

110TH CONGRESS  
2D SESSION

# H. R. 5839

To amend the Federal Food, Drug, and Cosmetic Act to improve the safety of drugs.

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## IN THE HOUSE OF REPRESENTATIVES

APRIL 17, 2008

Mr. BUYER (for himself, Mr. MATHESON, Mr. ROGERS of Michigan, and Mr. GENE GREEN of Texas) introduced the following bill; which was referred to the Committee on Energy and Commerce

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## A BILL

To amend the Federal Food, Drug, and Cosmetic Act to improve the safety of drugs.

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 “Safeguarding Amer-  
5 ica’s Pharmaceuticals Act of 2008”.

6 **SEC. 2. TABLE OF CONTENTS.**

7 The table of contents of this Act is as follows:

Sec. 1. Short title.

Sec. 2. Table of contents.

Sec. 3. Destruction of counterfeit drugs offered for import.

Sec. 4. Interim provisions to assure the safety of the wholesale distribution of prescription drugs.

Sec. 5. Unique standardized numerical identifiers for each prescription drug.

- Sec. 6. Prescription drug identification and tracking system.  
 Sec. 7. Facilitating prescription drug identification and tracking system for small pharmacies.  
 Sec. 8. Uniform national standards.  
 Sec. 9. Report to Congress.  
 Sec. 10. Requirements for licensure of wholesale distributors.  
 Sec. 11. Injunctions; civil penalties.  
 Sec. 12. State enforcement of Federal requirements.  
 Sec. 13. Study on threats to domestic prescription drug supply chain.

1 **SEC. 3. DESTRUCTION OF COUNTERFEIT DRUGS OFFERED**  
 2 **FOR IMPORT.**

3 Section 801(a) of the Federal Food, Drug, and Cos-  
 4 metic Act (21 U.S.C. 381(a)) is amended—

5 (1) in the third sentence—

6 (A) by striking “or (3) such” and inserting  
 7 “(3) such”; and

8 (B) by inserting “, or (4) such article is a  
 9 counterfeit drug,” before “then such article  
 10 shall be refused admission”; and

11 (2) by striking “Clause (2) of the third sen-  
 12 tence of this paragraph” and inserting “Notwith-  
 13 standing the preceding sentence, the Secretary of  
 14 the Treasury shall cause the destruction of any such  
 15 article refused admission if (1) the article is a drug,  
 16 the article appears to be adulterated, misbranded, or  
 17 in violation of section 505, and the article has a  
 18 value less than \$2,000 or such amount as the Sec-  
 19 retary of Health and Human Services may deter-  
 20 mine by regulation; or (2) the article appears to be

1 a counterfeit drug. Clause (2) of the third sentence  
2 of this subsection”.

3 **SEC. 4. INTERIM PROVISIONS TO ASSURE THE SAFETY OF**  
4 **THE WHOLESALE DISTRIBUTION OF PRE-**  
5 **SCRIPTION DRUGS.**

6 (a) IN GENERAL.—Subsection (e) of section 503 of  
7 the Federal Food, Drug, and Cosmetic Act (21 U.S.C.  
8 353) is amended—

9 (1) by striking paragraphs (1) and (3);

10 (2) by redesignating paragraph (2) as para-  
11 graph (4); and

12 (3) by inserting before paragraph (4), as so re-  
13 designated by paragraph (2) of this subsection, the  
14 following:

15 “(e) REGULATION OF WHOLESALE DISTRIBUTORS  
16 OF PRESCRIPTION DRUGS.—

17 “(1) INTERIM PROVISIONS.—

18 “(A) DEFINITIONS.—Except as otherwise  
19 noted, for purposes of this subsection—

20 “(i) for purposes of this paragraph  
21 and subsection (d) only, the term ‘author-  
22 ized distributor of record’ with respect to  
23 a prescription drug means a wholesale dis-  
24 tributor that has a written agreement for  
25 such drug currently in effect with the

1 drug's manufacturer (as defined in clause  
2 (iv)(I) or (II)) to distribute such drug;

3 “(ii) the term ‘co-licensed partner’  
4 means one of two or more persons who has  
5 the right to engage in the manufacturing  
6 or marketing of a prescription drug;

7 “(iii) the term ‘dispenser’ means a re-  
8 tail pharmacy, hospital pharmacy, or any  
9 other person authorized by law to dispense  
10 or administer prescription drugs;

11 “(iv) for purposes of this paragraph  
12 and subsection (d) only, the term ‘manu-  
13 facturer’ means, with respect to a prescrip-  
14 tion drug—

15 “(I) the person that holds the ap-  
16 plication approved under section 505  
17 or the license issued under section  
18 351 of the Public Health Service Act  
19 for the drug, or if the drug is not the  
20 subject of an approved application or  
21 license, the person identified on the  
22 original label of the drug as the man-  
23 ufacturer, distributor, or both;

24 “(II) a co-licensed partner of the  
25 person identified in subclause (I) that

1 obtains the drug directly from the  
2 person identified in subclause (I) or  
3 (III);

4 “(III) a person that manufac-  
5 tures the prescription drug for the  
6 person identified in subclause (I) or  
7 (II);

8 “(IV) a third-party logistics pro-  
9 vider operating on behalf of the per-  
10 son identified in subclause (I) or (II)  
11 that obtains the drug directly from  
12 the person identified in subclause (I),  
13 (II), or (III); or

