

106TH CONGRESS
2^D SESSION

H. CON. RES. 420

Providing for corrections in the enrollment of the bill H.R. 4461.

IN THE HOUSE OF REPRESENTATIVES

OCTOBER 10, 2000

Ms. KAPTUR (for herself and Mr. Obey) submitted the following concurrent resolution; which was referred to the Committee on Commerce, and in addition to the Committee on House Administration, for a period to be subsequently determined by the Speaker, in each case for consideration of such provisions as fall within the jurisdiction of the committee concerned

CONCURRENT RESOLUTION

Providing for corrections in the enrollment of the bill H.R.
4461.

1 *Resolved by the House of Representatives (the Senate*
2 *concurring)*, That, in the enrollment of the bill (H.R.
3 4461) making appropriations for Agriculture, Rural De-
4 velopment, Food and Drug Administration, and Related
5 Agencies programs for the fiscal year ending September
6 30, 2001, and for other purposes, the Clerk of the House
7 shall strike section 745 and insert the following:

1 SEC. 745. (a) SHORT TITLE.—This section may be
2 cited as the “Medicine Equity and Drug Safety Act of
3 2000”.

4 (b) FINDINGS.—Congress makes the following find-
5 ings:

6 (1) The cost of prescription drugs for Ameri-
7 cans continues to rise at an alarming rate.

8 (2) Millions of Americans, including medicare
9 beneficiaries on fixed incomes, face a daily choice be-
10 tween purchasing life-sustaining prescription drugs,
11 or paying for other necessities, such as food and
12 housing.

13 (3) Many life-saving prescription drugs are
14 available in countries other than the United States
15 at substantially lower prices, even though such drugs
16 were developed and are approved for use by patients
17 in the United States.

18 (4) Many Americans travel to other countries to
19 purchase prescription drugs because the medicines
20 that they need are unaffordable in the United
21 States.

22 (5) Americans should be able to purchase medi-
23 cines at prices that are comparable to prices for
24 such medicines in other countries, but efforts to en-
25 able such purchases should not endanger the gold

1 standard for safety and effectiveness that has been
2 established and maintained in the United States.

3 (c) IMPORTS AND EXPORTS.—Chapter VIII of the
4 Federal Food, Drug, and Cosmetic Act (21 U.S.C. 381
5 et seq.) is amended—

6 (1) in section 801(d)(1), by inserting “and sec-
7 tion 804” after “paragraph (2)”; and

8 (2) by adding at the end the following:

9 **“SEC. 804. IMPORTATION OF COVERED PRODUCTS.**

10 “(a) REGULATIONS.—

11 “(1) IN GENERAL.—The Secretary, after con-
12 sultation with the United States Trade Representa-
13 tive and the Commissioner of Customs, shall promul-
14 gate regulations permitting a pharmacist or whole-
15 saler to import into the United States covered prod-
16 ucts. Such regulations shall be promulgated as expe-
17 ditiously as possible, but in no case later than two
18 years after the date of the enactment of the Medi-
19 cine Equity and Drug Safety Act of 2000.

20 “(2) LIMITATION.—Regulations promulgated
21 under paragraph (1) shall—

22 “(A) require that safeguards are in place
23 that provide a reasonable assurance to the Sec-
24 retary that each covered product that is im-
25 ported is safe and effective for its intended use;

1 “(B) require that the pharmacist or whole-
2 saler importing a covered product complies with
3 the provisions of paragraph (3); and

4 “(C) contain such additional safeguards as
5 the Secretary may specify in order to ensure
6 the protection of the public health of patients in
7 the United States or to facilitate the importa-
8 tion of covered products.

9 “(3) INFORMATION AND RECORDS.—Regula-
10 tions promulgated under paragraph (1) shall require
11 such pharmacist or wholesaler to provide informa-
12 tion and records to the Secretary, including—

13 “(A) the name and amount of the active
14 ingredient of the product and description of the
15 dosage form;

16 “(B) the date that such product is shipped
17 and the quantity of such product that is
18 shipped, the point of origin and the United
19 States consignee of such product, and the price
20 paid for such product;

21 “(C) documentation from the foreign seller
22 specifying the original source of the product
23 and the amount of each lot of the product origi-
24 nally received;

1 “(D) the manufacturer’s lot or control
2 number of the product imported;

3 “(E) the name, address, and telephone
4 number of the importer and consignee, includ-
5 ing the professional license number of the im-
6 porter, if the importer is a pharmacist or phar-
7 maceutical wholesaler;

8 “(F) for a product that is—

9 “(i) coming from the first foreign re-
10 cipient of the product who received such
11 product from the manufacturer—

