

108TH CONGRESS
1ST SESSION

H. R. 608

To provide for prices of pharmaceutical products that are fair to the producer and the consumer, and for other purposes.

IN THE HOUSE OF REPRESENTATIVES

FEBRUARY 5, 2003

Mr. OWENS introduced the following bill; which was referred to the Committee on Energy and Commerce, and in addition to the Committee on the Judiciary, 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

A BILL

To provide for prices of pharmaceutical products that are fair to the producer and the consumer, and for other purposes.

1 *Be it enacted by the Senate and House of Representa-*
2 *tives of the United States of America in Congress assembled,*

3 **SECTION 1. SHORT TITLE.**

4 This Act may be cited as the “Pharmaceutical Prod-
5 ucts Price Equity Act”.

6 **SEC. 2. FINDINGS.**

7 The Congress finds the following:

1 (1) Modern life enhancing and life sustaining
2 drugs are the products of decades of scientific re-
3 search and practice.

4 (2) The refining and production of products by
5 American pharmaceutical enterprises must be appro-
6 priately compensated.

7 (3) The pricing of American pharmaceutical
8 products varies greatly from country to country with
9 the corporate owners of such products voluntarily
10 assuming no losses by always selling their products
11 above the cost of production.

12 (4) Considering the vital life and death nature
13 of pharmaceutical products, it is appropriate that
14 the United States Government, in harmony with
15 other nations belonging to the World Trade Organi-
16 zation, should engage in the reasonable regulation of
17 the prices of pharmaceutical products.

18 **SEC. 3. REASONABLE LIMITS ON PROFITS OF PHARMA-**
19 **CEUTICAL PRODUCTS.**

20 (a) **PRESIDENTIAL AUTHORITY.**—The President
21 shall issue such orders and regulations, and establish such
22 procedures and reporting requirements, as the President
23 determines to be appropriate to ensure that no pharma-
24 ceutical product (as defined by the President in such regu-
25 lation or order) is sold to any consumer in the United

1 States at a price that is more than 6 percent above the
2 average retail price at which such pharmaceutical product
3 is sold in the 5 most industrialized, free-market countries,
4 other than the United States, as determined by the Presi-
5 dent.

6 (b) DELEGATION.—The President may delegate the
7 performance of any function under this section to any offi-
8 cer of any Federal department or agency who has been
9 appointed by the President, by and with the consent of
10 the Senate.

11 (c) CONFIDENTIALITY OF INFORMATION.—All infor-
12 mation reported to or otherwise obtained by any person
13 exercising any authority under this section which contains
14 or relates to a trade secret or other matter referred to
15 in section 1905 of title 18, United States Code, shall be
16 considered confidential for purposes of that section, except
17 that such information may be disclosed to any other offi-
18 cer or employee of the United States involved in carrying
19 out this section solely for the purpose of carrying out, and
20 enforcing compliance with, this section.

21 (d) SUBPOENA POWER AND PRODUCTION OF DOCU-
22 MENTS.—

23 (1) IN GENERAL.—The officer of any agency or
24 department to whom the President has delegated
25 any authority under this section, may—

1 (A) examine any books, papers, records, or
2 other data of any person which is relevant to
3 the enforcement of this section or to any rec-
4 ordkeeping or reporting requirement prescribed
5 for the purpose of carrying out this section; and

6 (B) summon any person, an officer or em-
7 ployee of any person (including a former officer
8 or employee), or any person having possession,
9 custody, or care of the reports and records re-
10 quired to be made or maintained pursuant to
11 this section, to appear at a time and place
12 named in the summons and to produce such
13 books, papers, records, or other data, and to
14 give testimony, under oath, as may be relevant
15 or material to an investigation or procedure
16 under this section.

17 (2) ADMINISTRATIVE ASPECTS OF SUMMONS.—

18 (A) PRODUCTION AT DESIGNATED SITE.—

19 A summons issued pursuant to this section may
20 require that books, papers, records, or other
21 data stored or maintained at any place be pro-
22 duced at any designated location in any State
23 or in any territory or other place subject to the
24 jurisdiction of the United States not more than
25 500 miles distant from any place where the per-

1 son summoned operates or conducts business in
2 the United States.

