowed this nongermane bill to be tacked on to a pill bill, to which it has no relevance whatsoever. But the House decided to go ahead in this way, so we are working on this nongermane amendment.

And while we abuse our regular procedures in this way, we cannot get a budget, we cannot move a balanced budget amendment, we cannot move the President's crime proposal. But, we have plenty of time for nongermane amendments.

My amendment strikes a portion of the bill which relates to catalog and mail-order sales, requiring that catalog indicate whether the goods being offered for sale are foreign or United States.

I notice that very few of the speakers who said it was merely a labeling bill indicated that it was also a highly discriminatory bill against people offering goods for sale by mail. It singles out the catalog houses and those who sell by mail against those who sell by newspaper ads, by television ads, by telephone calls, by dropping flyers at your home. None of these are obligated to tell you whether the goods are foreign made or not. But the mail-order houses must.

What bothers me about this is that if it is so good, if it is so wonderful for America to have these goods designated, why do not American producers do so now? Why is it necessary that it be made mandatory by law? I would think that if we are proud of what we produce, we would put "Made in U.S.A." on it, and I think many producers do. You and I will normally purchase those goods.

But the problem here is that we have a subtle form of protectionism in which our trading partners are being asked to jump through new hoops. They are being subjected to protectionism already in the form of new customs regulations to which they object very violently and which has caused those regulations to be temporarily suspended.

That conflict is going to cost us exports and is going to cost us jobs. It means lower farm prices and fewer jobs in industry. It is very hard to see that the bill before us is going to gain us any net jobs.

We have been told that this is the largest low-level industry, or entry-level industry, and, therefore, it is going to have trouble. Any industry which has a low-skill level is going to be subject to competition. We know that. And it is good for the consumers of this country to have competition so that they can buy the best product at the best price.

However, the proponents did not say that the textile industry is one of the most protected industries in the United States, has been since the GATT was created. We, the United States have the highest textile tariffs in the world and, of course, we have quotas under the multifiber agreement that compare with the rest of the world. We also have, of course, these regulations which now make it even more difficult to bring in textile materials.

It has been said that these people want to be protected against allegedly unfair trade subsidized imports. The trade laws apply, and if imports are subsidized the normal relief action can be sought.

It is also said that our textile producers are fighting against unconscionable tariffs abroad. At least one speaker said that. Our tariffs are higher than anybody's, so if theirs are unconscionable, certainly ours are, too.

The next thing is that the bill really does not have much to do with the consumer. I doubt that anybody here has gotten any letters from consumers saying they would like to have this labeling or that they need to read in their catalog that the material comes from someplace else or from the United States.

As a matter of fact, the labeling laws are now clear and do require that the U.S. origin be noted on stuff now. It is true that not every piece of textile goods within a bale or box or carton is required to be labeled. That is going to be an extra cost, of course, for the consumer. Whether the consumer wants to bear that cost, or has been consulted, there has been no showing or no demonstration here.

So what we are doing here is that unless you pass my amendment, the catalog houses must determine 6 months in advance, whenever they decide to print their catalog, where they are going to get their material. They are going to have to put that in their catalog, send it out to the printer. If they run out of the material or the supplier cannot supply it, there is no way that they can exchange it, even if they want to exchange foreign-made goods which they could not obtain, for U.S.-made products.

The CHAIRMAN. The time of the gentleman from Minnesota [Mr. FRENZEL] has expired.

(By unanimous consent, Mr. FRENZEL was allowed to proceed for 3 additional minutes.).

Mr. FRENZEL. If they cannot get foreign-made goods and are obliged, and would like to order, U.S.-made goods as a substitute, they would not be able to do so because of the advance notice that they need in printing their catalog.

□ 1520

For some reason we have singled out the catalog houses for discriminatory treatment. The FTC gives the best clue for the reason. It says the people cannot see the material before they buy it. My guess is that an awful lot of consumers do not closely scrutinize material in any instance. Nevertheless, it does seem to me that this is highly discriminatory.

What is the difference between the catalog seller and the person making the telephone approach? There is none. But the catalog seller is saddled with a new regulation.

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

Mr. FRENZEL. I yield to the gentleman.

Mr. FRANK. I thank the gentleman for yielding.

The gentleman has again said that one problem for the gentleman in this bill is that it discriminates and that it requires catalog sellers to do something that newspaper and flyer sellers do not. If the bill were amended to require that people who sell by newspaper and flyer and telephone had to follow the same rule; that is, if the discrimination were eliminated by broadening it, would that in any way minimize the gentleman's opposition to it?

Mr. FRENZEL. I think I would be more inclined to vote for it because I suspect you would then have difficulty passing the bill.

Mr. FRANK. If the gentleman would yield further, would that minimize the gentleman's oppostion to the amendment offered by the gentleman from South Carolina?

Mr. FRENZEL. In my judgment, it would not. But I would feel better if everyone were in the same bag, even if it is a lousy bag.

Mr. FRANK. If the gentleman would yield further, the gentleman would still be opposed to the amendment. In fact, he would probably argue then that it would be even worse?

Mr. FRENZEL. My objection to the bill would be minimized, and I would not seek to remove the catalog houses from a position of distress that everyone else would then be in.

If the gentleman wishes to move that amendment, I would be delighted to support the amendment.

Mr. FRANK. Well, afterwards, I would need some time to draft it. Maybe we will work on it. I will thank the gentleman for his cosponsorship.

Mr. FRENZEL. I thank the gentleman for his help and for reinforcing my point that we are discriminating.

As I was saying at the time the gentleman made his observations, if a telephone seller who calls has foreign goods to offer, there is no compulsion on that seller to describe the goods as foreign or regular. There is no compulsion in newspaper ads. There is no compulsion in television or radio ads.

It seems to me we have jumped on one burgeoning form of salesmanship in the United States and tried to attach some sort of extra penalty, which may not be terribly expensive and may not burden the consumer greatly, but still is an extra burden. It will take away a little flexibility from that type of merchandiser.

In my judgment the whole amendment, the Derrick amendment, is unwise policy. I think much of the sting would be taken out of it if we could remove the section that discriminates against catalog houses. I urge the adoption of my amendment.

Mr. DERRICK. Mr. Chairman, I rise in opposition to the amendment.

Mr. Chairman, I cannot understand why the proponent of this amendment has any objection to people being able to make an educated choice on purchases. Certainly they have that right to make that educated choice in a catalog.

As the gentleman well knows, that this point that we reached here is a compromise. We started out with a suggestion, and there were those who wanted to make it the country of origin; each country, as opposed to U.S.A.- or foreign-made. As the gentleman also knows, some of your major catalog houses today already do this. Many other catalog houses are in the process of doing this in anticipation of the passing of this legislation.

Why should people not have an opportunity to look in a catalog and see where these goods are made? The idea that a company does not know what the product is going to be when they write the catalog is absurd. To say that they are going to write the catalog before they get the products, why, my goodness, that is ridiculous.

They have 90 days under this amendment. Any catalogs that have already been written; any catalogs that are printed 90 days after the enactment of this legislation are not covered. That should give ample time to get probably into the fall of 1985. I would ask the membership to please oppose this amendment based on those observations.

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

Mr. DERRICK. I yield to the gentleman.

Mr. CAMPBELL. I thank the gentleman for yielding, and I certainly want to join him in opposition to this amendment. I want to raise another point: The gentleman pointed out that in the catalog sales that you are allowing people to make an informed purchase. Now, people buy from that book, the goods are shipped to their home, and then they have it.

The author of the amendment that we are in opposition to made another statement. He said this discriminates against newspaper advertising, and so forth. Newspaper advertising generally advertises a store where you go and purchase something, and the people go to purchase it and their label is on it there. I just do not think that that comparison can be made. I think that the compromise that has been worked out to label either made in the U.S.A. or foreign-made is sufficient, and I urge the defeat of this amendment.

Mr. DERRICK. I thank the gentleman and I yield back the balance of my time.

Mr. BROYHILL. Mr. Chairman, I rise in opposition to the gentleman's amendment.

Mr. Chairman, I must oppose the amendment offered by the gentleman from Minnesota. He has certainly been an ally of mine in a number of battles here on the floor of the House, but I feel very strongly about this particular provision. This provision only requires that there be a disclosure of country of origin in catalogs and mail order material. This is certainly a fair requirement.

I want to point out to the Members, in answer to the arguments made by the gentleman from Minnesota, that many catalogs are currently providing this kind of information in their catalogs. I have in my hand a catalog that is issued by one of the more prestigious organizations in the United States and all through this catalog they provide this kind of country-of-origin information. In many instances they say that the goods are imported.

All that the amendment that is offered by the gentleman from South Carolina says is that the description in the catalog must disclose whether a

textile product is imported or domestically made so that consumers can make an educated decision. Mr. Chairman, I would like to point out that the Federal Trade Commission in the past has issued advisory opinions stating that country-of-origin information ought to be included in mail order promotional material since consumers do not have the opportunity to inspect the merchandise prior to purchase. All we are saying is that if it is made domestically that that information must be put into the catalog.

The gentleman has indicated that there be some extra expense to this. I am not aware of any additional costs. As I have already pointed out, a number of merchandisers are already including this type of information in their catalog, and apparently if there is added expense, they feel that it is worth whatever minimal added expense it is.

I might point out that I have requested information on the cost that would be imposed by item-by-item disclosure and, as of this moment, the catalog and mail order industry people have failed to supply this information to me despite my numerous requests for that information.

Mr. Chairman, this requirement is not burdensome; it is not expensive, and it is in the consumers' interest to know where the product is made; that is, whether it is imported or whether it is made domestically.

I also want to repeat what the gentleman from South Carolina has already said, and that is that a compromise has already been made on this issue. When the bill was originally written, it required the actual country of origin be disclosed. But in order to accommodate the mail order and catalog people, we amended that to say that all they had to indicate was whether a particular textile product is imported. That change was made to ease whatever burden might be placed on them.

For that reason, I would urge that we reject the amendment by the gentleman from Minnesota, and that we retain the language that is in the amendment offered by the gentleman from South Carolina.

□ 1530

Mr. JENKINS. Mr. Chairman, I rise in opposition to the amendment.

Mr. Chairman, I shall not take the 5 minutes, but I rise to point out and try to correct the statement made by my dear friend and seatmate over in the Committee on Ways and Means, the gentleman from Minnesota, that this is not a special provision just for the textile industry, that we are charting a new course. I realize that the gentleman from Minnesota does not have a great number of textile or apparel industries in his district, but he does have a great number of dairies and dairy products that are processed up in Minnesota, and there is in existing law today a requirement that all imported dairy products show the country of origin and there is in law today a provision that all domestically produced dairy products, cheeses, show not only that it is made in the United States but there is a requirement that it show the exact address where it is processed.

So this is not a burdensome amendment for one particular segment of the industry. It is already in existence in the dairy industry. We are simply asking for this very small amendment that will be of some benefit to the textile and apparel industry.

So I would urge my colleagues to defeat the amendment offered by my dear friend, the gentleman from Minnesota.

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

Mr. JENKINS. I would be happy to yield to the gentleman from Minnesota.

Mr. FRENZEL. I thank the gentleman for yielding.

Mr. Chairman, I thank my distinguished friend for his important contribution, and perhaps if he and the distinguished gentleman from Massachusetts next to him put in a repealer on this amendment we can clean it out for both dairy and textiles and probably improve the lot of the American consumer along with it from a price standpoint.

Mr. JENKINS. The gentleman would support, I am sure, the elimination on dairy products.

Mr. FRENZEL. Yes, and if the gentleman would yield further, I said textiles is the most protected industry in the United States. I do not mean to imply that agriculture generally and dairy specifically is not protected as well. It is simply part of a pattern of American protectionism. Every country has it. I would like to avoid it as much as possible, and this is not a virulent form that we face in this particular bill. It is simply adding another log to the fire.

Mr. JENKINS. I urge my colleagues to oppose the amendment offered by the gentleman from Minnesota.

The CHAIRMAN. The question is on the amendment offered by the gentleman from Minnesota [Mr. FRENZEL] to the amendment offered by the gentleman from South Carolina [Mr. DERRICK], as amended.

The question was taken; and on a division (demanded by Mr. FRENZEL) there were—ayes 3, noes 23.