12 “(I) documentation dem-
13 onstrating that such product came
14 from such recipient and was received
15 by such recipient from such manufac-
16 turer;

17 “(II) documentation of the
18 amount of each lot of the product re-
19 ceived by such recipient to dem-
20 onstrate that the amount being im-
21 ported into the United States is not
22 more than the amount that was re-
23 ceived by such recipient;

24 “(III) documentation dem-
25 onstrating that a statistically valid

1 sample of each lot of the initial im-
2 ported shipment was tested at an ap-
3 propriate Food and Drug Administra-
4 tion approved United States labora-
5 tory for authenticity and degradation
6 by the importer or manufacturer of
7 such product;

8 “(IV) documentation dem-
9 onstrating that a statistically valid
10 sample of all subsequent shipments
11 from such recipient was tested at an
12 appropriate Food and Drug Adminis-
13 tration approved United States lab-
14 oratory for authenticity and degrada-
15 tion by the importer or manufacturer
16 of such product; and

17 “(V) certification from the im-
18 porter or manufacturer of such prod-
19 uct that the product is approved for
20 marketing in the United States and
21 meets all labeling requirements under
22 this Act; and

23 “(ii) not coming from the first foreign
24 recipient of the product, documentation
25 demonstrating that a statistically valid

1 sample of each lot was tested for authen-
2 ticity and degradation at an appropriate
3 Food and Drug Administration approved
4 United States laboratory by the importer
5 or manufacturer of such product, and
6 meets all labeling requirements under this
7 Act;

8 “(G) complete data derived from all tests
9 necessary to assure that the product is in com-
10 pliance with established specifications and
11 standards, including laboratory records; and

12 “(H) any other information that the Sec-
13 retary determines is necessary to ensure the
14 protection of the public health of patients in the
15 United States.

16 “(4) RECORDS MAINTAINED BY SECRETARY.—
17 Records described in paragraph (3) shall be main-
18 tained by the Secretary for a period of time deter-
19 mined to be necessary by the Secretary.

20 “(5) RECORDS MAINTAINED BY IMPORTER.—
21 The pharmacist or wholesaler who imports a covered
22 product as described in paragraph (1) shall maintain
23 records documenting the resale price for such prod-
24 uct for a period of time specified by the Secretary.

1 Such records shall be provided upon request to fa-
2 cilitate the studies under this section.

3 “(b) TESTING.—

4 “(1) IN GENERAL.—Testing referred to in sub-
5 paragraphs (F) and (G) of subsection (a)(3) may be
6 conducted by the pharmacist or wholesaler who is
7 importing such product, or by the manufacturer of
8 the product, in a Food and Drug Administration ap-
9 proved laboratory. Such testing may also be con-
10 ducted by an independent laboratory under contract
11 with such pharmacist, wholesaler, or manufacturer.

12 “(2) AUTHENTICATION.—

13 “(A) IN GENERAL.—In conducting tests
14 under paragraph (1), the manufacturer of such
15 product shall provide to the pharmacist or
16 wholesaler, information—

17 “(i) to authenticate such product and
18 confirm that the labeling of such product
19 complies with labeling requirements under
20 this Act; and

21 “(ii) to indicate if such product is eli-
22 gible for importation under this section.

23 “(B) CONFIDENTIALITY.—Information
24 supplied under subparagraph (A) and sub-
25 section (a)(3)(A) shall not be disclosed for any

1 purpose not authorized by this section. Any per-
2 son who knowingly and willingly discloses such
3 information for purposes not authorized by this
4 section shall be imprisoned for a period not to
5 exceed 18 months, fined in accordance with title
6 18, United States Code, or both.

7 “(3) DISCRETION.—The Secretary may waive
8 or modify testing requirements described under sub-
9 section (a)(3) if agreements have been entered into
10 by the Secretary that ensure the safety and effec-
11 tiveness of the product imported from a specific
12 country, or through a specific distribution chain cer-
13 tified by the Secretary.

14 “(c) APPROVED LABELING.—The manufacturer of a
15 covered product shall provide to the importer involved
16 written authorization for the importer to use at no cost
17 the approved labeling for such product.

18 “(d) NON-DISCRIMINATION.—No manufacturer of a
19 covered product may take actions that discriminate
20 against, or cause other persons to discriminate against,
21 United States pharmacists or wholesalers regarding the
22 sale or distribution of covered products.