3 (B) FEES AND TRAVEL EXPENSES.—Per-
4 sons summoned under this section shall be paid
5 the same fees and mileage for travel in the
6 United States that are paid witnesses in the
7 courts of the United States.

8 (C) NO LIABILITY FOR EXPENSES.—The
9 United States shall not be liable for any ex-
10 pense, other than an expense described in sub-
11 paragraph (B), incurred in connection with the
12 production of books, papers, records, or other
13 data under this section.

14 (3) SERVICE OF SUMMONS.—Service of a sum-
15 mons issued under this section may be by registered
16 mail or in such other manner calculated to give ac-
17 tual notice as the officer delegated by the President
18 may prescribe by regulation.

19 (4) CONTUMACY OR REFUSAL.—

20 (A) REFERRAL TO ATTORNEY GENERAL.—
21 In case of contumacy by a person issued a sum-
22 mons under this subsection or a refusal by such
23 person to obey such summons, the officer
24 issuing the summons shall refer the matter to
25 the Attorney General.

1 (B) JURISDICTION OF COURT.—The Attor-
2 ney General may invoke the aid of any court of
3 the United States within the jurisdiction of
4 which—

5 (i) the investigation which gave rise to
6 the summons is being or has been carried
7 on;

8 (ii) the person summoned is an inhab-
9 itant; or

10 (iii) the person summoned carries on
11 business or may be found,

12 to compel compliance with the summons.

13 (C) COURT ORDER.—The court may issue
14 an order requiring the person summoned to ap-
15 pear before the Secretary or his delegate to
16 produce books, papers, records, and other data,
17 to give testimony as may be necessary to ex-
18 plain how such material was compiled and
19 maintained, and to pay the costs of the pro-
20 ceeding.

21 (D) FAILURE TO COMPLY WITH ORDER.—
22 Any failure to obey the order of the court may
23 be punished by the court as a contempt thereof.

24 (E) SERVICE OF PROCESS.—All process in
25 any case under this subsection may be served in

1 any judicial district in which such person may
2 be found.

3 **SEC. 4. ENFORCEMENT.**

4 (a) INJUNCTIONS AND OTHER RELIEF.—

5 (1) IN GENERAL.—Whenever it appears to the
6 officer authorized by the President to exercise au-
7 thority under this Act, that any person has engaged,
8 is engaged, or is about to engage in any act or prac-
9 tice that constitutes a violation of any regulation or
10 order prescribed or issued pursuant to section 3, the
11 officer may request the Attorney General to bring an
12 action in an appropriate district court of the United
13 States to enjoin such act or practice.

14 (2) REMEDIES.—Upon a proper showing in any
15 action under paragraph (1), the court—

16 (A) shall issue a temporary restraining
17 order or grant a preliminary or permanent in-
18 junction without bond;

19 (B) may also issue a mandatory injunction
20 commanding any person to comply with any
21 order or injunction issued or granted under
22 subparagraph (A); and

23 (C) may order restitution of moneys re-
24 ceived in violation of any regulation prescribed

1 or order issued under section 3 or any order
2 issued or injunction granted under this section.

3 (b) PENALTIES.—

4 (1) CRIMINAL.—Whoever knowingly violates
5 any regulation prescribed or order issued under sec-
6 tion 3 shall be fined not more than the amount
7 equal to 200 percent of the amount of the sale re-
8 lated to each violation.

9 (2) CIVIL.—

10 (A) IN GENERAL.—Whoever violates any
11 regulation prescribed or order issued under sec-
12 tion 3 shall be liable to the United States for
13 a civil penalty of not more than 200 percent of
14 the amount by which such person was unjustly
15 enriched in connection with such violation.

16 (B) CONTINUING VIOLATIONS.—A separate
17 violation occurs for each sale of a pharma-
18 ceutical product in violation of a regulation pre-
19 scribed or order issued under section 3.

20 (C) ASSESSMENT.—

21 (i) WRITTEN NOTICE.—Any penalty
22 imposed under subparagraph (A) may be
23 assessed and collected by the officer au-
24 thorized by the President to exercise au-
25 thority under this Act by written notice.