14 “(V) the exclusive distributor of  
15 the person identified in subclause (I)  
16 or (II) that obtains the drug directly  
17 from the person identified in sub-  
18 clause (I), (II), or (III);

19 “(v) the term ‘exclusive distributor’  
20 means any person who contracts with an-  
21 other person to provide or coordinate  
22 warehousing, distribution, or other services  
23 on behalf of such person and who takes  
24 title to that person’s prescription drug, but  
25 who does not have general responsibility to

1 direct the sale or disposition of that per-  
2 son’s prescription drug;

3 “(vi) the term ‘prescription drug’  
4 means a drug subject to subsection (b);

5 “(vii) the term ‘third party logistics  
6 provider’ means a person that, by agree-  
7 ment with another person, is responsible  
8 for providing or coordinating distribution,  
9 warehousing, and related services with re-  
10 spect to a prescription drug on behalf of  
11 that person, but that does not take title to  
12 such drug and does not have general re-  
13 sponsibility to direct the sale or distribu-  
14 tion of the prescription drug;

15 “(viii) for purposes of subsection (d)  
16 and this subsection, the term ‘wholesale  
17 distribution’ means the sale, purchase,  
18 trade, or delivery of a prescription drug be-  
19 tween and within any State, but does not  
20 include—

21 “(I) intracompany sales, pur-  
22 chases, trades, or transfers of any  
23 prescription drug between members of  
24 an affiliated group (as that term is

1 defined in section 1504 of the Inter-  
2 nal Revenue Code);

3 “(II) the purchase or other ac-  
4 quisition by a hospital or other health  
5 care entity that is a member of a  
6 group purchasing organization of a  
7 drug for its own use from the group  
8 purchasing organization or from other  
9 hospitals or health care entities that  
10 are members of such organizations;

11 “(III) the sale, purchase, or  
12 trade of a drug or an offer to sell,  
13 purchase, or trade a drug by a chari-  
14 table organization to a nonprofit affil-  
15 iate of the organization to the extent  
16 otherwise permitted by law;

17 “(IV) the sale, purchase, or trade  
18 of a drug or an offer to sell, purchase,  
19 or trade a drug among hospitals or  
20 other health care entities that are  
21 under common control;

22 “(V) the sale, purchase, or trade  
23 of a drug or an offer to sell, purchase,  
24 or trade a drug for emergency medical  
25 reasons;

1 “(VI) the sale, purchase, or trade  
2 of a drug, an offer to sell, purchase,  
3 or trade a drug, or the dispensing of  
4 a drug under a prescription executed  
5 in accordance with subsection (b);

6 “(VII) the distribution of drug  
7 samples by a manufacturer’s rep-  
8 resentative or an authorized dis-  
9 tributor of record’s representative;

10 “(VIII) the sale, purchase, or  
11 trade of blood or blood components in-  
12 tended for transfusion;

13 “(IX) drug returns, when con-  
14 ducted by a dispenser or wholesale  
15 distributor in accordance with the re-  
16 quirements of subparagraph (D);

17 “(X) the sale of minimal quan-  
18 tities of drugs by retail pharmacies to  
19 licensed practitioners for office use; or

20 “(XI) the sale, purchase, or trade  
21 of prescription drugs when such drugs  
22 are contained in sealed medical or  
23 surgical kits that have been assembled  
24 in a facility registered with the Food  
25 and Drug Administration as a device

1 manufacturer under section 510(c)  
2 and such drug was purchased by the  
3 kit assembler directly from the manu-  
4 facturer of such drug; and

5 “(ix) the term ‘wholesale distributor’  
6 means any person engaged in wholesale  
7 distribution, except a common carrier.

8 “(B) MANUFACTURER PACKING LIST.—

9 The manufacturer of a prescription drug shall  
10 provide to each wholesale distributor or dis-  
11 penser to whom it delivers such drug a packing  
12 list or comparable document, in paper or elec-  
13 tronic form, that identifies the proprietary and  
14 established names of the drug, the National  
15 Drug Code number of the drug, the strength of  
16 the drug, the container size of the drug, the  
17 number of containers of the drug, the lot num-  
18 ber or numbers of the drug, the date of the  
19 transaction, and the names and addresses of  
20 the manufacturer and the person to whom the  
21 drug is being delivered.

22 “(C) STATEMENT OF DISTRIBUTION HIS-  
23 TORY.—Each person engaged in wholesale dis-  
24 tribution of a prescription drug (except a manu-  
25 facturer that is engaged in the wholesale dis-

1           tribution of a prescription drug, or a wholesale  
2           distributor on whose behalf a manufacturer de-  
3           livers a prescription drug directly to a dis-  
4           penser) shall provide to each wholesale dis-  
5           tributor or dispenser to whom such person de-  
6           livers such a drug before, or at the time of,  
7           each wholesale distribution, one of the fol-  
8           lowing:

9                   “(i) DIRECT PURCHASE PEDIGREE.—

10                   “(I) If the person providing the  
11                   statement is an authorized distributor  
12                   of record for such drug and purchased  
13                   such drug directly from the manufac-  
14                   turer, a statement on the invoice,  
15                   whether in paper or electronic form,  
16                   stating that such person is an author-  
17                   ized distributor of record for such  
18                   drug; and such person purchased the  
19                   specific unit of the prescription drug  
20                   directly from the manufacturer.

