

109TH CONGRESS
2D SESSION

H. R. 4769

To amend the Federal Food, Drug, and Cosmetic Act, the Controlled Substances Import and Export Act, and the Public Health Service Act to impose requirements respecting Internet pharmacies, to require manufacturers to implement chain-of-custody procedures, to restrict an exemption respecting the importation of controlled substances for personal use, and for other purposes.

IN THE HOUSE OF REPRESENTATIVES

FEBRUARY 16, 2006

Mr. NORWOOD (for himself and Mr. STRICKLAND) introduced the following bill; which was referred to the Committee on Energy and Commerce

A BILL

To amend the Federal Food, Drug, and Cosmetic Act, the Controlled Substances Import and Export Act, and the Public Health Service Act to impose requirements respecting Internet pharmacies, to require manufacturers to implement chain-of-custody procedures, to restrict an exemption respecting the importation of controlled substances for personal use, 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,*

1 **SECTION 1. SHORT TITLE.**

2 This Act may be cited as the “Prescription Drug
3 Abuse Elimination Act of 2006”.

4 **SEC. 2. INTERNET PHARMACIES.**

5 (a) IN GENERAL.—Chapter V of the Federal Food,
6 Drug, and Cosmetic Act (21 U.S.C. 351 et seq.) is amend-
7 ed by inserting after section 503A the following:

8 **“SEC. 503B. INTERNET SALE OF PRESCRIPTION DRUGS.**

9 “(a) IN GENERAL.—

10 “(1) PROHIBITIONS.—Subject to paragraph (2),
11 it is a violation of this section—

12 “(A) for any person to sell a prescription
13 drug in interstate commerce through an Inter-
14 net site—

15 “(i) if the Internet site is an illegal
16 Internet pharmacy under subsection (b);
17 “(ii) if the person fails to comply with
18 the treating provider verification require-
19 ments of subsection (c); or

20 “(iii) if the person fails to submit the
21 notices required by subsection (d); or

22 “(B) for any person to own or operate an
23 illegal Internet pharmacy in interstate com-
24 merce.

25 “(2) EXCEPTION.—Any person who sells a pre-
26 scription drug through an Internet site, or who owns

1 or operates an Internet pharmacy, is deemed to meet
2 the requirements of this section for purposes of such
3 sale, ownership, or operation if the Internet site or
4 Internet pharmacy is certified by the National Asso-
5 ciation of Boards of Pharmacy's Verified Internet
6 Pharmacy Practice Sites program.

7 “(b) INTERNET PHARMACY REQUIREMENTS.—

8 “(1) IN GENERAL.—For purposes of this sec-
9 tion:

10 “(A) The term ‘Internet pharmacy’ means
11 an Internet site, inside or outside the State in-
12 volved, that—

13 “(i) is used or attempted to be used
14 to communicate with, or obtain informa-
15 tion from, a person for the purpose of fill-
16 ing or refilling a prescription; or

17 “(ii) is otherwise used in the practice
18 of pharmacy, including dispensing, distrib-
19 uting or delivery of, or aiding in the deliv-
20 ery of, a prescription drug to a person.

21 “(B) The term ‘illegal Internet pharmacy’
22 means an Internet pharmacy that fails to com-
23 ply with this subsection.

1 “(2) REQUIREMENTS.—An Internet pharmacy
2 shall provide to any individual who accesses the
3 pharmacy the following information:

4 “(A) The street address and telephone
5 number of—

6 “(i) the Internet pharmacy’s place of
7 business; and

8 “(ii) the Internet pharmacy’s super-
9 vising pharmacist.

10 “(B) All States in which the Internet phar-
11 macy is licensed or otherwise authorized to dis-
12 pense prescription drugs.

13 “(C) If the Internet pharmacy makes re-
14 ferrals to, or solicits on behalf of, a practitioner
15 or a group of practitioners for prescription serv-
16 ices—

17 “(i) the name, street address, and
18 telephone number of such practitioner or
19 group; and

20 “(ii) each State in which each practi-
21 tioner involved is licensed or otherwise au-
22 thorized to prescribe drugs.