1 (ii) FINALITY OF ASSESSMENT.—If,
2 with respect to any assessment under
3 clause (i), a hearing is not requested pur-
4 suant to subparagraph (F) within the pe-
5 riod of time allowed under such subpara-
6 graph, the assessment shall constitute a
7 final and unappealable order.

8 (D) AUTHORITY TO MODIFY OR REMIT
9 PENALTY.—Any officer authorized by the Presi-
10 dent to exercise authority under this Act may
11 compromise, modify, or remit any penalty which
12 such officer may assess or had already assessed
13 under subparagraph (A).

14 (E) MITIGATING FACTORS.—In deter-
15 mining the amount of any penalty imposed
16 under subparagraph (A), the officer authorized
17 by the President to exercise authority under
18 this Act shall take into account the appropriate-
19 ness of the penalty with respect to—

20 (i) the size of financial resources and
21 good faith of the person charged;

22 (ii) the gravity of the violation;

23 (iii) the history of previous violations;

24 and

1 (iv) such other matters as justice may
2 require.

3 (F) HEARING.—The person against whom
4 any penalty is assessed under this paragraph
5 shall be afforded an agency hearing if such per-
6 son submits a request for such hearing within
7 20 days after the issuance of the notice of as-
8 sessment.

9 (G) COLLECTION.—

10 (i) REFERRAL.—If any person fails to
11 pay an assessment after any penalty as-
12 sessed under this paragraph has become
13 final, the officer who imposed the penalty
14 shall recover the amount assessed by ac-
15 tion in the appropriate United States dis-
16 trict court.

17 (ii) APPROPRIATENESS OF PENALTY
18 NOT REVIEWABLE.—In any civil action
19 under clause (i), the validity and appro-
20 priateness of the penalty shall not be sub-
21 ject to review.

22 (H) DISBURSEMENT.—All penalties col-
23 lected under authority of this paragraph shall
24 be deposited into the Treasury.

1 (I) REGULATIONS.—Any officer authorized
2 by the President to exercise authority under
3 this Act shall prescribe regulations establishing
4 such procedures as may be necessary to carry
5 out this paragraph.

6 **SEC. 5. CIVIL LIABILITY.**

7 (a) LIABILITY ESTABLISHED.—Any person who vio-
8 lates any regulation prescribed or order issued under this
9 Act with respect to any other person shall be liable to such
10 person in an amount equal to the sum of the amounts
11 determined under each of the following paragraphs:

12 (1) ACTUAL DAMAGES.—The greater of—

13 (A) the amount of any actual damage sus-
14 tained by such person as a result of such fail-
15 ure; or

16 (B) any amount paid by the injured person
17 to the violator.

18 (2) PUNITIVE DAMAGES.—

19 (A) INDIVIDUAL ACTIONS.—In the case of
20 any action by an individual, such additional
21 amount as the court may allow.

22 (B) CLASS ACTIONS.—In the case of a
23 class action, the sum of—

1 (i) the aggregate of the amount which
2 the court may allow for each named plain-
3 tiff; and

4 (ii) the aggregate of the amount
5 which the court may allow for each other
6 class member, without regard to any min-
7 imum individual recovery.

8 (3) ATTORNEYS' FEES.—In the case of any suc-
9 cessful action to enforce any liability under para-
10 graph (1) or (2), the costs of the action, together
11 with reasonable attorneys' fees.

12 (b) FACTORS TO BE CONSIDERED IN AWARDING PU-
13 NITIVE DAMAGES.—In determining the amount of any li-
14 ability of any person under section (a), the court shall con-
15 sider, among other relevant factors—

16 (1) the frequency and persistence of noncompli-
17 ance by the violator;

18 (2) the nature of the noncompliance;

19 (3) the extent to which such noncompliance was
20 intentional; and

21 (4) in the case of any class action, the number
22 of consumers adversely affected.

1 **SEC. 6. AUTHORIZATION OF APPROPRIATIONS.**

2 There are authorized to be appropriated to the Presi-
3 dent for fiscal years 2003, 2004, and 2005, such sums
4 as may be necessary to carry out this Act.

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