21                   “(II) If the person providing the  
22                   statement is a member of the affili-  
23                   ated group (as that term is defined in  
24                   section 1504 of the Internal Revenue  
25                   Code) of an authorized distributor of

1 record that purchased such drug di-  
2 rectly from the manufacturer, and  
3 such person obtained such drug from  
4 such authorized distributor of record  
5 directly or by means of one or more  
6 transactions involving only members  
7 of such affiliated group, a statement  
8 on the invoice, whether in paper or  
9 electronic form, identifying such au-  
10 thorized distributor of record; stating  
11 that such person is a member of the  
12 affiliated group (as that term is de-  
13 fined in section 1504 of the Internal  
14 Revenue Code) of such authorized dis-  
15 tributor of record; and stating that  
16 such authorized distributor of record  
17 purchased the specific unit of the pre-  
18 scription drug directly from the manu-  
19 facturer.

20 “(ii) STANDARD PEDIGREE.—For all  
21 situations not described in clause (i), a  
22 statement, whether in paper or electronic  
23 form, identifying each wholesale distribu-  
24 tion of such drug, back to the authorized  
25 distributor of record for such drug or a

1 member of the affiliated group (as that  
2 term is defined in section 1504 of the In-  
3 ternal Revenue Code) of such authorized  
4 distributor of record that provided one of  
5 the statements described in clause (i), or,  
6 if there is no such authorized distributor of  
7 record, back to the manufacturer of such  
8 drug, and including the following:

9 “(I) The proprietary and estab-  
10 lished names of the drug.

11 “(II) The drug’s National Drug  
12 Code number.

13 “(III) Strength.

14 “(IV) Container size.

15 “(V) Number of containers.

16 “(VI) The drug’s lot or control  
17 number or numbers.

18 “(VII) The business name and  
19 address of all parties to each prior  
20 transaction involving the drug, start-  
21 ing with the authorized distributor of  
22 record who provided the original  
23 statement of distribution history re-  
24 quired under clause (i) or, if there is  
25 no such authorized distributor of

1 record, back to the manufacturer of  
2 such drug.

3 “(VIII) The date of each pre-  
4 vious transaction involving such drug,  
5 back to the authorized distributor of  
6 record who provided the original  
7 statement of distribution history re-  
8 quired under clause (i) or, if there is  
9 no such authorized distributor of  
10 record, back to the manufacturer of  
11 such drug.

12 “(D) RETURNS.—

13 “(i) IN GENERAL.—A wholesale dis-  
14 tributor or dispenser may return prescrip-  
15 tion drugs to a wholesale distributor, man-  
16 ufacturer, or a person acting on behalf of  
17 the wholesale distributor or the manufac-  
18 turer, provided the requirements of clauses  
19 (ii) and (iii) are met.

20 “(ii) SALEABLE RETURNS.—

21 “(I) MISTAKEN ORDERS.—A  
22 wholesale distributor or dispenser may  
23 return to the selling wholesale dis-  
24 tributor prescription drugs that are  
25 the result of a mistake in ordering or

1 shipment. For subsequent sales or  
2 trades of such returned drugs, the re-  
3 turn of such prescription drugs is not  
4 required to be reflected in the state-  
5 ment pursuant to clause (i) or (ii) of  
6 subparagraph (C) provided—

7 “(aa) a return authorization  
8 is requested by the returning  
9 wholesale distributor or dispenser  
10 within 7 days of receipt of such  
11 mistaken order or shipment; and

12 “(bb) the return is accom-  
13 panied by a certified statement,  
14 in written or electronic form, that  
15 such drug was received from the  
16 wholesale distributor to which it  
17 is being returned by mistake or  
18 ordered in error and that such  
19 drug was stored and handled  
20 under proper conditions while in  
21 the possession and control of the  
22 returning party.

23 “(II) OTHER RETURNS.—For re-  
24 turns not described in subclause (I), a  
25 wholesale distributor or dispenser may

1 return prescription drugs under the  
2 following conditions:

3 “(aa) If a prescription drug  
4 was delivered to a person with a  
5 statement in accord with sub-  
6 paragraph (C)(i), the drug may  
7 be returned to the wholesale dis-  
8 tributor from which it was pur-  
9 chased provided it is accom-  
10 panied with a certified statement,  
11 in written or electronic form, that  
12 such drug was purchased from  
13 the wholesale distributor and  
14 such drug was stored and han-  
15 dled under proper conditions  
16 while in the possession and con-  
17 trol of the returning party. For  
18 subsequent sales or trades of  
19 such returned drugs, the return  
20 of such prescription drugs is not  
21 required to be reflected in the  
22 statement of distribution history  
23 required under subparagraph  
24 (C)(i).

1           “(bb) If a prescription drug  
2 was delivered to a person with a  
3 statement pursuant to subpara-  
4 graph (C)(ii), the drug may be  
5 returned to the wholesaler from  
6 which it was purchased provided  
7 the return is accompanied by the  
8 statement that was received pur-  
9 suant to subparagraph (C)(ii)  
10 and a certified statement that  
11 such drug was purchased from  
12 the wholesale distributor and was  
13 stored and handled under proper  
14 conditions while in the possession  
15 and control of the returning  
16 party. For subsequent sales or  
17 trades of such returned drugs,  
18 the return of such prescription  
19 drugs shall be reflected in the  
20 statement of distribution history  
21 required under subparagraph  
22 (C)(ii).

