107TH CONGRESS 1ST SESSION

H. R. 1574

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

April 24, 2001

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.
 - (2) The refining and production of products by American pharmaceutical enterprises must be appropriately compensated.
 - (3) The pricing of American pharmaceutical products varies greatly from country to country with the corporate owners of such products voluntarily assuming no losses by always selling their products 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 PHARMA19 CEUTICAL PRODUCTS.

20 (a) President Authority.—The President shall issue such orders and regulations, and establish such procedures and reporting requirements, as the President determines to be appropriate to ensure that no pharma-ceutical product (as defined by the President in such regulation or order) is sold to any consumer in the United

5

6

7

8

9

10

- 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
- department to whom the President has delegated
- 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

(B) summon any person, an officer or employee of any person (including a former officer or employee), or any person having possession, custody, or care of the reports and records required to be made or maintained pursuant to this section, to appear at a time and place named in the summons and to produce such books, papers, records, or other data, and to give testimony, under oath, as may be relevant or material to an investigation or procedure under this section.

(2) Administrative aspects of summons.—

(A) Production at designated site.—
A summons issued pursuant to this section may require that books, papers, records, or other data stored or maintained at any place be produced at any designated location in any State or in any territory or other place subject to the jurisdiction of the United States not more than 500 miles distant from any place where the per-

- son summoned operates or conducts business in the United States.
 - (B) FEES AND TRAVEL EXPENSES.—Persons summoned under this section shall be paid the same fees and mileage for travel in the United States that are paid witnesses in the courts of the United States.
 - (C) NO LIABILITY FOR EXPENSES.—The United States shall not be liable for any expense, other than an expense described in subparagraph (B), incurred in connection with the production of books, papers, records, or other data under this section.
 - (3) SERVICE OF SUMMONS.—Service of a summons issued under this section may be by registered mail or in such other manner calculated to give actual notice as the officer delegated by the President may prescribe by regulation.

(4) Contumacy or refusal.—

(A) Referral to attorney general.—
In case of contumacy by a person issued a summons under this subsection or a refusal by such person to obey such summons, the officer issuing the summons shall refer the matter to 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 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.— (A) IN GENERAL.—Whoever violates any 10 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-

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 2002, 2003, and 2004, such sums

4 as may be necessary to carry out this Act.

 \bigcirc