23 “(D) A statement that the Internet phar-
24 macy will dispense prescription drugs only upon
25 a showing of a prescription.

1 “(c) TREATING PROVIDER VERIFICATION REQUIRE-
2 MENTS.—The treating provider verification requirements
3 of this subsection are as follows:

4 “(1) IN GENERAL.—Subject to paragraph (2), a
5 person may sell a prescription drug in interstate
6 commerce through an Internet site only if—

7 “(A) the sale is in accordance with a pre-
8 scription of the treating provider of the patient
9 involved;

10 “(B) the seller verifies the prescription in
11 accordance with paragraph (3);

12 “(C) the seller maintains a record of direct
13 communications in accordance with paragraph
14 (4); and

15 “(D) the seller complies with the prohibi-
16 tion of paragraph (5) against alteration of the
17 prescription.

18 “(2) LIMITATION.—The treating provider
19 verification requirements of this subsection apply
20 with respect to a prescription drug only if—

21 “(A) the prescription drug is included in
22 schedule II, III, or IV of section 202(c) of the
23 Controlled Substances Act; or

24 “(B) the Secretary for purposes of this
25 section identifies the prescription drug as po-

1 tentially subject to abuse, diversion, and mis-
2 use.

3 “(3) VERIFICATION REQUIREMENT.—

4 “(A) REQUIREMENT.—A seller verifies a
5 prescription in accordance with this paragraph
6 if—

7 “(i) the patient involved or the pa-
8 tient’s treating provider presents the pre-
9 scription, directly or by facsimile or elec-
10 tronic mail, to the seller; or

11 “(ii) the seller verifies the prescription
12 by direct communication with the treating
13 provider involved.

14 “(B) INFORMATION.—When seeking
15 verification of a prescription under subpara-
16 graph (A)(ii), a seller shall provide to the treat-
17 ing provider the following information:

18 “(i) Patient’s full name and address.

19 “(ii) Identification of the drug by a
20 national drug code number.

21 “(iii) Quantity to be dispensed.

22 “(iv) Date of patient request.

23 “(v) Date and time of verification re-
24 quest.

1 “(vi) Name of contact person at sell-
2 er’s company, including facsimile and tele-
3 phone number.

4 “(C) VERIFICATION EVENTS.—A prescrip-
5 tion is verified under subparagraph (A)(ii) only
6 if one of the following occurs:

7 “(i) The treating provider confirms
8 the prescription is accurate by direct com-
9 munication with the seller.

10 “(ii) The treating provider informs
11 the seller that the prescription is inac-
12 curate and provides the accurate prescrip-
13 tion.

14 “(iii) The treating provider fails to
15 communicate with the seller within 48
16 hours, or a similar time as defined by the
17 Commissioner of Food and Drugs, after
18 receiving from the seller the information
19 described in subparagraph (B).

20 “(D) INVALID PRESCRIPTION.—If a treat-
21 ing provider informs a seller before the deadline
22 under subparagraph (C)(iii) that the prescrip-
23 tion is inaccurate or expired, the seller shall not
24 fill the prescription. The treating provider shall
25 specify the basis for the inaccuracy or invalidity

1 of the prescription. If the prescription commu-
2 nicated by the seller to the treating provider is
3 inaccurate, the treating provider shall correct it.

4 “(4) RECORD REQUIREMENT.—A seller shall
5 maintain for at least 2 years a record of all direct
6 communications with a treating provider regarding
7 the sale of a prescription drug, including verification
8 of the prescription involved.

9 “(5) NO ALTERATION.—

10 “(A) IN GENERAL.—A seller may not alter
11 a prescription for a prescription drug.

12 “(B) EXCEPTIONS.—Notwithstanding sub-
13 paragraph (A)—

14 “(i) if the same prescription drug is
15 manufactured by the same company and
16 sold under multiple labels to individual
17 providers, the seller may fill the prescrip-
18 tion with a prescription drug manufactured
19 by that company under another label; and

20 “(ii) the seller may fill the prescrip-
21 tion with a generic version of the prescrip-
22 tion drug.

23 “(6) DEFINITIONS.—In this subsection:

1 “(A) The term ‘direct communication’ in-
2 cludes communication by telephone, facsimile,
3 or electronic mail.