23           “(iii) NON-SALEABLE RETURNS.—A  
24 wholesale distributor, manufacturer, or a  
25 person acting on behalf of the wholesale

1 distributor or manufacturer may accept a  
2 return of a non-saleable prescription drug  
3 including, but not limited to, recalled, ex-  
4 pired, or damaged drugs without the state-  
5 ment required under subparagraph (C)(i)  
6 or (C)(ii). However, such drugs may not be  
7 resold and a wholesale distributor, manu-  
8 facturer, or a person acting on behalf of  
9 the wholesale distributor or manufacturer  
10 must destroy the drug.

11 “(E) LIST OF AUTHORIZED DISTRIBUTORS  
12 OF RECORD.—The manufacturer (as defined in  
13 subclauses (I) and (II) of subparagraph (A)(iv))  
14 of a prescription drug shall—

15 “(i) maintain a list of the authorized  
16 distributors of record of such drug at its  
17 corporate offices;

18 “(ii) make such list publicly available,  
19 including placement on its Internet  
20 website; and

21 “(iii) update such list not less than  
22 once a month.

23 “(F) APPLICABILITY.—The requirements  
24 of this paragraph shall not apply with respect  
25 to any prescription drug that is subject to a re-

1           requirement under paragraph (3) for an effective  
2           drug identification and tracking system based  
3           on standardized numerical identifiers.”.

4           (b) **EFFECTIVE DATE.**—The amendment made by  
5 subsection (a) shall take effect 180 days after the date  
6 of enactment of this Act.

7 **SEC. 5. UNIQUE STANDARDIZED NUMERICAL IDENTIFIERS**  
8                                   **FOR EACH PRESCRIPTION DRUG.**

9           (a) **IN GENERAL.**—Subsection (e) of section 503 of  
10 the Federal Food, Drug, and Cosmetic Act (21 U.S.C.  
11 353), as amended by section 4, is amended by inserting  
12 after paragraph (1) the following:

13                           “(2) **STANDARDIZED DRUG IDENTIFIERS.**—

14                                   “(A) **REPORT; DEVELOPMENT.**—

15   “(i) **REPORT ON PROMISING SECURITY**  
16   **TECHNOLOGIES.**—Not later than 18  
17   months after the date of enactment of the  
18   Safeguarding America’s Pharmaceuticals  
19   Act of 2008, the Secretary shall submit to  
20   the Committee on Energy and Commerce  
21   of the House of Representatives and the  
22   Committee on Health, Education, Labor,  
23   and Pensions of the Senate a report evalu-  
24   ating the feasibility and operational effi-  
25   ciencies of adopting the security tech-

1 nologies including barcodes, Radio-Fre-  
2 quency Identification Tags, nanotechnol-  
3 ogy, or other promising track and trace  
4 technology throughout the prescription  
5 drug supply chain. The report shall assess  
6 the cost-effectiveness and benefits of apply-  
7 ing such technologies at the pallet, case,  
8 unit, and tablet levels, including the ability  
9 to defeat repackaging, enhance product  
10 identification or validation, and improve  
11 the overall security of the prescription drug  
12 supply chain.

13 “(ii) CONSIDERATION.—The Secretary  
14 shall consider the findings made in the re-  
15 port submitted under clause (i) when de-  
16 veloping a standard numerical identifier  
17 under section 505D(b)(2).

18 “(iii) ANNOUNCEMENT OF DEVELOP-  
19 MENT OF STANDARDIZED NUMERICAL  
20 IDENTIFIER.—Not later than March 27,  
21 2010, the Secretary shall announce the de-  
22 velopment of a standardized numerical  
23 identifier under section 505D(b)(2) by  
24 means of a notice published in the Federal  
25 Register.

1 “(B) HIGH-RISK DRUGS.—

2 “(i) CRITERIA; LIST.—Not later than  
3 March 27, 2010, and periodically there-  
4 after, the Secretary shall develop, and shall  
5 notify members of the supply chain regard-  
6 ing, the following:

7 “(I) Criteria the Secretary will  
8 use to determine whether a drug is at  
9 high risk for counterfeiting or diver-  
10 sion.

11 “(II) A list identifying prescrip-  
12 tion drugs that are at high risk of di-  
13 version or counterfeiting. In devel-  
14 oping or updating such list, the Sec-  
15 retary shall consult with the manufac-  
16 turer of each drug involved, as well as  
17 with members of the supply chain and  
18 relevant Federal enforcement agen-  
19 cies, and, at least 1 year before in-  
20 cluding any drug in the list, provide  
21 the manufacturer of the drug and  
22 members of the supply chain notice of  
23 the Secretary’s intent to include the  
24 drug in the list.

1           “(ii) REQUIREMENT.—Not later than  
2           18 months after the date of notice in the  
3           Federal Register described in subpara-  
4           graph (A)(iii), each manufacturer or re-  
5           packager of a prescription drug that ap-  
6           pears on the list of high risk drugs estab-  
7           lished under clause (i) shall apply a stand-  
8           ardized numerical identifier that is unique  
9           to each unit (namely, a package from  
10          which the drug may be repackaged or dis-  
11          pensed) of the drug. The identifier shall be  
12          applied by the manufacturer or repackager  
13          (in which case the serialized number shall  
14          be linked to the numerical identifiers ap-  
15          plied by the manufacturer).