Mr. FRENZEL. Mr. Chairman, I demand a recorded vote, pending which I make the point of order that a quorum is not present.

The CHAIRMAN. The Chair will count for a quorum.

Mr. FRENZEL. Mr. Chairman, I withdraw both requests.

So the amendment to the amendment, as amended, was rejected.

AMENDMENT OFFERED BY MR. FRENZEL TO THE AMENDMENT OFFERED BY MR. DERRICK, AS AMENDED

Mr. FRENZEL. Mr. Chairman, I offer an amendment, numbered 3, to the amendment.

The Clerk read as follows:

Amendment offered by Mr. FRENZEL to the amendment offered by Mr. DERRICK: On page 2 of the amendment, on line 25, strike "or imported, or both." On page 4, line 2, strike "or imported, or both."

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

Mr. FRENZEL. Mr. Chairman, I do not want to go on here too long because it is obvious that my point of view is not shared by the Committee of the Whole. I have no desire to keep this body working longer than necessary.

If my colleagues opposed the previous amendment, they are not likely to be thrilled by this one. This also relates to the cataloging but rather than deleting all the requirements for cataloging, it would only delete the ones relating to imported materials.

Mr. Chairman, I have said on a couple of occasions that I think it is a good thing that catalog houses, where they can, where it fits their merchandising, and where they think their customers and customers want it, produce their catalogs in such a way as to give maximum information, including the situs of production.

I also believe it is a good thing for U.S. firms to promote U.S.-made commodities. I usually tilt that way in buying, myself. My judgment is that if the product offered is a good one and the price is right, then Americans are going to buy them.

What I object to is compulsory regulations in the marketplace to force people to do things that are not necessarily good policy. I particularly object to them when they are made in a discriminatory way against a single set of advertisers.

I believe that this is a good amendment and that it should be adopted. I have no illusions about its success.

Mr. DERRICK. Mr. Chairman, I rise in opposition to the amendment.

My position is basically the same as it was to the prior amendment. Of course, this amendment does a little less, but it is bad for the same reasons.

The CHAIRMAN. The question is on the amendment offered by the gentleman from Minnesota [Mr. FRENZEL] to the amendment offered by the gentleman from South Carolina [Mr. DERRICK], as amended.

The amendment to the amendment, as amended, was rejected.

AMENDMENT OFFERED BY MR. FRENZEL TO THE AMENDMENT OFFERED BY MR. DERRICK, AS AMENDED

Mr. FRENZEL. Mr. Chairman, I offer an amendment, numbered 4, to the amendment.

The Clerk read as follows:

Amendment offered by Mr. FRENZEL to the amendment offered by Mr. DERRICK: On page 5 of the amendment, strike on line 19 "ninety" and insert in lieu thereof "one hundred and eighty".

Mr. FRENZEL. Mr. Chairman, this amendment changes the effective date of the bill as it applies to the regulations on catalog houses from 90 days after passage to 180 days after passage.

Earlier in discussions here I indicated the difficulties of producing catalogs in advance of a season. Catalog houses are even now, of course, putting together their catalogs for the spring. If this bill is passed promptly, as I believe it will be, and signed either in September or October, those catalogs which are now at the printers or perhaps on the way are going to have to be recalled.

I do not think it is the intention of the promoters of this amendment, or of the dedicated and heroic protectors of the textile industry to unnecessarily hurt anybody who happens to be in the catalog merchandising business. I would think that it would not be a major sacrifice if we deferred for an additional 90 days the effective date of this bill as it affects the catalog houses.

Again, since the House seems so determined to pass this bill, I am not optimistic about the amendment's chances, but I feel compelled to offer it because I believe at least in the beginning we ought to give this class of merchandisers and their customers a little more time to put the first catalog together so the FTC or the Department of Justice or one of our gimlet-eyed Representatives of North or South Carolina does not haul them off to jail.

□ 1540

It seems to me that we could temper whatever hard-hearted justice we intend to deliver with a little mercy. I hope the amendment to extend the effective date with respect to catalogs only might be extended by only 90 days.

Mr. DERRICK. Mr. Chairman, I rise in opposition to the amendment.

I put a ditto on the other remarks I have made about the preparedness, but in addition to this, this is also a compromise that has been reached on the 90 days.

It is my understanding that the Direct Mail Association supports it or has raised no objection to it. It was not even raised as an objection in the Senate.

Further I would like to say that many of the large retailers are already doing this, and many of our smaller retailers are already doing it. Many of them are already gearing up to doing it in anticipation of this bill passing.

As far as the 90 days are concerned, no catalogs will have to be recalled. Any catalog that is printed before 90 days after the enactment of this bill will not have to have any of these requirements in it.

Let me make one final point. If we put this in, this will mean that the bill will have to go to conference, and that probably means that it will not get through; very likely it will not get through during this term of Congress. So I think it is very important that we vote "no."

Mr. BROYHILL. Mr. Chairman, I move to strike the requisite number of words, and I rise in opposition to the amendment.

I will take my full 5 minutes, but I just want to say that the gentleman from South Carolina [Mr. DERRICK] is entirely correct. This amendment is simply not needed because the disclosures that are required under the terms of this bill are prospective in nature, not retroactive. They would apply only to those catalogs that are produced 90 days after enactment. I want to assure the gentleman that it does not in any way apply to catalogs that are being put together today or that were printed before the effective date and which may still be in use.

I also want to point out this fact: It is interesting that the textile and apparel industry strongly supports this title. Many of them are importers, as we know, and they do not perceive this 90-day effective date as being too tight a deadline to meet. This is somewhat ironic since the textile industry does have a greater burden to shoulder since they have to place, for the first time, new labels in their products, whereas the catalog and direct-mail people simply have to put a new line in their typed descriptive material.

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

Mr. BROYHILL. I yield to the gentleman from Minnesota.

Mr. FRENZEL. Mr. Chairman, I thank the gentleman for yielding.

I certainly do not want to cause the gentleman any delay in applying whatever protection or extra incentive to sales of U.S. goods he can find, but 90 days is a pretty short time for putting a catalog together. It is true that many of the large catalog houses such as the one that the gentleman showed me that sells to rich folks probably have already done so. Who was it, Sears Roebuck?

Mr. BROYHILL. Sears Roebuck.

Mr. FRENZEL. Yes, Sears Roebuck. The large houses that have billions of dollars like the makers of that catalog probably can do that. However, when we are talking about something being offered by a small mail order house for Easter or spring and the catalog is already in process, it is likely to be difficult. Yes, it is prospective, but it is only 90 days prospective.

Mr. Chairman, I thank the gentleman for yielding, and I regret that he would not see fit to support the amendment.

Mr. BROYHILL. Again, Mr. Chairman, I argue that this 90-day effective date is not burdensome. It does not apply to catalogs that are put together now or printed in the time prior to the effective date.

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

Mr. BROYHILL. I yield to the gentleman from South Carolina.

Mr. CAMPBELL. Mr. Chairman, I just want to underscore the point the gentleman from South Carolina [Mr. DERRICK] made. Not only is this not needed, but this amendment, however innocuous it might seem to be, could kill the bill because it could force us to a conference and time is running out. For that reason, if nothing else, I think we should oppose the amendment.

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

Mr. BROYHILL. I yield to the gentleman from Massachusetts.

Mr. FRANK. Mr. Chairman, I thank the gentleman for yielding.

Obviously the plea that these poor, struggling ma-and-pa catalogers only have 90 days has some appeal, except the reality is that they have much more than 90 days. This is not a new issue. This is not the first day it came up. It is not immediately being enacted.

This issue has been a live one for some time. It was discussed here, and people knew it was coming. So any catalog printer with any prudence has been on notice that we were likely to do this. If they were not able to get the message before now, they just do not want to get the message. They had considerably more than 90 days if they knew that this was coming, and I think they were advised that it was coming.

Mr. FRENZEL. Mr. Chairman, I have got to say that that is a better argument than the one that says that if the bill goes to conference, it will lose.

Mr. FRANK. Mr. Chairman, if the gentleman will yield, I want to thank the gentleman for that.

The CHAIRMAN. The question is on the amendment offered by the gentleman from Minnesota [Mr. FRENZEL] to the amendment offered by the gentleman from South Carolina [Mr. DERRICK], as amended.

The question was taken; and the Chairman announced that the noes appeared to have it.

Mr. FRENZEL. Mr. Chairman, I demand a recorded vote, and pending that, I make the point of order that a quorum is not present.

The CHAIRMAN. Evidently a quorum is not present. Pursuant to the provisions of clause 2 of rule XXIII, the Chair announces that he will reduce to a minimum of 5 minutes the period of time within which a vote by electronic device, if ordered, will be taken on the pending question following the quorum call. Members will record their presence by electronic device.

The call was taken by electronic device.

The following Members responded to their names:

[Roll No. 377]

Albosta	Evans (IA)	Luken
Anderson	Evans (IL)	Lundine
Andrews (NC)	Fascell	Lungren
Andrews (TX)	Fazio	Mack
Annunzio	Feighan	Madigan
Anthony	Fiedler	Markey
Applegate	Fields	Marlenee
AuCoin	Fish	Marriott
Badham	Foglietta	Martin (IL)
Barnes	Ford (TN)	Martin (NY)
Bartlett	Fowler	Martinez
Bateman	Frank	Mavroules
Bates	Franklin	Mazzoli
Bedell	Frenzel	McCain
Bennett	Garcia	McCandless
Bereuter	Gaydos	McCloskey
Berman	Gejdenson	McCollum
Bevill	Gekas	McEwen
Biaggi	Gephardt	McGrath
Bilirakis	Gilman	McHugh
Boehlert	Gingrich	McKernan
Boggs	Glickman	McNulty
Boland	Gonzalez	Mica
Boner	Goodling	Michel
Bonior	Gore	Mikulski
Borski	Gramm	Miller (CA)
Bosco	Green	Miller (OH)
Boxer	Guarini	Mineta
Breaux	Gunderson	Minish
Britt	Hall (OH)	Mitchell
Brooks	Hall, Ralph	Moakley
Broomfield	Hall, Sam	Molinari
Brown (CA)	Hamilton	Mollohan
Brown (CO)	Hammerschmidt	Montgomery
Broyhill	Hansen (UT)	Moore
Bryant	Hartnett	Moorhead
Burton (CA)	Hatcher	Morrison (CT)
Burton (IN)	Hawkins	Morrison (WA)
Byron	Hayes	Mrazek
Campbell	Hefner	Murphy
Carper	Hertel	Murtha
Carr	Hightower	Myers
Chandler	Hiler	Natcher
Chappell	Hillis	Nichols
Chappie	Holt	Nielson
Cheney	Hopkins	Nowak
Clarke	Howard	O'Brien
Clay	Hoyer	Oakar
Clinger	Hubbard	Oberstar
Coats	Huckaby	Obey
Coelho	Hughes	Olin
Coleman (MO)	Hunter	Ortiz
Coleman (TX)	Hutto	Ottinger
Collins	Hyde	Oxley
Conable	Ireland	Packard
Conte	Jacobs	Panetta
Conyers	Jeffords	Parris
Cooper	Jenkins	Patman
Coughlin	Johnson	Patterson
Courter	Jones (NC)	Paul
Coyne	Jones (OK)	Pease
Craig	Jones (TN)	Penny
Crane, Daniel	Kaptur	Pepper
Crane, Philip	Kasich	Petri
Crockett	Kastenmeier	Pickle
D'Amours	Kemp	Porter
Daniel	Kennelly	Price
Dannemeyer	Kildee	Pursell
Darden	Kindness	Quillen
Daschle	Kogovsek	Rahall
Daub	Kolter	Ratchford
Davis	Kostmayer	Ray
de la Garza	Kramer	Regula
Derrick	LaFalce	Reid
DeWine	Lagomarsino	Richardson
Dickinson	Lantos	Ridge
Dicks	Latta	Rinaldo
Dixon	Leath	Ritter
Donnelly	Lehman (CA)	Robinson
Dorgan	Lehman (FL)	Rodino
Downey	Lent	Roe
Dreier	Levin	Roemer
Duncan	Levine	Rogers
Durbin	Levitas	Rose
Dwyer	Lewis (CA)	Roth
Dymally	Lipinski	Roukema
Dyson	Livingston	Rowland
Eckart	Lloyd	Roybal
Edgar	Loeffler	Russo
Edwards (CA)	Long (LA)	Sabo
Edwards (OK)	Long (MD)	Savage
Emerson	Lott	Sawyer
English	Lowery (CA)	Schaefer
Erdreich	Lowry (WA)	Schneider
Erlenborn	Lujan	Schroeder
Schulze	Spratt	Weber
Schumer	St Germain	Weiss
Selberling	Staggers	Wheat
Sensenbrenner	Stangeland	Whitehurst
Sharp	Stokes	Whitley
Shaw	Stratton	Whittaker
Shumway	Studds	Whitten
Shuster	Sundquist	Williams (MT)
Sikorski	Swift	Williams (OH)
Siljander	Synar	Wilson
Sisisky	Tallon	Wirth
Skeen	Tauke	Wise
Skelton	Thomas (CA)	Wolf
Slattery	Thomas (GA)	Wolpe
Smith (IA)	Torricelli	Wortley
Smith (NE)	Udall	Wyden
Smith (NJ)	Valentine	Wylie
Smith, Denny	Vander Jagt	Yates
Snowe	Vento	Yatron
Snyder	Volkmer	Young (AK)
Solarz	Walker	Young (FL)
Solomon	Watkins	Young (MO)
Spence	Waxman	Zschau

□ 1600

The CHAIRMAN. Three hundred fifty-four Members have answered to their names, a quorum is present, and the Committee will resume its business.