4 “(B) The term ‘generic version of the pre-
5 scription drug’ means, with respect to a pre-
6 scription drug, a drug for which an application
7 is approved under section 505(j) and for which
8 the relevant listed drug described in section
9 505(j)(2) is such prescription drug.

10 “(C) The term ‘seller’ means a person that
11 sells a prescription drug in interstate commerce
12 through an Internet site.

13 “(D) The term ‘treating provider’ means a
14 health care provider (including a nurse) licensed
15 by law to administer the prescription drug in-
16 volved who—

17 “(i) has performed a documented pa-
18 tient evaluation of the individual involved
19 (including a patient history and physical
20 examination) to establish the diagnosis for
21 which the prescription drug involved is pre-
22 scribed, has discussed with the individual
23 his or her treatment options and the risks
24 and benefits of treatment, and maintains

1 contemporaneous medical records on the
2 individual;

3 “(ii) is providing care in consultation
4 with a health care provider described in
5 clause (i) and who has access to the med-
6 ical records of the patient involved; or

7 “(iii) is providing care as part of an
8 on-call or cross-coverage arrangement with
9 a health care provider described in clause
10 (i).

11 “(d) STATE NOTICE REQUIREMENTS.—A person that
12 sells a prescription drug in interstate commerce through
13 an Internet site shall provide to each State authority that
14 licenses or otherwise authorizes the person to dispense the
15 prescription drug the following information:

16 “(1) A statement that the person is selling pre-
17 scription drugs through an Internet site.

18 “(2) The name, Internet address, street ad-
19 dress, and telephone number of the person’s busi-
20 ness for selling such drugs.

21 “(e) DEFINITION.—In this section, the term ‘pre-
22 scription drug’ means a drug subject to section 503(b).”.

23 (b) INCLUSION AS PROHIBITED ACT.—Section 301 of
24 the Federal Food, Drug, and Cosmetic Act (21 U.S.C.

1 331) is amended by inserting after paragraph (k) the fol-
2 lowing:

3 “(l) The sale of a prescription drug, or the ownership
4 or operation of an illegal Internet pharmacy, in violation
5 of section 503B.”.

6 (c) LINKS TO ILLEGAL INTERNET PHARMACY.—Sec-
7 tion 302 of the Federal Food, Drug, and Cosmetic Act
8 (21 U.S.C. 332) is amended by adding at the end the fol-
9 lowing:

10 “(c) In the case of a violation of section 503B relat-
11 ing to an illegal Internet pharmacy, the district courts of
12 the United States and the United States courts of the Ter-
13 ritories shall have jurisdiction to order a provider of an
14 interactive computer service to remove, or disable access
15 to, a site violating such section, or a link to a site violating
16 such section, that resides on a computer server that such
17 provider controls or operates. Such relief shall—

18 “(1) be available only after provision to the pro-
19 vider of notice and an opportunity to appear;

20 “(2) not impose any obligation on the provider
21 to monitor its service or to affirmatively seek facts
22 indicating activity violating section 503B;

23 “(3) specify the provider to which the relief ap-
24 plies; and

1 “(4) specifically identify the location of the site
2 or link to be removed, or to which access is to be
3 disabled.”.

4 **SEC. 3. DISTRIBUTION AND LABELING OF DRUGS.**

5 (a) DRUG PEDIGREES.—With respect to any State
6 that imposes a requirement on the manufacturer or dis-
7 tributor of a drug to provide information to persons receiv-
8 ing the drug regarding prior sales, purchases, or trades
9 of the drug, the Secretary of Health and Human Services
10 shall—

11 (1) encourage the State to allow the manufac-
12 turer or distributor to take advantage of techno-
13 logical advances, including by providing such infor-
14 mation electronically; and

15 (2) at the request of the State, provide tech-
16 nical assistance in implementing the requirement.