16          “(C) OTHER DRUGS.—

17                 “(i) IN GENERAL.—Each manufac-  
18                 turer or repackager of a prescription drug  
19                 not described in subparagraph (B) shall  
20                 apply a standardized numerical identifier  
21                 that is unique to each unit of the drug, in  
22                 accordance with a compliance timetable es-  
23                 tablished by the Secretary through rule-  
24                 making under section 553 of title 5,  
25                 United States Code. Such timetable may

1 establish different compliance dates for dif-  
2 ferent types of drugs. The identifier shall  
3 be applied by the manufacturer or repack-  
4 ager (in which case the serialized number  
5 shall be linked to the numerical identifiers  
6 applied by the manufacturer).

7 “(ii) REGULATIONS.—The Secretary  
8 shall issue proposed regulations to imple-  
9 ment this subparagraph not later than the  
10 date that is 1 year after the date of the  
11 notice in the Federal Register described in  
12 subparagraph (A)(iii), and promulgate  
13 final regulations not later than 2 years  
14 after the date of such Federal Register no-  
15 tice. In proposing or promulgating such  
16 regulations, the Secretary shall consult  
17 with members of the supply chain and take  
18 into account the economic and technical  
19 feasibility of compliance by manufacturers,  
20 repackagers, wholesale distributors, and  
21 dispensers and for different types of drugs.  
22 Such regulations shall not establish a com-  
23 pliance date for any drug that is earlier  
24 than the date that is 3 years after the date

1 of the Federal Register notice described in  
2 subparagraph (A)(iii).

3 “(iii) EXEMPTION FROM IDENTIFICA-  
4 TION REQUIREMENT.—The regulations  
5 under clause (ii) shall include a process  
6 under which a manufacturer or repackager  
7 may request an exemption from the identi-  
8 fication requirement if it can demonstrate  
9 to the Secretary’s satisfaction that—

10 “(I) the requirement would ad-  
11 versely affect the safety, effectiveness,  
12 purity, or potency of the drug or  
13 would not be technologically feasible;  
14 and

15 “(II) the concerns underlying the  
16 request could not reasonably be ad-  
17 dressed by measures such as package  
18 redesign or use of overwraps.”.

19 (b) VALIDATION.—Paragraph (2) of section 505D(b)  
20 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C.  
21 355e) is amended by striking “validation,”.

22 **SEC. 6. PRESCRIPTION DRUG IDENTIFICATION AND TRACK-**  
23 **ING SYSTEM.**

24 Subsection (e) of section 503 of the Federal Food,  
25 Drug, and Cosmetic Act (21 U.S.C. 353), as amended by

1 section 5, is amended by inserting after paragraph (2) the  
2 following:

3 “(3) EFFECTIVE DRUG IDENTIFICATION AND  
4 TRACKING SYSTEM.—

5 “(A) IN GENERAL.—The Secretary shall  
6 issue regulations to establish an effective drug  
7 identification and tracking system through  
8 which drug manufacturers, repackagers, whole-  
9 sale distributors, and dispensers may authen-  
10 ticate the wholesale distribution history of any  
11 prescription drug that is subject to a require-  
12 ment for a standardized numerical identifier  
13 under paragraph (2).

14 “(B) CONTENT OF REGULATIONS.—The  
15 regulations under subparagraph (A) shall—

16 “(i) establish standards for electroni-  
17 cally accessible and interoperable databases  
18 through which drug manufacturers, re-  
19 packagers, wholesale distributors, and dis-  
20 pensers may authenticate the wholesale  
21 distribution history of prescription drugs  
22 using the numerical identifiers required  
23 under paragraph (2), while maintaining  
24 the proprietary information of each entity;

1           “(ii) require the manufacturer or re-  
2           packager of a prescription drug to apply  
3           such numerical identifier in at least 1  
4           standardized form that is electronically  
5           readable;

6           “(iii) require the repackager of a pre-  
7           scription drug to link electronically within  
8           such databases the numerical identifier ap-  
9           plied to the drug by the repackager to the  
10          numerical identifiers applied to the drug  
11          by the manufacturer or previous repack-  
12          ager;

13          “(iv) require each person that receives  
14          a prescription drug in wholesale distribu-  
15          tion to authenticate the transaction history  
16          of the drug by authenticating the numer-  
17          ical identifier with the appropriate data-  
18          base; and

19          “(v) require protections to ensure pa-  
20          tient privacy, in compliance with the regu-  
21          lations promulgated under section 264(c)  
22          of the Health Insurance Portability and  
23          Accountability Act of 1996.

24          “(C) ISSUANCE OF REGULATIONS.—

1           “(i) CONSIDERATIONS.—In developing  
2           the regulations under subparagraph (A),  
3           the Secretary shall consider the technical  
4           feasibility of compliance—

5                   “(I) by manufacturers, repack-  
6                   agers, wholesale distributors, and dis-  
7                   pensers, including small businesses;  
8                   and

9                   “(II) for different types of drugs.