RECORDED VOTE

The CHAIRMAN. The pending business is the demand of the gentleman from Minnesota [Mr. FRENZEL] for a recorded vote. Five minutes will be allowed for the vote.

A recorded vote was ordered.

The vote was taken by electronic device, and there were—ayes 36, noes 323, answered "present" 1, not voting 72, as follows:

[Roll No. 378]

AYES—36

Anderson	Evans (IA)	Petri
Bereuter	Frenzel	Sabo
Burton (IN)	Green	Schaefer
Chandler	Jeffords	Smith (IA)
Clinger	Kastenmeier	Smith (NE)
Conable	Kramer	Smith, Denny
Crane, Daniel	Livingston	Stangeland
Crane, Philip	Lungren	Tauke
Dannemeyer	McCandless	Vento
Daub	Miller (OH)	Walker
English	Morrison (WA)	Weber
Erlenborn	Paul	Zschau

NOES—323

Albosta	Byron	Dorgan
Andrews (NC)	Campbell	Downey
Andrews (TX)	Carper	Dreier
Annunzio	Carr	Duncan
Anthony	Chappell	Durbin
Applegate	Chappie	Dwyer
Archer	Cheney	Dymally
AuCoin	Clarke	Dyson
Badham	Clay	Eckart
Barnes	Coats	Edgar
Bartlett	Coelho	Edwards (AL)
Bateman	Coleman (MO)	Edwards (CA)
Bates	Coleman (TX)	Edwards (OK)
Bedell	Collins	Emerson
Bennett	Conte	Erdreich
Berman	Conyers	Evans (IL)
Bevill	Cooper	Fazio
Biaggi	Coughlin	Feighan
Bilirakis	Courter	Fiedler
Boehlert	Coyne	Fields
Boggs	Craig	Fish
Boland	Crockett	Foglietta
Boner	D'Amours	Ford (TN)
Bonior	Daniel	Fowler
Borski	Darden	Frank
Bosco	Daschle	Franklin
Boxer	Davis	Frost
Breaux	de la Garza	Garcia
Britt	Dellums	Gaydos
Brooks	Derrick	Gejdenson
Broomfield	DeWine	Gekas
Brown (CA)	Dickinson	Gephardt
Brown (CO)	Dicks	Gilman
Broyhill	Dingell	Gingrich
Bryant	Dixon	Glickman
Burton (CA)	Donnelly	Gonzalez
Goodling	Marlenee	Roth
Gore	Marriott	Roukema
Gramm	Martin (IL)	Rowland
Gray	Martin (NY)	Roybal
Guarini	Martinez	Russo
Gunderson	Mavroules	Savage
Hall (OH)	Mazzoli	Sawyer
Hall, Ralph	McCain	Scheuer
Hall, Sam	McCloskey	Schneider
Hamilton	McCollum	Schroeder
Hammerschmidt	McEwen	Schulze
Hansen (UT)	McGrath	Schumer
Harrison	McHugh	Selberling
Hartnett	McKernan	Sensenbrenner
Hatcher	McKinney	Sharp
Hawkins	McNulty	Shaw
Hayes	Michel	Shumway
Hefner	Miller (CA)	Shuster
Hertel	Mineta	Sikorski
Hightower	Minish	Siljander
Hiler	Mitchell	Sisisky
Hillis	Moakley	Skeen
Holt	Molinari	Skelton
Hopkins	Mollohan	Slattery
Howard	Montgomery	Smith (NJ)
Hoyer	Moore	Snowe
Hubbard	Moorhead	Snyder
Huckaby	Morrison (CT)	Solarz
Hughes	Mrazek	Solomon
Hunter	Murphy	Spence
Hutto	Murtha	Spratt
Hyde	Myers	St Germain
Ireland	Natcher	Staggers
Jacobs	Nichols	Stokes
Jenkins	Nielson	Stratton
Johnson	Nowak	Studds
Jones (NC)	O'Brien	Sundquist
Jones (OK)	Oakar	Swift
Jones (TN)	Oberstar	Synar
Kaptur	Obey	Tallon
Kasich	Olin	Thomas (CA)
Kemp	Ortiz	Thomas (GA)
Kennelly	Ottinger	Torricelli
Kildee	Oxley	Udall
Kindness	Packard	Valentine
Kogovsek	Panetta	Vander Jagt
Kolter	Parris	Volkmer
Kostmayer	Patman	Watkins
LaFalce	Patterson	Waxman
Lagomarsino	Pease	Weaver
Lantos	Penny	Weiss
Latta	Pepper	Wheat
Leath	Pickle	Whitehurst
Lehman (CA)	Porter	Whitley
Lehman (FL)	Price	Whittaker
Lent	Pursell	Whitten
Levin	Quillen	Williams (MT)
Levine	Rahall	Williams (OH)
Levitas	Ratchford	Wilson
Lipinski	Ray	Wirth
Lloyd	Regula	Wise
Loeffler	Reid	Wolf
Long (LA)	Richardson	Wolpe
Long (MD)	Ridge	Wortley
Lott	Rinaldo	Wyden
Lowery (CA)	Ritter	Wylie
Lowry (WA)	Robinson	Yates
Lujan	Rodino	Yatron
Lundine	Roe	Young (AK)
Mack	Roemer	Young (FL)
Madigan	Rogers	Young (MO)
Markey	Rose	

ANSWERED "PRESENT"—1

Mikulski

NOT VOTING—72

Ackerman	Gregg	Pashayan
Addabbo	Hall (IN)	Pritchard
Akaka	Hance	Rangel
Alexander	Hansen (ID)	Roberts
Aspin	Harkin	Rostenkowski
Barnard	Heftel	Rudd
Bellenson	Horton	Shannon
Bethune	Kazen	Shelby
Billey	Kleczka	Simon
Bonker	Leach	Smith (FL)
Boucher	Leland	Smith, Robert
Carney	Lewis (CA)	Stark
Corcoran	Lewis (FL)	Stenholm
Dowdy	Luken	Stump
Early	MacKay	Tauzin
Fascell	Martin (NC)	Taylor
Ferraro	Matsui	Torres
Flippo	McCurdy	Towns
Florio	McDade	Traxler
Foley	Mica	Vandergriff
Ford (MI)	Moody	Vucanovich
Fuqua	Neal	Walgren
Gibbons	Nelson	Winn
Gradison	Owens	Wright

□ 1610

So the amendment to the amendment as amended, was rejected.

The result of the vote was announced as above recorded.

● Mr. DARDEN. Mr. Chairman, I rise today in support of the Derrick amendment to H.R. 3605, the Drug Price Competition Act. This amendment would strengthen current law by requiring that origin labels be displayed in a clear and conspicuous manner on textile products. Placing such labels on textile and apparel products would allow American consumers to choose between products made in the United States and foreign goods. These regulations would also be helpful to the Customs Service in stopping transshipped and other mishandled textile and apparel imports.

It is no secret that the U.S. textile industry has been struggling to survive in the wake of surging imports of foreign textile and apparel goods. The textile and apparel imports for the first 7 months of 1984 increased 44 percent over imports from the same period last year, exceeding 6 billion square yards. At the current rate, textile and apparel imports might well pass last year's record level by almost 3 billion square yards. These imports have had a crippling effect on the textile industry in Georgia. In the past 2 years, 20 textile plants in Georgia have closed and employment in the State's textile industry has dropped from 115,000 to its current level of 106,600 largely as a result of foreign competition. A large number of the individuals affected by this decline in Georgia's textile industry are my constituents.

Mr. Chairman, this amendment would in no way alter the current regulations regarding the importation of textile and apparel goods. It is strictly a consumer information proposal and will give Americans an opportunity to make a knowledgeable decision about buying products made by Americans. When the American consumer goes to buy a car, or a television, or a camera, he has an obvious choice between American-made products and foreign goods. Why should that same consumer not make a similar decision between products when buying clothing? I feel we should give the consumer this option and, therefore, I strongly favor this proposal. I urge my colleagues to support and vote in favor of this amendment.●

The CHAIRMAN. The question is on the amendment offered by the gentleman from South Carolina [Mr. DERRICK] as amended.

The amendment, as amended, was agreed to.

Mr. MINISH. Mr. Chairman, I rise to add my vigorous support for H.R. 3605, the Drug Price Competition and Patent Term Restoration Act.

I commend the outstanding work of my distinguished colleagues, Messrs. WAXMAN, DINGELL, and KASTENMEIER for their assiduous efforts on behalf of this legislation.

As we have discussed here today, this bill would make more low-cost generic drugs available by establishing a generic drug approval procedure for pioneer drugs first approved after 1962. Under our current law, this approval method is available for pioneer drugs approved before 1962. A lengthy and expensive application procedure is required for generic copies of drugs approved after 1962. Consequently, it has been difficult for generic manufacturers to submit such applications and the buying public are the losers.

Many patents have already expired for some frequently prescribed medications first approved after 1962 and many other important ones will be expiring in the next few years. It is estimated that availability of generic copies of drugs approved after 1962 would save consumers $920 million over the next 12 years. The Congressional Budget Office has observed that 10 generic versions of popular drugs now on the market cost half as much as their brand-name equivalents.

Generic drugs are a valuable resource for combating the high costs of health care. Everyone in this country will benefit by enactment of this legislation, but I feel it is particularly important that our senior citizens who fill more prescriptions than other segments of our population, can save money on their medical bills. Moreover, it is reported that the Federal Government spent $2.4 billion for drugs in the medicaid program for the poor, and in veteran and military hospitals in 1983. Therefore, this bill is not just a matter of assistance to individuals, but an important savings for our Federal budget as well.

This bill also extends the patent life for brand-name, pioneer drugs. This extension was included to help protect the investment in research and development that manufacturers undertake to develop pioneer drugs.

I wholeheartedly endorse this significant measure and call on my colleagues for their assistance in seeing that H.R. 3605 passes the House today.

● Mr. MOORHEAD. Mr. Chairman, I rise in support of the compromise bill, S. 2926, passed by the other body, late August 10, 1984. S. 2926 represents a significant gain for the American public. It speeds the marketing by generic drug firms of previously approved drugs following patent expiration. It also reestablishes a portion of the patent incentives for research-intensive drug firms which today lose much of their patent term during the Federal premarket review process.

Compared with H.R. 3605, S. 2926 contains some real improvements. Title II of that bill relating to patent term extension has been simplified. The complicated and unnecessary eligibility requirements for a patent to be extended have been removed and I applaud the other body for having done so. A particularly disturbing provision, however, was maintained and I am concerned by its implications and consequences, if enacted. Specifically, I refer to section 202 which would retroactively overrule the recent Federal Court of Appeals decision in Roche against Bolar.

Enactment of this section would create an unprecedented exception to the exclusionary rights to which a patent holder is entitled during the patent term. Overturning the Bolar decision would allow experimental use of a drug product prior to expiration of the patent. There is no legitimate basis for distinguishing between the exclusionary rights accorded a pharmaceutical manufacturer during the patent term and those enjoyed by any other patent holder.