23 “(e) STUDY AND REPORT.—

24 “(1) STUDY.—The General Accounting Office
25 shall conduct a study on the imports permitted

1 under this section, taking into consideration the in-
2 formation received under subsection (a). In con-
3 ducting such study, the Office shall—

4 “(A) evaluate importer’s compliance with
5 regulations, determine the number of ship-
6 ments, if any, permitted under this section that
7 have been determined to be counterfeit, mis-
8 branded, or adulterated; and

9 “(B) consult with the United States Trade
10 Representative and United States Patent and
11 Trademark Office to evaluate the effect of im-
12 portations permitted under this Act on trade
13 and patent rights under Federal law.

14 “(2) REPORT.—Not later than 5 years after the
15 effective date of final regulations issued pursuant to
16 this section, the General Accounting Office shall pre-
17 pare and submit to Congress a report containing the
18 study described in paragraph (1).

19 “(f) CONSTRUCTION.—Nothing in this section shall
20 be construed to limit the statutory, regulatory, or enforce-
21 ment authority of the Secretary relating to importation
22 of covered products, other than the importation described
23 in subsection (a).

24 “(g) DEFINITIONS.—In this section:

25 “(1) COVERED PRODUCT.—

1 “(A) IN GENERAL.—The term ‘covered
2 product’ means a prescription drug product
3 under section 503(b)(1) that meets the applica-
4 ble requirements of section 505, and is ap-
5 proved by the Food and Drug Administration
6 and manufactured in a facility identified in the
7 approved application and is not adulterated
8 under section 501 or misbranded under section
9 502.

10 “(B) CHARITABLE CONTRIBUTIONS; PAR-
11 ENTERAL DRUGS.—Notwithstanding any other
12 provision of this section, section 801(d)(1)—

13 “(i) continues to apply to a covered
14 product donated at no cost by the manu-
15 facturer of the drug to a charitable or hu-
16 manitarian organization, including the
17 United Nations and affiliates, or to a gov-
18 ernment of a foreign country; and

19 “(ii) continues to apply to a covered
20 product that is a parenteral drug the im-
21 portation of which pursuant to subsection
22 (a) is determined by the Secretary to pose
23 a threat to the public health.

24 “(2) PHARMACIST.—The term ‘pharmacist’
25 means a person licensed to practice pharmacy under

1 State law, including the dispensing and selling of
2 prescription drugs, or an entity licensed or otherwise
3 authorized as a pharmacy under State law.

4 “(3) WHOLESALER.—The term ‘wholesaler’
5 means a person licensed as a wholesaler or dis-
6 tributor of prescription drug products in the United
7 States pursuant to section 503(e)(2)(A).

8 “(4) DISCRIMINATION.—The term ‘discrimina-
9 tion’ includes with respect to United States phar-
10 macists or wholesalers a contract provision, a limita-
11 tion on supply, or other measure which has the ef-
12 fect of providing U.S. pharmacists or wholesalers ac-
13 cess to covered products on terms or conditions that
14 are less favorable than the terms or conditions pro-
15 vided to any foreign purchaser (other than a chari-
16 table purchaser) of such products, or otherwise has
17 the effect of restricting the access of United States
18 pharmacists or wholesalers to prescription drugs
19 that can be imported into the United States under
20 this section.

21 “(h) FUNDING.—For the purpose of carrying out this
22 section—

23 “(1) there is hereby appropriated, out of any
24 money in the Treasury not otherwise appropriated,
25 \$23,000,000 for fiscal year 2001; and

1 “(2) there are authorized to be appropriated for
2 fiscal year 2002 and each subsequent fiscal year
3 such sums as may be necessary.

4 “(i) CONDITIONS.—Regulations promulgated under
5 subsection (a)(1) shall become effective only if the Sec-
6 retary certifies to the Congress that the implementation
7 of this section will pose no greater risk to the public’s
8 health and safety than would otherwise apply.”.

9 (d) PROHIBITED ACT.—

10 (1) IN GENERAL.—Section 301 of the Federal
11 Food, Drug, and Cosmetic Act (21 U.S.C. 331) is
12 amended by adding at the end the following:

13 “(aa) The importation of a covered product in viola-
14 tion of section 804, the falsification of any record required
15 to be maintained or provided to the Secretary under such
16 section, or any other violation of requirements under such
17 section.”.

18 (2) ENHANCED PENALTIES.—Section 303(b) of
19 the Federal Food, Drug, and Cosmetic Act (21
20 U.S.C. 333(b)) is amended by adding at the end the
21 following:

22 “(6) Notwithstanding subsection (a), any person who
23 is a manufacturer or importer of a covered product pursu-
24 ant to section 804(a) and knowingly fails to comply with
25 a requirement of subsection (b), (c), or (d) of section 804

1 that is applicable to such manufacturer or importer, re-
2 spectively, shall be imprisoned for not more than 10 years
3 or fined not more than \$1,000,000, or both.”.

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