10           “(ii) TIMING.—The Secretary shall  
11           issue proposed regulations under subpara-  
12           graph (A) not later than March 31, 2010,  
13           and shall issue final regulations not later  
14           than the date that is 1 year after the date  
15           of such proposed regulations.

16           “(iii) COMPLIANCE DATE.—With re-  
17           gard to any drug, the regulations under  
18           subparagraph (A) shall not require compli-  
19           ance on a date that is—

20                   “(I) earlier than 18 months or  
21                   later than 2 years after the date on  
22                   which such drug is subject to a re-  
23                   quirement for the application of a  
24                   standardized numerical identifier  
25                   under paragraph (2)(B); or

1                   “(II) earlier than 6 months or  
2                   later than 9 months after the date on  
3                   which such drug is subject to a re-  
4                   quirement for the application of a  
5                   standardized numerical identifier  
6                   under paragraph (2)(C).

7                   In determining the compliance dates of  
8                   such regulations, the Secretary shall take  
9                   into consideration operational and tech-  
10                  nical feasibility and provide sufficient time  
11                  for inventory conversion across the supply  
12                  chain.

13                  “(D) GAO STUDY AND REPORT.—The  
14                  Comptroller General of the United States shall  
15                  conduct a study on the availability and cost of  
16                  technologies to dispensers to comply with this  
17                  subsection during the 12-month period begin-  
18                  ning on the date of the Secretary’s notice of  
19                  proposed regulations under subsection (C)(ii).  
20                  Not later than the end of such 12-month pe-  
21                  riod, the Comptroller General shall submit to  
22                  the Secretary and to the Congress a report on  
23                  such study and shall include in the report rec-  
24                  ommendations to facilitate the adoption of iden-

1           tification and tracking system technology by  
2           dispensers.”.

3 **SEC. 7. FACILITATING PRESCRIPTION DRUG IDENTIFICA-**  
4                   **TION AND TRACKING SYSTEM FOR SMALL**  
5                   **PHARMACIES.**

6           (a) GRANTS FOR ADOPTION OF TECHNOLOGY.—

7                   (1) IN GENERAL.—The Secretary of Health and  
8           Human Services shall award grants to eligible enti-  
9           ties to facilitate the purchase and enhance the utili-  
10          zation of a drug identification and tracking system  
11          to ensure the security and integrity of the drug sup-  
12          ply chain.

13                   (2) ELIGIBILITY.—To be eligible to receive a  
14          grant under paragraph (1), an entity shall—

15                           (A) submit to the Secretary an application  
16                           at such time, in such manner, and containing  
17                           such information as the Secretary may require;

18                           (B) agree to provide matching funds in ac-  
19                           cordance with paragraph (4); and

20                           (C) be an independent pharmacy.

21                   (3) USE OF FUNDS.—Amounts received under a  
22          grant under this subsection shall be used to facili-  
23          tate the purchase of qualified identification and  
24          tracking technology systems required to comply with  
25          section 503(e) of the Federal Food, Drug, and Cos-

1        metic Act, as amended by sections 4, 5, and 6 of  
2        this Act.

3           (4) MATCHING REQUIREMENT.—To be eligible  
4        for a grant under this subsection, an entity shall  
5        contribute non-Federal contributions to the costs of  
6        carrying out the activities for which the grant is  
7        awarded in an amount equal to \$1 for each \$3 of  
8        Federal funds provided under the grant.

9           (5) PREFERENCE IN AWARDING GRANTS.—In  
10        awarding grants under this subsection, the Secretary  
11        shall give preference to independent pharmacies that  
12        meet the definition of a small business concern in  
13        section 3 of the Small Business Act (15 U.S.C. 632)  
14        by having annual gross revenues of \$6,500,000 or  
15        less.

16        (b) AMOUNT OF GRANTS.—Upon receiving the report  
17        required by section 503(e)(3)(D) of the Federal Food,  
18        Drug, and Cosmetic Act, as amended by sections 4, 5, and  
19        6 of this Act, the Secretary shall assess the findings of  
20        the report and provide grants to independent pharmacies  
21        in an amount deemed appropriate by the Secretary and  
22        based on the information provided by the Comptroller  
23        General.

24        (c) REPORTS.—Not later than 1 year after receiving  
25        a grant under this section, an entity that receives such

1 grant shall submit to the Secretary a report on the impact  
2 of the grant. Each such report shall include—

3 (1) a description of the financial costs and ben-  
4 efits of the technology system implemented and of  
5 the entities to which such costs and benefits accrue;

6 (2) an analysis of the impact of the grant on  
7 acquiring technology necessary to comply with sec-  
8 tion 503(e)(3) of the Federal Food, Drug, and Cos-  
9 metic Act, as amended by sections 4, 5, and 6 of  
10 this Act;

11 (3) a description of the use of the grant; and

12 (4) such other information as may be required  
13 by the Secretary.

14 (d) DEFINITIONS.—

15 (1) INDEPENDENT PHARMACY.—The term  
16 “independent pharmacy” means a pharmacy which  
17 is not owned (or operated) by a publicly traded com-  
18 pany.

19 (2) PUBLICLY TRADED COMPANY.—The term  
20 “publicly traded company” means a company that is  
21 an issuer within the meaning of section 2(a)(7) of  
22 the Sarbanes-Oxley Act of 2002 (15 U.S.C.  
23 7201(a)(7)).