In addition, the proposed reversal of Roche against Bolar, especially if done retroactively, is clearly in conflict with the position which the United States has advocated internationally. For many years now we have been urging developing countries to adopt and to use strong and effective patent laws. Should section 202 be enacted, the world patent community might conclude that the actions of the United States do not always agree with its words. The United States could be seen to be diminishing patent rights for pharmaceuticals at the same time we are asking others to increase such rights. Another fundamental problem of the current language of section 202 concerns the constitutional implications of retroactive reversal of the Bolar decision. Apparently the other body had similar concerns. But instead of amending section 202 to avoid its retroactive application, the other body added a section 301 providing that the remainder of this act shall not be affected if any provision is declared unconstitutional. In my opinion, Congress should not enact legislation containing constitutional deficiencies. Those who have engaged in previous patent infringement in violation of existing law should not be rewarded by retroactively legitimizing their conduct without forcing the payment of appropriate compensation to the injured parties. For this reason, section 202 should be amended to permit experimental use of a drug by a nonpatentee only during the period for which the patent has been extended.

I know this change will not be made, but I would like the record to show that there are some of us including the administration who strongly believe that that reversal of the Bolar case is not good policy. But I will nonetheless vote in favor of the compromise.●

● Mr. WALGREN. Mr. Chairman, I urge support for H.R. 3605, the Drug Price Competition and Patent Term Restoration Act of 1984, and I hope the House will approve it. This bill will accomplish two objectives. First, it will make available almost immediately

nearly twice as many low-cost, generic drugs as are now available. Second, it will create new incentives for research and development by restoring the patent time lost by a development of a new drug while waiting for approval by the Federal Food and Drug Administration.

H.R. 3605 will make hundreds of new low-cost, generic drugs available by speeding up the approval process for these drugs. As the current law stands, all drugs approved after 1962 can only be made available in generic form through a long and involved testing process. This process is unnecessary because the active ingredient in the generic drug is identical to that in the name-brand drug. Under H.R. 3605, this testing process would be speeded up tremendously without endangering the safety to the consumer. As well as making more generic drugs available to the public, this bill will create new incentives for R&D in the pharmaceutical industry. As the current law stands, a newly discovered drug will receive a patent for 17 years. During that period no one except the patent holder can produce the drug. This 17-year period is considered to be fair by most people. Often, however, the drug approval process takes between 5 and 10 years. As a result, the pharmaceutical companies lose much of the time during which they would not have to compete with other firms. The result is that the patent period is inadvertently cut short and R&D becomes much less profitable, and the public loses out on the opportunity to use new drugs that would otherwise be developed.

Under H.R. 3605 this inequity would be redressed because the pharmaceutical companies will have an opportunity to extend their patents once their product is approved. This will encourage more research, a goal we should favor in an effort to relieve pain and cure diseases that still plague mankind.

The consumers of this country should welcome this bill because it could save $1 billion over the next 10 years. In my own district in Pittsburgh this is especially important to many people whose budgets are still feeling the pinch of the lagging recession.

This bill should also help the elderly who live on a fixed income, but who must spend 3½ times more than the rest of the population on health care. People over 65 average six doctor visits a year compared to only four for people in the 25 to 44 age group. And the elderly spend substantially more on drugs than the rest of the population.

H.R. 3605 addresses several needs and carefully balances the needs of the industry with the health needs of the people in our society. I certainly hope that Members on both sides of the aisle will place their support, and vote, for this bill.●

● Mr. COLEMAN of Texas. Mr. Chairman, I rise in strong support of this bill and ask to revise and extend my remarks.

Mr. Chairman, this is a good bill that the House should pass. American senior citizens and consumers can save an estimated $920 million over the next 12 years as a result of this legislation that could dramatically increase the availability of low-cost, generic drugs. The bill represents another step toward free-market ecomomics in the pharmaceutical industry, and it provides easier entry into the marketplace for generic substitutes of brand-name drugs, which often enjoy long periods of market exclusivity.

All of us complain about the rising costs of goods and services, and nowhere is inflation more evident than in health-care costs. Consequently, nowhere is the rising cost of health care felt more than by our elderly. Two factors create a "misery index" for the elderly in health care costs: One, living on a fixed income; and two, rising costs. Mr. Chairman, this bill begins to ease the terrible burden carried by our senior citizens by allowing them to participate in the lower prices a free-market economy can produce. Rather than being forced to pay higher prices because of bureacratic redtape, the elderly of this Nation will have the opportunity to shop around for the best, most equitable prices. Rather than having to sacrifice other needs for life-sustaining drugs, the elderly will be given the opportunity to fulfill all their needs. This bill is fair and it is needed, and there is no reason it should not become law.●

The CHAIRMAN. Are there further amendments? If not, the question is on the committee amendment in the nature of a substitute, as amended.

The committee amendment in the nature of a substitute, as amended, was agreed to.

The CHAIRMAN. Under the rule, the Committee rises.

Accordingly the Committee rose; and the Speaker pro tempore [Mr. BROWN of California] 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, pursuant to House Resolution 569, he reported the bill back to the House with an amendment adopted by the Committee of the Whole.

The SPEAKER pro tempore. Under the rule, the previous question is ordered.

Is a separate vote demanded on any amendment to the committee amendment in the nature of a substitute adopted by the Committee of the Whole? If not, the question is on the amendment.

The amendment was agreed to.

The SPEAKER pro tempore. The question is on the engrossment and third reading of the bill.

The bill was ordered to be engrossed and read a third time, and was read the third time.

The SPEAKER pro tempore. The question is on the passage of the bill.

The question was taken; and the Speaker pro tempore announced that the ayes appeared to have it.

Mr. BROYHILL. Mr. Speaker, on that, I demand the yeas and nays.

The yeas and nays were ordered.

The vote was taken by electronic device, and there were—yeas 362, nays 0, not voting 70, as follows:

[Roll No. 379]

YEAS—362

Albosta	Dellums	Howard
Anderson	Derrick	Hoyer
Andrews (NC)	DeWine	Hubbard
Andrews (TX)	Dickinson	Huckaby
Annunzio	Dingell	Hughes
Anthony	Dixon	Hunter
Applegate	Donnelly	Hutto
Archer	Dorgan	Hyde
Aspin	Downey	Ireland
AuCoin	Dreier	Jacobs
Badham	Duncan	Jeffords
Barnes	Durbin	Jenkins
Bartlett	Dwyer	Johnson
Bateman	Dymally	Jones (NC)
Bates	Dyson	Jones (OK)
Bedell	Eckart	Jones (TN)
Bennett	Edgar	Kaptur
Bereuter	Edwards (AL)	Kasich
Berman	Edwards (CA)	Kastenmeier
Bevill	Edwards (OK)	Kemp
Biaggi	Emerson	Kennelly
Billrakis	English	Kildee
Boehlert	Erdreich	Kindness
Boggs	Erlenborn	Kogovsek
Boland	Evans (IA)	Kolter
Boner	Evans (IL)	Kostmayer
Bonior	Fascell	Kramer
Borski	Fazio	LaFalce
Boxer	Feighan	Lagomarsino
Breaux	Fiedler	Lantos
Britt	Fields	Latta
Brooks	Fish	Leath
Broomfield	Foglietta	Lehman (CA)
Brown (CA)	Ford (TN)	Lehman (FL)
Brown (CO)	Fowler	Lent
Broyhill	Frank	Levin
Bryant	Franklin	Levine
Burton (CA)	Frenzel	Levitas
Burton (IN)	Frost	Lewis (CA)
Byron	Garcia	Lipinski
Campbell	Gaydos	Livingston
Carper	Gejdenson	Lloyd
Carr	Gekas	Loeffler
Chandler	Gephardt	Long (LA)
Chappell	Gibbons	Long (MD)
Chappie	Gilman	Lott
Cheney	Gingrich	Lowery (CA)
Clarke	Glickman	Lowry (WA)
Clay	Gonzalez	Lujan
Clinger	Goodling	Lundine
Coats	Gore	Lungren
Coelho	Gramm	Mack
Coleman (MO)	Gray	Madigan
Coleman (TX)	Green	Markey
Collins	Guarini	Marlenee
Conable	Gunderson	Marriott
Conte	Hall (OH)	Martin (IL)
Conyers	Hall, Ralph	Martin (NY)
Cooper	Hall, Sam	Martinez
Coughlin	Hamilton	Mavroules
Courter	Hammerschmidt	Mazzoli
Coyne	Hansen (UT)	McCain
Craig	Harrison	McCandless
Crane, Daniel	Hartnett	McCloskey
Crane, Philip	Hatcher	McCollum
Crockett	Hawkins	McEwen
D'Amours	Hayes	McGrath
Daniel	Hefner	McHugh
Dannemeyer	Hertel	McKernan
Darden	Hightower	McKinney
Daschle	Hiler	McNulty
Daub	Hillis	Mica
Davis	Holt	Michel
de la Garza	Hopkins	Miller (CA)

Miller (OH)	Reid	St Germain
Mineta	Richardson	Staggers
Minish	Ridge	Stangeland
Mitchell	Rinaldo	Stokes
Moakley	Ritter	Stratton
Molinari	Robinson	Studds
Mollohan	Rodino	Sundquist
Montgomery	Roe	Swift
Moore	Roemer	Synar
Moorhead	Rogers	Tallon
Morrison (CT)	Rose	Tauke
Morrison (WA)	Roth	Thomas (CA)
Mrazek	Roukema	Thomas (GA)
Murphy	Rowland	Torricelli
Murtha	Roybal	Udall
Myers	Russo	Valentine
Natcher	Sabo	Vander Jagt
Nichols	Savage	Vento
Nielson	Sawyer	Volkmer
Nowak	Schaefer	Walker
O'Brien	Scheuer	Watkins
Oakar	Schneider	Waxman
Oberstar	Schroeder	Weaver
Obey	Schulze	Weber
Olin	Schumer	Weiss
Ortiz	Seiberling	Wheat
Oxley	Sensenbrenner	Whitehurst
Packard	Sharp	Whitley
Panetta	Shaw	Whittaker
Parris	Shumway	Whitten
Patman	Shuster	Williams (MT)
Patterson	Sikorski	Williams (OH)
Paul	Siljander	Wilson
Pease	Sisisky	Wirth
Penny	Skeen	Wise
Pepper	Skelton	Wolf
Petri	Slattery	Wolpe
Pickle	Smith (IA)	Wortley
Porter	Smith (NE)	Wyden
Price	Smith (NJ)	Wylie
Pritchard	Smith, Denny	Yates
Pursell	Snowe	Yatron
Quillen	Snyder	Young (AK)
Rahall	Solarz	Young (FL)
Ratchford	Solomon	Young (MO)
Ray	Spence	Zschau
Regula	Spratt	

NOT VOTING—70

Ackerman	Hall (IN)	Rangel
Addabbo	Hance	Roberts
Akaka	Hansen (ID)	Rostenkowski
Alexander	Harkin	Rudd
Barnard	Heftel	Shannon
Bellenson	Horton	Shelby
Bethune	Kazen	Simon
Billey	Kleczka	Smith (FL)
Bonker	Leach	Smith, Robert
Bosco	Leland	Stark
Boucher	Lewis (FL)	Stenholm
Carney	Luken	Stump
Corcoran	MacKay	Tauzin
Dicks	Martin (NC)	Taylor
Dowdy	Matsui	Torres
Early	McCurdy	Towns
Ferraro	McDade	Traxler
Flippo	Mikulski	Vandergriff
Florio	Moody	Vucanovich
Foley	Neal	Walgren
Ford (MI)	Nelson	Winn
Fuqua	Ottinger	Wright
Gradison	Owens	
Gregg	Pashayan	

□ 1630

So the bill was passed.

The result of the vote was announced as above recorded.

The title of the bill was amended so as to read: "A bill to amend the Federal Food, Drug, and Cosmetic Act to revise the procedures for new drug applications and to amend title 35, United States Code, to authorize the extension of the patents for certain regulated products, and for other purposes."

A motion to reconsider was laid on the table.

Mr. WAXMAN. Mr. Speaker, pursuant to the provisions of House Resolution 569, I call up from the Speaker's table the Senate bill (S. 1538) to amend the patent laws of the United States, and ask for its immediate consideration.