17 (b) CHAIN-OF-CUSTODY REQUIREMENTS.—Chapter
18 V of the Federal Food, Drug, and Cosmetic Act (21
19 U.S.C. 351 et seq.) (as amended by section 2) is amend-
20 ed—

21 (1) in section 502, by adding at the end the fol-
22 lowing:

23 “(x) If it is a drug with respect to which the manufac-
24 turer, importer, distributor, or retailer fails to comply with
25 the chain-of-custody requirements of section 503C.”; and

1 (2) by inserting after section 503B (as added
2 by section 2) the following:

3 **“SEC. 503C. CHAIN-OF-CUSTODY REQUIREMENTS.**

4 “(a) IN GENERAL.—Not later than January 1, 2007,
5 the Secretary shall promulgate chain-of-custody require-
6 ments applicable to each manufacturer, importer, dis-
7 tributor, and retailer of a prescription drug.

8 “(b) MANUFACTURERS.—The chain-of-custody re-
9 quirements promulgated under this section shall require
10 each manufacturer of a prescription drug—

11 “(1) to incorporate a unique identifier into the
12 packaging or labeling of the drug;

13 “(2) to track the drug through the point of de-
14 livery to the retailer of the drug; and

15 “(3) to maintain, either directly or through a
16 contractor, a database on the movement of the drug.

17 “(c) IMPORTERS, DISTRIBUTORS, AND RETAILERS.—
18 The chain-of-custody requirements promulgated under
19 this section shall require each importer, distributor, and
20 retailer of a prescription drug to assist in the tracking
21 of the drug under this section by reporting the receipt of
22 the drug to the manufacturer.

23 “(d) PRESCRIPTION DRUG.—In this section, the term
24 ‘prescription drug’ means a drug subject to section 503(b).

1 “(e) EFFECTIVE DATE.—The chain-of-custody re-
2 quirements promulgated by the Secretary under this sec-
3 tion shall take effect on January 1, 2009.”.

4 (c) GRANTS FOR COMMUNITY PHARMACISTS.—The
5 Secretary of Health and Human Services may make
6 grants to community pharmacists to assist such phar-
7 macists to comply with tracking requirements imposed on
8 such pharmacists by drug manufacturers, importers, or
9 distributors as a result of the amendments made by sub-
10 section (b).

11 **SEC. 4. RESTRICTION ON PERSONAL USE EXEMPTION FOR**
12 **IMPORTING CONTROLLED SUBSTANCES.**

13 Paragraph (2) of section 1006(a) of the Controlled
14 Substances Import and Export Act (21 U.S.C. 956(a)) is
15 amended by striking “may not import the controlled sub-
16 stance” and all that follows and inserting: “may not im-
17 port the controlled substance into the United States—

18 “(1) in an amount that exceeds 50 dosage units
19 of the controlled substance; or

20 “(2) in the case of a controlled substance in
21 schedule II, III, or IV, more than 1 time during any
22 30-day period.”.

1 **SEC. 5. WORKING GROUP ON PHARMACEUTICAL COUNTER-**
2 **FEITING.**

3 (a) ESTABLISHMENT.—The Secretary of Health and
4 Human Services (in this section referred to as the “Sec-
5 retary”), acting through the Commissioner of Food and
6 Drugs, shall convene a working group (in this section re-
7 ferred to as the “working group”) to conduct a study and
8 submit a report on pharmaceutical counterfeiting.

9 (b) MEMBERS.—The Secretary shall invite to serve
10 as members of the working group representatives of the
11 following:

12 (1) Domestic regulatory agencies.

13 (2) Domestic and international law enforcement
14 officials.

15 (3) Multinational organizations, such as the
16 World Trade Organization and the World Health
17 Organization.

18 (4) The United States Trade Representative.

19 (5) The pharmaceutical industry.

20 (6) Trade associations, including associations
21 representing each step of the pharmaceutical deliv-
22 ery system (including representatives of drug manu-
23 facturers and pharmacists).

24 (c) STUDY.—The study conducted by the working
25 group on pharmaceutical counterfeiting shall consider the
26 following:

1 (1) How to enhance supply-chain security.

2 (2) Consumer education on counterfeiting
3 issues.

4 (3) Employing technology designed to frustrate
5 organized and sophisticated criminals intent on com-
6 promising the world's drug supply.

7 (4) How industry could assist law enforcement
8 by analyzing suspected counterfeit drugs to deter-
9 mine authenticity.