24 (3) SECRETARY.—The term “Secretary” means  
25 the Secretary of Health and Human Services.

1 (e) AUTHORIZATION OF APPROPRIATIONS.—

2 (1) IN GENERAL.—There are authorized to be  
3 appropriated such sums as may be necessary to  
4 carry out this section.

5 (2) AVAILABILITY.—Amounts appropriated pur-  
6 suant to paragraph (1) shall remain available  
7 throughout the 2-year period following the date of  
8 issuance of final regulations under section  
9 503(e)(3)(A) of the Federal Food, Drug, and Cos-  
10 metic Act, as amended by sections 4, 5, and 6 of  
11 this Act.

12 **SEC. 8. UNIFORM NATIONAL STANDARDS.**

13 Subsection (e) of section 503 of the Federal Food,  
14 Drug, and Cosmetic Act (21 U.S.C. 353), as amended by  
15 sections 4, 5, and 6 of this Act, is amended by adding  
16 at the end the following:

17 “(5) UNIFORM NATIONAL STANDARDS.—Effec-  
18 tive 180 days after the date of enactment of the  
19 Safeguarding America’s Pharmaceuticals Act of  
20 2008, no State or political subdivision of a State  
21 may establish or continue in effect any requirement  
22 with respect to statements of distribution history,  
23 manufacturer packing lists, unique standardized nu-  
24 merical identifiers, or drug identification and track-  
25 ing systems for prescription drugs that is different

1 from, or in addition to, any requirement under this  
2 subsection.”.

3 **SEC. 9. REPORT TO CONGRESS.**

4 If the Secretary of Health and Human Services does  
5 not issue any proposed or final regulations by the dates  
6 described in paragraphs (2) and (3) of section 503(e) of  
7 the Federal Food, Drug, and Cosmetic Act, as amended  
8 by sections 4, 5, and 6 of this Act, the Secretary shall  
9 provide the Committee on Energy and Commerce of the  
10 House of Representatives and the Committee on Health,  
11 Education, Labor, and Pensions of the Senate a report  
12 explaining the reasons why action on the proposed or final  
13 regulations did not occur and specifying the date by which  
14 the Secretary will issue such regulations.

15 **SEC. 10. REQUIREMENTS FOR LICENSURE OF WHOLESALE**  
16 **DISTRIBUTORS.**

17 (a) REQUIREMENTS.—Section 503(e)(4) of the Fed-  
18 eral Food, Drug, and Cosmetic Act, as so redesignated  
19 by section 4(a)(2) of this Act is amended—

20 (1) in subparagraph (B), by striking the second  
21 sentence and inserting the following: “Such guide-  
22 lines shall prescribe requirements for—

23 “(i) the storage and handling of such drugs;

24 “(ii) the establishment and maintenance of  
25 records of the distributions of such drugs;

1           “(iii) the payment to the State of a bond or  
2 other equivalent means of security in an amount  
3 deemed appropriate by the State;

4           “(iv) the conduct of mandatory background  
5 checks and fingerprinting of facility manager and  
6 his or her designated representative;

7           “(v) the establishment and implementation of  
8 qualifications for key personnel;

9           “(vi) in accordance with subparagraph (C), the  
10 mandatory physical inspection prior to licensure of  
11 any facility to be used in the wholesale distribution;  
12 and

13           “(vii) in accordance with subparagraph (D), the  
14 prohibition of certain persons from receiving or  
15 maintaining licensure for wholesale distribution.”;  
16 and

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

18           “(C) The guidelines under subparagraph (B) shall in-  
19 clude requirements for the mandatory physical inspection  
20 prior to licensure of any facility to be used, pursuant to  
21 such licensure, in wholesale distribution. Such require-  
22 ments shall allow a State to accept a satisfactory inspec-  
23 tion report from a relevant State or Federal inspection  
24 authority, or from a third party inspection or accreditation  
25 program that meets criteria and standards developed by

1 an advisory group consisting of representatives of the  
2 State, distributors, manufacturers, pharmacies and other  
3 stakeholders, in place of the State conducting the inspec-  
4 tion.

5 “(D) The guidelines under subparagraph (B) shall in-  
6 clude requirements to prohibit a person from receiving or  
7 maintaining licensure for wholesale distribution if the per-  
8 son—

9 “(i) has been convicted of any felony for con-  
10 duct relating to wholesale distribution, any felony  
11 violation of sections 301(i) or (k) of this Act, or any  
12 felony violation of 18 U.S.C. 1365 involving a drug  
13 or biologic (relating to product tampering); or

14 “(ii) the person has engaged in a pattern of vio-  
15 lating the requirements of this section, or State re-  
16 quirements for licensure, that presents a threat of  
17 serious adverse health consequences or death to hu-  
18 mans.”.