The Clerk read the title of the Senate bill.

MOTION OFFERED BY MR. WAXMAN

Mr. WAXMAN. Mr. Speaker, I offer a motion.

The Clerk read as follows:

Mr. WAXMAN moves to strike out all after the enacting clause of the Senate bill, S. 1538, and to insert in lieu thereof the provisions of the bill, H.R. 3605, as passed, as follows:

That this Act may be cited as the "Drug Price Competition and Patent Term Restoration Act of 1984".

TITLE I—ABBREVIATED NEW DRUG APPLICATIONS

SECTION 101. Section 505 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 355) is amended by redesignating subsection (j) as subsection (k) and inserting after subsection (i) the following:

"(j)(1) Any person may file with the Secretary an abbreviated application for the approval of a new drug.

"(2)(A) An abbreviated application for a new drug shall contain—

"(i) information to show that the conditions of use prescribed, recommended, or suggested in the labeling proposed for the new drug have been previously approved for a drug listed under paragraph (6) (hereinafter in this subsection referred to as a 'listed drug');

"(ii)(I) if the listed drug referred to in clause (i) has only one active ingredient, information to show that the active ingredient of the new drug is the same as that of the listed drug,

"(II) if the listed drug referred to in clause (i) has more than one active ingredient, information to show that the active ingredients of the new drug are the same as those of the listed drug, or

"(III) if the listed drug referred to in clause (i) has more than one active ingredient and if one of the active ingredients of the new drug is different and the application is filed pursuant to the approval of a petition filed under subparagraph (C), information to show that the other active ingredients of the new drug are the same as the active ingredients of the listed drug, information to show that the different active ingredient is an active ingredient of a listed drug or of a drug which does not meet the requirements of section 201(p), and such other information respecting the different active ingredient with respect to which the petition was filed as the Secretary may require;

"(iii) information to show that the route of administration, the dosage form, and the strength of the new drug are the same as those of the listed drug referred to in clause (i) or, if the route of administration, the dosage form, or the strength of the new drug is different and the application is filed pursuant to the approval of a petition filed under subparagraph (C), such information respecting the route of administration, dosage form, or strength with respect to which the petition was filed as the Secretary may require;

"(iv) information to show that the new drug is bioequivalent to the listed drug referred to in clause (i), except that if the application is filed pursuant to the approval of a petition filed under subparagraph (C), information to show that the active ingredients of the new drug are of the same pharmacological or therapeutic class as those of the listed drug referred to in clause (i) and the new drug can be expected to have the same therapeutic effect as the listed drug when administered to patients for a condition of use referred to in clause (i);

"(v) information to show that the labeling proposed for the new drug is the same as the labeling approved for the listed drug referred to in clause (i) except for changes required because of differences approved under a petition filed under subparagraph (C) or because the new drug and the listed drug are produced or distributed by different manufacturers;

"(vi) the items specified in clauses (B) through (F) of subsection (b)(1);

"(vii) a certification, in the opinion of the applicant and to the best of his knowledge, with respect to each patent which claims the listed drug referred to in clause (i) or which claims a use for such listed drug for which the applicant is seeking approval under this subsection and for which information is required to be filed under subsection (b) or (c)—

"(I) that such patent information has not been filed,

"(II) that such patent has expired,

"(III) of the date on which such patent will expire, or

"(IV) that such patent is invalid or will not be infringed by the manufacture, use, or sale of the new drug for which the application is submitted; and

"(viii) if with respect to the listed drug referred to in clause (i) information was filed under subsection (b) or (c) for a method of use patent which does not claim a use for which the applicant is seeking approval under this subsection, a statement that the method of use patent does not claim such a use.

The Secretary may not require that an abbreviated application contain information in addition to that required by clauses (i) through (viii).

"(B)(i) An applicant who makes a certification described in subparagraph (A)(vii)(IV) shall include in the application a statement that the applicant will give the notice required by clause (ii) to—

"(I) each owner of the patent which is the subject of the certification or the representative of such owner designated to receive such notice, and

"(II) the holder of the approved application under subsection (b) for the drug which is claimed by the patent or a use of which is claimed by the patent or the representative of such holder designated to receive such notice.

"(ii) The notice referred to in clauses (i) shall state that an application, which contains data from bioavailability or bioequivalence studies, has been submitted under this subsection for the drug with respect to which the certification is made to obtain approval to engage in the commercial manufacture, use, or sale of such drug before the expiration of the patent referred to in the certification. Such notice shall include a detailed statement of the factual and legal basis of the applicant's opinion that the patent is not valid or will not be infringed.

"(iii) If an application is amended to include a certification described in subparagraph (A)(vii)(IV), the notice required by clause (ii) shall be given when the amended application is submitted.

"(C) If a person wants to submit an abbreviated application for a new drug which has a different active ingredient or whose route of administration, dosage form, or strength differ from that of a listed drug, such person shall submit a petition to the Secretary seeking permission to file such an application. The Secretary shall approve or disapprove a petition submitted under this subparagraph within ninety days of the

date the petition is submitted. The Secretary shall approve such a petition unless the Secretary finds—

"(I) that investigations must be conducted to show the safety and effectiveness of the drug or of any of its active ingredients, the route of administration, the dosage form, or strength which differ from the listed drug; or

"(II) that any drug with a different active ingredient may not be adequately valuated for approval as safe and effective on the basis of the information required to be submitted in an abbreviated application.

"(3) Subject to paragraph (4), the Secretary shall approve an application for a drug unless the Secretary finds—

"(A) the methods used in, or the facilities and controls used for, the manufacture, processing, and packing of the drug are inadequate to assure and preserve its identity, strength, quality, and purity;

"(B) information submitted with the application is insufficient to show that each of the proposed conditions of use have been previously approved for the listed drug referred to in the application;

"(C)(i) if the listed drug has only one active ingredient, information submitted with the application is insufficient to show that the active ingredient is the same as that of the listed drug,

"(ii) if the listed drug has more than one active ingredient, information submitted with the application is insufficient to show that the active ingredients are the same as the active ingredients of the listed drug, or

"(iii) if the listed drug has more than one active ingredient and if the application is for a drug which has an active ingredient different from the listed drug, information submitted with the application is insufficient to show—

"(I) that the other active ingredients are the same as the active ingredients of the listed drug, or

"(II) that the different active ingredient is an active ingredient of a listed drug or a drug which does not meet the requirements of section 201(p),

or no petition to file an application for the drug with the different ingredient was approved under paragraph (2)(C);

"(D)(i) if the application is for a drug whose route of administration, dosage form, or strength of the drug is the same as the route of administration, dosage form, or strength of the listed drug referred to in the application, information submitted in the application is insufficient to show that the route of administration, dosage form, or strength is the same as that of the listed drug, or

"(ii) if the application is for a drug whose route of administration, dosage form, or strength of the drug is different from that of the listed drug referred to in the application, no petition to file an application for the drug with the different route of administration, dosage form, or strength was approved under paragraph (2)(C);

"(E) if the application was filed pursuant to the approval of a petition under paragraph (2)(C), the application did not contain the information required by the Secretary respecting the active ingredient, route of administration, dosage form, or strength which is not the same;

"(F) information submitted in the application is insufficient to show that the drug is bioequivalent to the listed drug referred to in the application or, if the application was filed pursuant to a petition approved under paragraph (2)(C), information submitted in the application is insufficient to show that the active ingredients of the new drug are of the same pharmacological or therapeutic class as those of the listed drug referred to in paragraph (2)(A)(i) and that the new drug can be expected to have the same therapeutic effect as the listed drug when administered to patients for a condition of use referred to in such paragraph;

"(G) information submitted in the application is insufficient to show that the labeling proposed for the drug is the same as the labeling approved for the listed drug referred to in the application except for changes required because of differences approved under a petition filed under paragraph (2)(C) or because the drug and the listed drug are produced or distributed by different manufacturers;

"(H) information submitted in the application or any other information available to the Secretary shows that (i) the inactive ingredients of the drug are unsafe for use under the conditions prescribed, recommended, or suggested in the labeling proposed for the drug, or (ii) the composition of the drug is unsafe under such conditions because of the type or quantity of inactive ingredients included or the manner in which the inactive ingredients are included;

"(I) the approval under subsection (c) of the listed drug referred to in the application under this subsection has been withdrawn or suspended for grounds described in the first sentence of subsection (e), the Secretary has published a notice of opportunity for hearing to withdraw approval of the listed drug under subsection (c) for grounds described in the first sentence of subsection (e), the approval under this subsection of the listed drug referred to in the application under this subsection has been withdrawn or suspended under paragraph (5), or the Secretary determined that the listed drug has been withdrawn from sale for safety or effectiveness reasons;

"(J) the application does not meet any other requirement of paragraph (2)(A); or

"(K) the application contains an untrue statement of material fact.

"(4)(A) Within one hundred and eighty days of the initial receipt of an application under paragraph (2) or within such additional periods as may be agreed upon by the Secretary and the applicant, the Secretary shall approve or disapprove the application.

"(B) The approval of an application submitted under paragraph (2) shall be made effective on the last applicable date determined under the following:

"(i) If the applicant only made a certification described in subclause (I) or (II) of paragraph (2)(A)(vii) or in both such subclauses, the approval may be made effective immediately.

"(ii) If the applicant made a certification described in subclause (III) of paragraph (2)(A)(vii), the approval may be made effective on the date certified under subclause (III).

"(iii) If the applicant made a certification described in subclause (IV) of paragraph (2)(A)(vii), the approval shall be made effective immediately unless an action is brought for infringement of a patent which is the subject of the certification before the expiration of forty-five days from the date the notice provided under paragraph (2)(B)(i) is received. If such an action is brought before the expiration of such days, the approval shall be made effective upon the expiration of the thirty-month period beginning on the date of the receipt of the notice provided under paragraph (2)(B)(i) or such shorter or longer period as the court may order because either party to the action failed to reasonably cooperate in expediting the action, except that—

"(I) if before the expiration of such period the court decides that such patent is invalid or not infringed, the approval shall be made effective on the date of the court decision,

"(II) if before the expiration of such period the court decides that such patent has been infringed, the approval shall be made effective on such date as the court orders under section 271(e)(4)(A) of title 35, United States Code, or

"(III) if before the expiration of such period the court grants a preliminary injunction prohibiting the applicant from engaging in the commerical manufacture or sale of the drug until the court decides the issues of patent validity and infringement and if the court decides that such patent is not invalid or not infringed, the approval shall be made effective on the date of such court decision.

In such an action, each of the parties shall reasonably cooperate in expediting the action. Until the expiration of forty-five days from the date the notice made under paragraph (2)(B)(1) is received, no action may be brought under section 2201 of title 28, United States Code, for a declaratory judgment with respect to the patent. Any action brought under section 2201 shall be brought in the judicial district where the defendant has its principal place of business or a regular and established place of business.

"(iv) If the application contains a certification described in subclause (IV) of paragraph (2)(A)(vii) and if for a drug for which a previous application has been submitted under this subsection containing such a certification, the application shall be made effective not earlier than one hundred and eighty days after—

"(I) the date the Secretary receives notice from the applicant under the previous application of the first commercial marketing of the drug under the previous applications, or

"(II) the date of a decision of a court in an action described in clause (iii) holding the patent which is the subject of the certification to be invalid or not infringed,

whichever is earlier.

"(C) If the Secretary decides to disapprove an application, the Secretary shall give the applicant notice of an opportunity for a hearing before the Secretary on the question of whether such application is approvable. If the applicant elects to accept the opportunity for hearing by written request within thirty days after such notice, such hearing small commence not more than ninety days after the expiration of such thirty days unless the Secretary and the applicant otherwise agree. Any such hearing shall thereafter be conducted on an expedited basis and the Secretary's order thereon shall be issued within ninety days after the date fixed by the Secretary for filing final briefs.

"(D)(i) If an application (other than an abbreviation new drug application) submitted under subsection (b) for a drug, no active ingredient (including any ester or salt of the active ingredient) of which has been approved in any other application under subsection (b), was approved during the period beginning January 1, 1982, and ending of the date of the enactment of this subsection, the Secretary may not make the approval of an application submitted under this subsection which refers to the drug for which the subsection (b) application was submitted effective before the expiration of ten years from the date of the approval of the application under subsection (b).