10 (5) How industry can collaborate on issues re-
11 lated to pharmaceutical counterfeiting without re-
12 vealing trade secrets or other confidential informa-
13 tion.

14 (d) REPORT.—Not later than 2 years after the date
15 of the enactment of this Act, the working group shall sub-
16 mit a report to the Congress on the results of the study
17 conducted under this section, including recommendations
18 on measures to reduce or eliminate problems associated
19 with pharmaceutical counterfeiting.

20 **SEC. 6. STUDY ON UNUSED CONTROLLED SUBSTANCES.**

21 (a) STUDY.—The Secretary of Health and Human
22 Services (in this section referred to as the “Secretary”),
23 acting through the Commissioner of Food and Drugs,
24 shall conduct a study to determine the best methods to

1 ensure that unused controlled substances are not diverted
2 for unlawful use.

3 (b) CONSULTATION.—In conducting the study re-
4 quired by this section, the Secretary shall consult with the
5 Administrator of the Drug Enforcement Administration,
6 appropriate law enforcement representatives, the Adminis-
7 trator of the Environmental Protection Agency, States
8 and municipalities (including State boards of pharmacy),
9 and representatives of the pharmaceutical industry.

10 (c) REPORT.—Not later than 2 years after the date
11 of the enactment of this Act, the Secretary shall submit
12 a report to the Congress on the results of the study con-
13 ducted under this section.

14 **SEC. 7. BASELINE RESEARCH ON PRESCRIPTION DRUG**
15 **ABUSE.**

16 (a) RESEARCH.—The Secretary of Health and
17 Human Services shall conduct research on issues related
18 to prescription drug abuse, including the following:

19 (1) Enhancing existing public use surveys and
20 other sources so as to provide appropriate baseline
21 data and data on the natural history and context of
22 prescription drug use in order to evaluate the extent
23 and nature of potential problems and guide correc-
24 tive actions which reduce the problems without unin-
25 tentionally hindering patient access.

1 (2) The phenomenon of iatrogenic addiction, in-
2 cluding the actual incidence and prevalence of iatro-
3 genic addiction, the factors that modulate the risk of
4 such addiction, and the extent to which concern
5 about iatrogenic addiction impacts health care deliv-
6 ery.

7 (3) Development of postapproval surveillance
8 approaches that can detect and address potential
9 risks of abuse and misuse, including risks in diverse
10 patient populations that did not previously appear at
11 risk for diversion or abuse, and in geographic re-
12 gions that have been relatively absent from risk.

13 (4) Methods to better translate new ideas about
14 terminology, diagnosis, and management of addic-
15 tion diseases into clinical practice at the primary
16 care and specialist levels.

17 (5) Reliable, useful assessment tools for addic-
18 tion in the clinical setting of initial and ongoing
19 treatment of conditions requiring the use of con-
20 trolled substances.

21 (6) Development of better methods of ensuring
22 patient adherence to prescribed drug regimens.

23 (7) Relative contributions of genetic, psycho-
24 social, environmental, and behavioral factors to ad-
25 diction to prescription opioids.

1 (b) REPORT.—Not later than 2 years after the date
 2 of the enactment of this Act, the Secretary of Health and
 3 Human Services shall submit to the Congress a report on
 4 the results of the research conducted under this section.

5 **SEC. 8. DATABASE FOR DRUG ABUSE MORTALITY REPORT-**
 6 **ING.**

7 Section 505 of the Public Health Service Act (42
 8 U.S.C. 290aa-4) is amended—

9 (1) in subparagraph (B) of subsection (c)(1), by
 10 striking “, as indicated in reports by coroners”; and

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

12 “(e) With respect to the activities of the Adminis-
 13 trator under subsections (a) and (c)(1)(B) relating to the
 14 collection of data on the number of deaths occurring as
 15 a result of substance abuse, the Administrator—

16 “(1) shall expand and intensify collection activi-
 17 ties to maintain a comprehensive, national database
 18 on such deaths; and

19 “(2) shall require medical examiners, coroners,
 20 and other appropriate persons to report to the Ad-
 21 ministrator for purposes of collecting data on such
 22 deaths.”.

○