"(ii) If an application submitted under subsection (b) for a drug, no active ingredient (including any ester or salt of the active ingredient) of which has been approved in any other application under subsection (b),

is approved after the date of the enactment of this subsection, no application may be submitted under this subsection which refers to the drug for which the subsection (b) application was submitted before the expiration of five years from the date of the approval of the application under subsection (b), except that such an application may be submitted under this subsection after the expiration of four years from the date of the approval of the subsection (b) application if it contains a certification of patent invalidity or noninfringement described in subclause (IV) of paragraph (2)(A)(vii). The approval of such an application shall be made effective in accordance with subparagraph (B) except that, if an action for patent infringement is commenced during the one-year period beginning forty-eight months after the date of the approval of the subsection (b) application, the thirty-month period referred to in subparagraph (B)(iii) shall be extended by such amount of time (if any) which is required for seven and one-half years to have elapsed from the date of approval of the subsection (b) application.

"(iii) If an application submitted under subsection (b) for a drug, which includes an active ingredient (including any ester or salt of the active ingredient) that has been approved in another application approved under subsection (b), is approved after the date of enactment of this subsection and if such application contains reports of new clinical investigations (other than bioavailability studies) essential to the approval of the application and conducted or sponsored by the applicant, the Secretary may not make the approval of an application submitted under this subsection for the conditions of approval of such drug in the subsection (b) application effective before the expiration of three years from the date of the approval of the application under subsection (b) for such drug.

"(iv) If a supplement to an application approved under subsection (b) is approved after the date of enactment of this subsection and the supplement contains reports of new clinical investigations (other than bioavailability studies) essential to the approval of the supplement and conducted or sponsored by the person submitting the supplement, the Secretary may not make the approval of an application submitted under this subsection for a change approved in the supplement effective before the expiration of three years from the date of the approval of the supplement under subsection (b).

"(v) If an application (or supplement to an application) submitted under subsection (b) for a drug, which includes an active ingredient (including any ester or salt of the active ingredient) that has been approved in another application under subsection (b), was approved during the period beginning January 1, 1982, and ending on the date of the enactment of this subsection, the Secretary may not make the approval of an application submitted under this subsection which refers to the drug for which the subsection (b) application was submitted or which refers to a change approved in a supplement to the subsection (b) application effective before the expiration of two years from the date of enactement of this subsection.

"(5) If a drug approved under this subsection refers in its approved application to a drug the approval of which was withdrawn or suspended for grounds described in the first sentence of subsection (e) or was withdrawn or suspended under this paragraph or which, as determined by the Secretary, has been withdrawn from sale for safety or effectiveness reasons, the approval of the drug under this subsection shall be withdrawn or suspended—

"(A) for the same period as the withdrawal or suspension under subsection (e) of this paragraph, or

"(B) if the listed drug has been withdrawn from sale, for the period of withdrawal from sale or, if earlier, the period ending on the date the Secretary determines that the withdrawal from sale is not for safety or effectiveness reasons.

"(6)(A)(i) Within sixty days of the date of the enactment of this subsection, the Secretary shall publish and make available to the public—

"(I) a list in alphabetical order of the official and proprietary name of each drug which has been approved for safety and effectiveness under subsection (c) before the date of the enactment of this subsection;

"(II) the date of approval if the drug is approved after 1981 and the number of the application which was approved; and

"(III) whether in vitro or in vivo bioequivalence studies, or both such studies, are required for applications filed under this subsection which will refer to the drug published.

"(ii) Every thirty days after the publication of the first list under clause (i) the Secretary shall revise the list to include each drug which has been approved for safety and effectiveness under subsection (c) or approved under this subsection during the thirty day-period.

"(iii) When patent information submitted under subsection (b) or (c) respecting a drug included on the list is to be published by the Secretary the Secretary shall, in revisions made under clause (ii), include such information for such drug.

"(B) A drug approved for safety and effectiveness under subsection (c) or approved under this subsection shall, for purposes of this subsection, be considered to have been published under subparagraph (A) on the date of its approval or the date of enactment, whichever is later.

"(C) If the approval of a drug was withdrawn or suspended for grounds described in the first sentence of subsection (e) or was withdrawn or suspended under paragraph (5) or if the Secretary determines that a drug has been withdrawn from sale for safety or effectiveness reasons, it may not be published in the list under subparagraph (A) or, if the withdrawal or suspension occurred after its publication in such list, it shall be immediately removed from such list—

"(i) for the same period as the withdrawal or suspension under subsection (e) or paragraph (5), or

"(ii) if the listed drug has been withdrawn from sale, for the period of withdrawal from sale or, if earlier, the period ending on the date the Secretary determines that the withdrawal from sale if not for safety or effectiveness reasons.

A notice of the removal shall be published in the Federal Register.

"(7) For purposes of this subsection:

"(A) The term 'bioavailability' means the rate and extent to which the active ingredient or therapeutic ingredient is absorbed from a drug and becomes available at the site of drug action.

"(B) A drug shall be considered to be bioequivalent to a listed drug if—

"(i) the rate and extent of absorption of the drug do not show a significant difference from the rate and extent of absorption of the listed drug when administered at the same molar dose of the therapeutic ingredient under similar experimental conditions in either a single dose or multiple doses; or

"(ii) the extent of absorbtion of the drug does not show a significant difference from the extent of absorption of the listed drug when administered at the same molar dose of the therapeutic ingredient under similar experimental conditions in either a single dose or multiple doses and the difference from the listed drug in the rate of absorption of the drug is intentional, is reflected in its proposed labeling, is not essential to the attainment of effective body drug concentrations on chronic use, and is considered medically insignificant for the drug.".

SEC. 102. (a)(1) Section 505(b) of such Act is amended by adding at the end the following: "The applicant shall file with the application the patent number and the expiration date of any patent which claims the drug for which the applicant submitted the application or which claims a method of using such drug and with respect to which a claim of patent infringement could reasonably be asserted if a person not licensed by the owner engaged in the manufacture, use, or sale of the drug. If an application is filed under this subsection for a drug and a patent which claims such drug or a method of using such drug is issued after the filing date but before approval of the application, the applicant shall amend the application to include the information required by the preceding sentence. Upon approval of the application, the Secretary shall publish information submitted under the two preceding sentences.".

(2) Section 505(c) of such Act is amended by inserting "(1)" after "(c), by redesignating paragraphs (1) and (2) as subparagraphs (A) and (B), respectively, and by adding at the end the following:

"(2) If the patent information described in subsection (b) could not be filed with the submission of an application under subsection (b) because the application was filed before the patent information was required under subsection (b) or a patent was issued after the application was approved under such subsection, the holder of an approved application shall file with the Secretary the patent number and the expiration date of any patent which claims the drug for which the application was submitted or which claims a method of using such drug and with respect to which a claim of patent infringement could reasonably be asserted if a person not licensed by the owner engaged in the manufacture, use, or sale of the drug. If the holder of an approved application could not file patent information under subsection (b) because it was not required at the time the application was approved, the holder shall file such information under this subsection not later than thirty days after the date of the enactment of this sentence, and if the holder of an approved application could not file patent information under subsection (b) because no patent had been issued when one application was filed or approved, the holder shall file such information under this subsection not later than thirty days after the date the patent involved is issued. Upon the submission of patent information under this subsection, the Secretary shall publish it.".

(3)(A) The first sentence of section 505(d) of such Act is amended by redesignating clause (6) as clause (7) and inserting after clause (5) the following: "(6) the application failed to contain the patent information prescribed by subsection (b); or".

(B) The first sentence of section 505(e) of such Act is amended by redesignating clause (4) as clause (5) and inserting after clause (3) the following: "(4) the patent information prescribed by subsection (c) was not filed within thirty days after the receipt of written notice from the Secretary specifying the failure to file such information; or".

(b)(1) Section 505(a) of such Act is amended by inserting "or (j)" after "subsection (b)".

(2) Section 505(c) of such Act is amended by striking out "this subsection" and inserting in lieu thereof "subsection (b)".

(3) The second sentence of section 505(e) of such Act is amended by inserting "submitted under subsection (b) or (j)" after "an application".

(4) The second sentence of section 505(e) is amended by striking out "(j)" each place it occurs in clause (1) and inserting in lieu thereof "(k)".

(5) Section 505(k)(1) of such Act (as so redesignated) is amended by striking out "pursuant to this section" and inserting in lieu thereof "under subsection (b) or (j)".

(6) Subsections (a) and (b) of section 527 of such Act are each amended by striking out "505(b)" each place it occurs and inserting in lieu thereof "505".

SEC. 103. (a) Section 505(b) of such Act is amended by inserting "(1)" after "(b)", by redesignating clauses (1) through (6) as clauses (A) through (F), respectively, and by adding at the end the following:

"(2) An application submitted under paragraph (1) for a drug for which the investigations described in clause (A) of such paragraph and relied upon by the applicant for approval of the application were not conducted by or for the applicant and for which the applicant has not obtained a right of reference or use from the person by or for whom the investigations were conducted shall also include—

"(A) a certification, in the opinion of the applicant and to the best of his knowledge, with respect to each patent which claims the drug for which such investigations were conducted or which claims a use for such drug for which the applicant is seeking approval under this subsection and for which information is required to be filed under paragraph (1) or subsection (c)—

"(i) that such patent information has not been filed.

"(ii) that such patent has expired.

"(iii) of the date on which such patent will expire, or

"(iv) that such patent is invalid or will not be infringed by the manufacture, use, or sale of the new drug for which the application is submitted; and

"(B) if with respect to the drug for which investigations described in paragraph (1)(A) were conducted information was filed under paragraph (1) or subsection (c) for a method of use patent which does not claim a use for which the applicant is seeking approval under this subsection, a statement that the method of use patent does not claim such a use.

"(3)(A) An applicant who makes a certification described in paragraph (2)(A)(iv) shall include in the application a statement that the applicant will give the notice required by subparagraph (B) to—

"(i) each owner of the patent which is the subject of the certification or the representative of such owner designated to receive such notice, and

"(ii) the holder of the approved application under subsection (b) for the drug which is claimed by the patent or a use of which is claimed by the patent or the representative of such holder designated to receive such notice.

"(B) The notice referred to in subparagraph (A) shall state that an application has been submitted under this subsection for the drug with respect to which the certification is made to obtain approval to engage in the commercial manufacture, use, or sale of the drug before the expiration of the patent referred to in the certification. Such notice shall include a detailed statement of the factual and legal basis of the applicant's opinion that the patent is not valid or will not be infringed.

"(C) If an application is amended to include a certification described in paragraph (2)(A)(iv), the notice required by subparagraph (B) shall be given when the amended application is submitted.".

(c) Section 505(c) of such Act (as amended by section 102(a)(2)) is amended by adding at the end the following:

"(3) The approval of an application filed under subsection (b) which contains a certification required by paragraph (2) of such subsection shall be made effective on the last applicable date determined under the following:

"(A) If the applicant only made a certification described in clause (i) or (ii) of subsection (b)(2)(A) or in both such clauses, the approval may be made effective immediately.

"(B) If the applicant made a certification described in clause (iii) of subsection (b)(2)(A), the approval may be made effective on the date certified under clause (iii).

"(C) If the applicant made a certification described in clause (iv) of subsection (b)(2)(A), the approval shall be made effective immediately unless an action is brought for infringement of a patent which is the subject of the certification before the expiration of forty-five days from the date the notice provided under paragraph (3)(B) is received. If such an action is brought before the expiration of such days, the approval may be made effective upon the expiration of the thirty-month period beginning on the date of the receipt of the notice provided under paragraph (3)(B) or such shorter or longer period as the court may order because either party to the action failed to reasonably cooperate in expediting the action, except that—

"(i) if before the expiration of such period the court decides that such patent is invalid or not infringed, the approval may be made effective on the date of the court decision,

"(ii) if before the expiration of such period the court decides that such patent has been infringed, the approval may be made effective on such date as the court orders under section 271(e)(4)(A) of title 35, United States Code, or

"(iii) if before the expiration of such period the court grants a preliminary injunction prohibiting the applicant from engaging in the commercial manufacture or sale of the drug until the court decides the issues of patent validity and infringement and if the court decides that such patent is not invalid or not infringed, the approval shall be made effective on the date of such court decision.

In such an action, each of the parties shall reasonably cooperate in expediting the action. Until the expiration of forty-five days from the date the notice made under paragraph (3)(B) is received, no action may be brought under section 2201 of title 28, United States Code, for a declaratory judgment with respect to the patent. Any action brought under such section 2201 shall be brought in the judicial district where the defendant has its principal place of business or a regular and established place of business.

"(D)(i) If an application (other than an abbreviated new drug application) submitted under subsection (b) for a drug, no active ingredient (including any ester or salt of the active ingredient) of which has been approved in any other application under subsection (b), was approved during the period beginning January 1, 1982, and ending on the date of the enactment of this subsection, the Secretary may not make the approval of another application for a drug for which the investigations described in clause (A) of subsection (b)(1) and relied upon by the applicant for approval of the application were not conducted by or for the applicant and for which the applicant has not obtained a right of reference or use from the person by or for whom the investigations were conducted effective before the expiration of ten years from the date of the approval of the application previously approved under subsection (b).

"(ii) If an application submitted under subsection (b) for a drug, no active ingredient (including any ester or salt of the active ingredient) of which has been approved in any other application under subsection (b), is approved after the date of the enactment of this clause, no application which refers to the drug for which the subsection (b) application was submitted and for which the investigations described in clause (A) of subsection (b)(1) and relied upon by the applicant for approval of the application were not conducted by or for the applicant and for which the applicant has not obtained a right of reference or use from the person by or for whom the investigations were conducted may be submitted under subsection (b) before the expiration of five years from the date of the approval of the application under subsection (b), except that such an application may be submitted under subsection (b) after the expiration of four years from the date of the approval of the subsection (b) application if it contains a certification of patent invalidity or noninfringement described in clause (iv) of subsection (b)(2)(a). The approval of such an application shall be made effective in accordance with this paragraph except that, if an action for patent infringement is commenced during the one-year period beginning forty-eight months after the date of the approval of the subsection (b) application, the thirty-month period referred to in subparagraph (C) shall be extended by such amount of time (if any) which is required for seven and one-half years to have elapsed from the date of approval of the subsection (b) application.

"(iii) If an application submitted under subsection (b) for a drug, which includes an active ingredient (including any ester or salt of the active ingredient) that has been approved in another application approved under subsection (b), is approved after the date of the enactment of this clause and if such application contains reports of new clinical investigations (other than bioavailability studies) essential to the approval of the application and conducted or sponsored by the applicant, the Secretary may not make the approval of an application submitted under subsection (b) for the conditions of approval of such drug in the approved subsection (b) application effective before the expiration of three years from the date of the approval of the application under subsection (b) if the investigations described in clause (A) of subsection (b)(1) and relied upon by the applicant for approval of the application were not conducted by or for the applicant and if the applicant has not obtained a right of reference or use from the person by or for whom the investigations were conducted.

"(iv) If a supplement to an application approved under subsection (b) is approved after the date of enactment of this clause and the supplement contains reports of new clinical investigations (other than bioavailability studies) essential to the approval of the supplement and conducted or sponsored by the person submitting the supplement, the Secretary may not make the approval of an application submitted under subsection

(b) for a change approved in the supplement effective before the expiration of three years from the date of the approval of the supplement under subsection (b) if the investigations described in clause (A) of subsection (b)(1) and relied upon by the applicant for approval of the application were not conducted by or for the applicant and if the applicant has not obtained a right of reference or use from the person by or for whom the investigations were conducted.

"(v) If an application (or supplement to an application) submitted under subsection (b) for a drug, which includes an active ingredient (including any ester or salt of the active ingredient) that has been approved in another application under subsection (b), was approved during the period beginning January 1, 1982, and ending on the date of the enactment of this clause, the Secretary may not make the approval of an application submitted under this subsection and for which the investigations described in clause (A) of subsection (b)(1) and relied upon by the applicant for approval of the application were not conducted by or for the applicant and for which the applicant has not obtained a right of reference or use from the person by or for whom the investigations were conducted and which refers to the drug for which the subsection (b) application was submitted effective before the expiration of two years from the date of enactment of this clause.".

SEC. 104. Section 505 of such Act is amended by adding at the end the following:

"(l) Safety and effectiveness data and information which has been submitted in an application under subsection (b) for a drug and which has not previously been disclosed to the public shall be made available to the public, upon request, unless extraordinary circumstances are shown—

"(1) if no work is being or will be undertaken to have the application approved,

"(2) if the Secretary has determined that the application is not approvable and all legal appeals have been exhausted,

"(3) if approval of the application under subsection (c) is withdrawn and all legal appeals have been exhausted,

"(4) if the Secretary has determined that such drug is not a new drug, or

"(5) upon the effective date of the approval of the first application under subsection (j) which refers to such drug or upon the date upon which the approval of an application under subsection (j) which refers to such drug could be made effective if such an application had been submitted.

"(m) For purposes of this section, the term 'patent' means a patent issued by the Patent and Trademark Office of the Department of Commerce.".

SEC. 105. (a) The Secretary of Health and Human Services shall promulgate, in accordance with the notice and comment requirements of section 553 of title 5, United States Code, such regulations as may be necessary for the administration of section 505 of the Federal Food, Drug, and Cosmetic Act, as amended by sections 101, 102, and 103 of this Act, within one year of the date of enactment of this Act.

(b) During the period beginning sixty days after the date of the enactment of this Act and ending on the date regulations promulgated under subsection (a) take effect, abbreviated new drug applications may be submitted in accordance with the provisions of section 314.2 of title 21 of the Code of Federal Regulations and shall be considered as suitable for any drug which has been approved for safety and effectiveness under section 505(c) of the Federal Food, Drug, and Cosmetic Act before the date of the enactment of this Act. If any such provision is inconsistent with the requirements of section 505(j) of the Federal Food, Drug, and Cosmetic Act, the Secretary shall consider the application under the applicable requirements of such section. The Secretary of Health and Human Services may not approve such an abbreviated new drug application which is filed for a drug which is described in sections 505(c)(3)(D) and 505(j)(4)(D) of the Federal Food, Drug, and Cosmetic Act except in accordance with such section.

SEC. 106. Section 2201 of title 28, United States Code, is amended by inserting "(a)" before "In a case" and by adding at the end the following:

"(b) For limitations on actions brought with respect to drug patents see section 505 of the Federal Food, Drug, and Cosmetic Act.".

TITLE II—PATENT EXTENSION

SEC. 201. (a) Title 35 of the United States Code is amended by adding the following new section immediately after section 155A:

"§ 156. Extension of patent term

"(a) The term of a patent which claims a product, a method of using a product, or a method of manufacturing a product shall be extended in accordance with this section from the original expiration date of the patent if—

"(1) the term of the patent has not expired before an application is submitted under subsection (d) for its extension;

"(2) the term of the patent has never been extended;

"(3) an application for extension is submitted by the owner of record of the patent or its agent and in accordance with the requirement of subsection (d);

"(4) the product has been subject to a regulatory review period before its commercial marketing or use;

"(5)(A) except as provided in subparagraph (B), the permission for the commercial marketing or use of the product after such regulatory review period is the first permitted commercial marketing or use of the product under the provision of law under which such regulatory review period occurred; or

"(B) in the case of a patent which claims a method of manufacturing the product which primarily uses recombinant DNA technology in the manufacture of the product the permission for the commercial marketing or use of the product after such regulatory review period is the first permitted commerical marketing or use of a product manufactured under the process claimed in the patent.

The product referred to in paragraphs (4) and (5) is hereinafter in this section referred to as the 'approved product'.

"(b) The rights derived from any patent the term of which is extended under this section shall during the period during which the patent is extended—

"(1) in the case of a patent which claims a product, be limited to any use approved for the approved product before the expiration of the term of the patent under the provision of law under which the applicable regulatory review occurred;

"(2) in the case of a patent which claims a method of using a product, be limited to any use claimed by the patent and approved for the approved product before the expiration of the term of the patent under the provision of law under which the applicable regulatory review occurred; and

"(3) in the case of a patent which claims a method of manufacturing a product, be limited to the method of manufacturing as used to make the approved product.

"(c) The term of a patent eligible for extension under subsection (a) shall be extended by the time equal to the regulatory review period for the approved product which period occurs after the date the patent is issued, except that—

"(1) each period of the regulatory review period shall be reduced by any period determined under subsection (d)(2)(B) during which the applicant for the patent extension did not act with due diligence during such period of the regulatory review period;

"(2) after any reduction required by paragraph (1), the period of extension shall include only one-half of the time remaining in the periods described in paragraphs (1)(B)(i), (2)(B)(i), and (3)(B)(i) of subsection (g);

"(3) if the period remaining in the term of a patent after the date of the approval of the approved product under the provision of law under which such regulatory review occurred when added to the regulatory review period as revised under paragraph (1) and (2) exceeds fourteen years, the period of extension shall be reduced so that the total of both such periods does not exceed fourteen years; and

"(4) in no event shall more than one patent be extended for the same regulatory review period for any product.

"(d)(1) To obtain an extension of the term of a patent under this section, the owner of record of the patent or its agent shall submit an application to the Commissioner. Such an application may only be submitted within the sixty-day period beginning on the date the product received permission under the provision of law under which the applicable regulatory review period occurred for commercial marketing or use. The application shall contain—

"(A) the identity of the approved product and the Federal statute under which regulatory review occurred;

"(B) the identity of the patent for which an extension is being sought and the identity of each claim of such patent which claims the approved product or a method of using or manufacturing the approved product;

"(C) information to enable the Commissioner to determine under subsections (a) and (b) the eligibility of a patent for extension and the rights that will be derived from the extension and information to enable the Commissioner and the Secretary of Health and Human Services to determine the period of the extension under subsection (g);

"(D) a brief description of the activities undertaken by the applicant during the applicable regulatory review period with respect to the approved product and the significant dates applicable to such activities; and

"(E) such patent or other information as the Commissioner may require.

"(2)(A) Within sixty days of the submittal of an application for extension of the term of a patent under paragraph (1), the Commissioner shall notify the Secretary of Health and Human Services if the patent claims any human drug product, a medical device, or a food additive or color additive or a method of using or manufacturing such a product, device, or additive and if the product, device, and additive are subject to the Federal Food, Drug, and Cosmetic Act, of the extension application and shall submit to the Secretary a copy of the application. Not later than 30 days after the receipt of an application from the Commissioner, the Secretary shall review the dates contained in the application pursuant to paragraph (1)(C) and determine the applicable regulatory review period, shall notify the Commissioner of the determination, and shall pub-

lish in the Federal Register a notice of such determination.

"(B)(i) If a petition is submitted to the Secretary under subparagraph (A), not later than one hundred and eighty days after the publication of the determination under subparagraph (A), upon which it may reasonably be determined that the applicant did not act with due diligence during the applicable regulatory review period, the Secretary shall, in accordance with regulations promulgated by the Secretary determine if the applicant acted with due diligence during the applicable regulatory review period. The Secretary shall make such determination not later than 90 days after the receipt of such a petition. The Secretary may not delegate the authority to make the determination prescribed by this subparagraph to an office below the Office of the Commissioner of Food and Drugs.

"(ii) The Secretary shall notify the Commissioner of the determination and shall publish in the Federal Register a notice of such determination together with the factual and legal basis for such determination. Any interested person may request, within the 60 day period beginning on the publication of a determination, the Secretary to hold an informal hearing on the determination. If such a request is made within such period, the Secretary shall hold such hearing not later than thirty days after the date of the request, or at the request of the person making the request, not later than sixty days after such date. The Secretary shall provide notice of the hearing to the owner of the patent involved and to any interested person and provide the owner and any interested person an opportunity to participate in the hearing. Within thirty days after the completion of the hearing, the Secretary shall affirm or revise the determination which was the subject of the hearing and notify the Commissioner of any revision of the determination and shall publish any such revision in the Federal Register.

"(3) For purposes of paragraph (2)(B), the term 'due diligence' means that degree of attention, continuous directed effort, and timeliness as may reasonably be expected from, and are ordinarily exercised by, person during a regulatory review period.

"(4) An application for the extension of the term of a patent is subject to the disclosure requirements prescribed by the Commissioner.

"(e)(1) A determination that a patent is eligible for extension may be made by the Commissioner solely on the basis of the representations contained in the application for the extension. If the Commissioner determines that a patent is eligible for extension under subsection (a) and that the requirements of subsection (d) have been complied with, the Comissioner shall issue to the applicant for the extension of the term of the patent a certificate of extension, under seal, for the period prescribed by subsection (c). Such certificate shall be recorded in the official file of the patent and shall be considered as part of the original patent.

"(2) If the term of a patent for which an application has been submitted under subsection (d) would expire before a certificate of extension is issued or denied under paragraph (1) respecting the application, the Commissioner shall extend, until such determination is made, the term of the patent for periods of up to one year if he determines that the patent is eligible for extension.

"(f) For purposes for this section:

"(1) The term 'product' means:

"(A) A human drug product.

"(B) Any medical device, food additive, or color additive subject to regulation under the Federal Food, Drug, and Cosmetic Act.

"(2) The term 'human drug product' means the active ingredient of a new drug, antibiotic drug, or human biological product (as those terms are used in the Federal Food, Drug, and Cosmetic Act and the Public Health Service Act) including any salt or ester of the active ingredient, as a single entity or in combination with another active ingredient.

"(3) The term 'major health or environmental effects test' means a test which is reasonably related to the evaluation of the health or environmental effects of a product, which requires at least six months to conduct, and the data from which is submitted to receive permission for commercial marketing or use. Periods of analysis or evaluation of test results are not to be included in determining if the conduct of a test required at least six months.

"(4)(A) Any reference to section 351 is a reference to section 351 of the Public Health Service Act.

"(B) Any reference to section 503, 505, 507, or 515 is a reference to section 503, 505, 507, or 515 of the Federal Food, Drug, and Cosmetic Act.

"(5) The term 'informal hearing' has the meaning prescribed for such term by section 201(y) of the Federal Food, Drug, and Cosmetic Act.

"(6) The term 'patent' means a patent issued by the United States Patent and Trademark Office.

"(g) For purposes of this section, the term 'regulatory review period' has the following meanings:

"(1)(A) In the case of a product which is a human drug product, the term means the period described in subparagraph (B) to which the limitation described in paragraph (4) applies.

"(B) The regulatory review period for a human drug product is the sum of—

"(i) the period beginning on the date an exemption under subsection (i) of section 505 or subsection (d) of section 507 became effective for the approved human drug product and ending on the date an application was initially submitted for such drug product under section 351, 505, or 507, and

"(ii) the period beginning on the date the application was initially submitted for the approved human drug product under section 351, subsection (b) of section 505, or section 507 and ending on the date such application was approved under such section.

"(2)(A) In the case of a product which is a food additive or color additive, the term means the period described in subparagraph (B) to which the limitation described in paragraph (4) applies.

"(B) The regulatory review period for a food or color additive is the sum of—

"(i) the period beginning on the date a major health or environmental effects test on the additive was initiated and ending on the date a petition was initially submitted with respect to the product under the Federal Food, Drug, and Cosmetic Act requesting the issuance of a regulation for use of the product, and

"(ii) the period beginning on the date a petition was initially submitted with respect to the product under the Federal Food, Drug, and Cosmetic Act requesting the issuance of a regulation for use of the product, and ending on the date such regulation became effective or, if objections were filed to such regulation, ending on the date such objections were resolved and commercial marketing was permitted or, if commercial marketing was permitted and later revoked pending further proceedings as a result of such objections, ending on the date such proceedings were finally resolved and commercial marketing was permitted.

"(3)(A) In the case of a product which is a medical device, the term means the period described in subparagraph (B) to which the limitation described in paragraph (4) applies.

"(B) The regulatory review period for a medical device is the sum of—

"(i) the period beginning on the date a clinical investigation on humans involving the device was begun and ending on the date an application was initially submitted with respect to the device under section 515, and

"(ii) the period beginning on the date an application was initially submitted with respect to the device under section 515 and ending on the date such application was approved under such Act or the period beginning on the date a notice of completion of a product development protocol was initially submitted under section 515(f)(5) and ending on the date the protocol was declared completed under section 515(f)(6).

"(4) A period determined under any of the preceding paragraphs is subject to the following limitations:

"(A) If the patent involved was issued after the date of the enactment of this section, the period of extension determined on the basis of the regulatory review period determined under any such paragraph may not exceed five years.

"(B) If the patent involved was issued before the date of the enactment of this section and—

"(i) no request for an exemption described in paragraph (1)(B) was submitted,

"(ii) no major health or environmental effects test described in paragraph (2) was initiated and no petition for a regulation or application for registration described in such paragraph was submitted, or

"(iii) no clinical investigation described in paragraph (3) was begun or product development protocol described in such paragraph was submitted,

before such date for the approved product the period of extension determined on the basis of the regulatory review period determined under any such paragraph may not exceed five years.

"(C) If the patent involved was issued before the date of the enactment of this section and if an action described in subparagraph (B) was taken before the date of the enactment of this section with respect to the approved product and the commercial marketing or use of the product has not been approved before such date, the period of extension determined on the basis of the regulatory review period determined under such paragraph may not exceed two years.

"(h) The Commissioner may establish such fees as the Commissioner determines appropriate to cover the costs to the Office of receiving and acting upon applications under this section.".

(b) The analysis for chapter 14 of title 35 of the United States Code is amended by adding at the end thereof the following:

"156. Extension of patent term.".

SEC. 202. Section 271 of title 35, United States Code is amended by adding at the end the following:

"(e)(1) It shall not be an act of infringement to make, use, or sell, a patented invention (other than a new animal drug or veterinary biological product (as those terms are used in the Federal Food, Drug, and Cosmetic Act and the Act of March 4, 1913)) solely for uses reasonably related to the development and submission of information under a Federal law which regulates the manufacture, use, or sale of drugs.

"(2) It shall be an act of infringement to submit an application under section 505(j) of the Federal Food, Drug, and Cosmetic Act or described in section 505(b)(2) of such Act for a drug claimed in a patent or the use of which is claimed in a patent, if the purpose of such submission is to obtain approval under such Act to engage in the commercial manufacture, use, or sale of a drug claimed in a patent or the use of which is claimed in a patent before the expiration of such patent.

"(3) In any action for patent infringement brought under this section, no injunctive or other relief may be granted which would prohibit the making, using, or selling of a patented invention under paragraph (1).

"(4) For an act of infringement described in paragraph (2)—

"(A) the court shall order the effective date of any approval of the drug involved in the infringement to be a date which is not earlier than the date of the expiration of the patent which has been infringed,

"(B) injunctive relief may be granted against an infringer to prevent the commercial manufacture, use, or sale of an approved drug, and

"(C) damages or other monetary relief may be awarded against and infringer only if there has been commercial manufacture, use, or sale of an approved drug.

The remedies prescribed by subparagraphs (A), (B), and (C) are the only remedies which may be granted by a court for an act of infringement described in paragraph (2), except that a court may award attorney fees under section 285.".

SEC. 203. Section 282 of title 35, United States Code, is amended by adding at the end the following:

"Invalidity of the extension of a patent term or any portion thereof under section 156 of this title because of the material failure—

"(1) by the applicant for the extension, or

"(2) by the Commissioner,

to comply with the requirements of such section shall be a defense in any action involving the infringement of a patent during the period of the extension of its term and shall be pleaded. A due diligence determination under section 156(d)(2) is not subject to review; in such an action.".

TITLE III—AMENDMENTS TO THE TEXTILE FIBER PRODUCTS IDENTIFICATION ACT AND THE WOOL PRODUCTS LABELING ACT OF 1939

SEC. 301. Subsection (b) of section 4 of the Textile Fiber Products Identification Act (15 U.S.C. 70b) is amended by adding at the end thereof the following new paragraph:

"(5) If it is a textile fiber product processed or manufactured in the United States, it be so identified.".

SEC. 302. Subsection (e) of section 4 of the Textile Fiber Products Identification Act (15 U.S.C. 70b) is amended to read as follows:

"(e) For purposes of this Act, in addition to the textile fiber products contained therein, a package of textile fiber products intended for sale to the ultimate consumer shall be misbranded unless such package has affixed to it a stamp, tag, label, or other means of identification bearing the information required by subsection (b), with respect to such contained textile fiber products, or is transparent to the extent it allows for the clear reading of the stamp, tag, label, or other means of identification on the textile fiber product, or in the case of hosiery items, this section shall not be construed as requiring the affixing of a stamp, tag, label, or other means of identification to each hosiery product contained in a package if (1) such hosiery products are intended for sale to the ultimate consumer in such package, (2) such package has affixed to it a stamp, tag, label, or other means of identification bearing, with respect to the hosiery products contained therein, the information required by subsection (b), and (3) the information on the stamp, tag, label, or other means of identification affixed to such package is equally applicable with respect to each textile fiber product contained therein.".

SEC. 303. Section 4 of the Textile Fiber Products Identification Act (15 U.S.C. 70b) is amended by adding at the end thereof the following new subsections:

"(i) For the purposes of this Act, a textile fiber product shall be considered to be falsely or deceptively advertised in any mail order catalog or mail order promotional material which is used in the direct sale or direct offering for sale of such textile fiber product, unless such textile fiber product description states in a clear and conspicuous manner that such textile fiber product is processed or manufactured in the United States of America, or imported, or both.

"(j) For purposes of this Act, any textile fiber product shall be misbranded if a stamp, tag, label, or other identification conforming to the requirements of this section is not on or affixed to the inside center of the neck midway between the shoulder seams or, if such product does not contain a neck, in the most conspicuous place on the inner side of such product, unless it is on or affixed on the outer side of such product, or in the case of hosiery items on the outer side of such product or package.".

SEC. 304. Paragraph (2) of section 4(a) of the Wool Products Labeling Act of 1939 (15 U.S.C. 68(a)(2)) is amended by adding at the end of thereof the following new subparagraph: "(D) the name of the country where processed or manufactured.".

SEC. 305. Section 4 of the Wool Products Labeling Act of 1939 (15 U.S.C. 68b) is amended by adding at the end thereof the following new subsections:

"(e) For the purposes of this Act, a wool product shall be considered to be falsely or deceptively advertised in any mail order promotional material which is used in the direct sale or direct offering for sale of such wool product, unless such wool product description states in a clear and conspicuous manner that such wool product is processed or manufactured in the United States of America, or imported, or both.

"(f) For purposes of this Act, any wool product shall be misbranded if a stamp, tag, label, or other identification conforming to the requirements of this section is not on or affixed to the inside center of the neck midway between the shoulder seams or, if such product does not contain a neck, in the most conspicuous place on the inner side of such product, unless it is on or affixed on the outer side of such product or in the case of hosiery items, on the outer side of such product or package.".

SEC. 306. Section 5 of the Wool Products Labeling Act of 1939 (15 U.S.C. 68c) is amended—

(1) by striking out "Any person" in the first paragraph and inserting in lieu thereof "(a) Any person",

(2) by striking out "Any person" in the second paragraph and inserting in lieu thereof "(b) Any person", and

(3) by inserting after subsection (b) (as designated by this section) the following new subsection:

"(c) For the purposes of subsections (a) and (b) of this section, any package of wool products intended for sale to the ultimate consumer shall also be considered a wool product and shall have affixed to it a stamp, tag, label, or other means of identification bearing the information required by section 4, with respect to the wool products contained therein, unless such package of wool products is transparent to the extent that it allows for the clear reading of the stamp, tag, label, or other means of identification affixed to the wool product, or in the case of hosiery items this section shall not be construed as requiring the affixing of a stamp, tag, label, or other means of identification to each hosiery product contained in a package if (1) such hosiery products are intended for sale to the ultimate consumer in such package, (2) such package has affixed to it a stamp, tag, label, or other means of identification bearing, with respect to the hosiery products contained therein, the information required by subsection (4), and (3) the information on the stamp, tag, label, or other means of identification affixed to such package is equally applicable with respect to each hosiery product contained therein.".

SEC. 307. The amendments made by this title shall be effective ninety days after the date of enactment of this Act.

The motion was agreed to.

The Senate bill was ordered to be read a third time, was read the third time, and passed.

The title of the Senate bill was amended so as to read: "A bill to amend the Federal Drug, and Cosmetic Act to revise the procedures for new drug applications and to amend title 35, United States Code, to authorize the extension of the patents for certain regulated products, and for other purposes."

A motion to reconsider was laid on the table.

A similar House bill (H.R. 3605) was laid on the table.