19 (b) EFFECTIVE DATE.—The Secretary of Health and  
20 Human Services shall by regulation issue the guidelines  
21 required by section 503(e)(4) of the Federal Food, Drug,  
22 and Cosmetic Act, as amended by subsection (a), not later  
23 than 180 days after the date of the enactment of this Act.  
24 Section 503(e)(4) of such Act, as so amended, shall take  
25 effect upon the expiration of 2 years after the date such

1 regulations are promulgated. The Secretary shall by regu-  
2 lation establish conditions under which a person who is  
3 licensed by a State to engage in wholesale distribution pur-  
4 suant to guidelines set forth in part 205 of title 21 of  
5 the Code of Federal Regulations, as it existed on the date  
6 of amendment of this act, may continue such wholesale  
7 distribution if such person is unable to obtain a timely  
8 State inspection under section 503(e)(4)(C) of the Federal  
9 Food, Drug, and Cosmetic Act, as amended by subsection  
10 (a), solely because of the State’s resource limitations.

11 **SEC. 11. INJUNCTIONS; CIVIL PENALTIES.**

12 (a) INJUNCTION PROCEEDINGS.—Subsection (a) of  
13 section 302 of the Federal Food, Drug, and Cosmetic Act  
14 (21 U.S.C. 332) is amended by deleting “paragraphs (h),  
15 (i), and (j)” and inserting “paragraphs (h) and (j)”.

16 (b) CIVIL PENALTY.—Subsection (f) of section 303  
17 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C.  
18 333) is amended—

19 (1) by redesignating paragraphs (5), (6), and  
20 (7) as paragraphs (6), (7), and (8);

21 (2) by inserting after paragraph (4) the fol-  
22 lowing:

23 “(5)(A) Any person who violates paragraph (2) or (3)  
24 of section 301(i) shall be subject to a civil monetary pen-  
25 alty of not more than \$50,000 in the case of an individual

1 and \$250,000 in the case of any other person for such  
2 violation, not to exceed \$500,000 for all such violations  
3 adjudicated in a single proceeding.

4 “(B) A civil monetary penalty under this paragraph  
5 shall be paid to the United States, except that, in a pro-  
6 ceeding brought by a State under section 310(c)(1), 50  
7 percent of a civil monetary penalty under this paragraph  
8 shall be paid to the State.

9 “(C) Amounts paid to the United States under this  
10 paragraph shall be—

11 “(i) deposited in the account providing appro-  
12 priations for salaries and expenses of the Food and  
13 Drug Administration; and

14 “(ii) subject to the availability of appropria-  
15 tions, used by the Secretary to prevent and address  
16 unlawful counterfeiting and diversion of drugs, in-  
17 cluding through enforcement of paragraphs (2) and  
18 (3) of section 301(i) and investigation of potential  
19 violations of such paragraphs.

20 “(D) For fiscal year 2009 and each subsequent fiscal  
21 year, there is authorized to be appropriated to the Sec-  
22 retary for the programs and activities described in sub-  
23 paragraph (C)(ii) an amount equal to the total amount  
24 paid to the United States under this paragraph during the  
25 preceding fiscal year, to remain available until expended.”;

1           (3) in paragraph (6), as so redesignated, by  
2 striking the term “paragraph (1), (2), (3), or (4)”  
3 each place such term appears and inserting “para-  
4 graph (1), (2), (3), (4), or (5)”;

5           (4) in paragraph (7), as so redesignated, by  
6 striking “paragraph (5)(A)” and inserting “para-  
7 graph (6)(A)”;

8           (5) in paragraph (8), as so redesignated, by  
9 striking the term “paragraph (6)” each place such  
10 term appears and inserting “paragraph (7)”.

11 **SEC. 12. STATE ENFORCEMENT OF FEDERAL REQUIRE-**  
12 **MENTS.**

13           Section 310 of the Federal Food, Drug, and Cosmetic  
14 Act (21 U.S.C. 337) is amended by adding at the end the  
15 following:

16           “(c)(1) A State may bring in its own name and within  
17 its jurisdiction proceedings for the civil enforcement, or  
18 to restrain violations, of paragraph (2) or (3) of section  
19 301(i) or paragraph (1), (2), and (3) of section 503(e)  
20 if the drug or person that is the subject of the proceedings  
21 is located in the State.

22           “(2) No proceeding may be commenced by a State  
23 under paragraph (1)—

1           “(A) before 30 days after the State has given  
2 written notice to the Secretary that the State in-  
3 tends to bring such proceeding;

4           “(B) before 90 days after the State has given  
5 written notice to the Secretary of such intent if the  
6 Secretary has, within such 30 days, commenced an  
7 informal or formal enforcement action pertaining to  
8 the violation which would be the subject of such pro-  
9 ceeding; or

10           “(C) if the Secretary is diligently prosecuting a  
11 proceeding in court pertaining to the violation, has  
12 settled such proceeding, or has settled the informal  
13 or formal enforcement action pertaining to such vio-  
14 lation.”.

15 **SEC. 13. STUDY ON THREATS TO DOMESTIC PRESCRIPTION**  
16 **DRUG SUPPLY CHAIN.**

17           (a) **IN GENERAL.**—Not later than 18 months after  
18 the date of the enactment of the Safeguarding America’s  
19 Pharmaceuticals Act of 2008, the Secretary of Health and  
20 Human Services, in consultation with Federal health and  
21 security agencies including the Department of Homeland  
22 Security and the Department of Justice, shall—

23           (1) complete a study on threats to the domestic  
24 prescription drug supply chain; and

1           (2) submit a report to the Congress describing  
2           the results of the study and making recommenda-  
3           tions for improvement.

4           (b) ISSUES TO BE STUDIED.—The study conducted  
5           under this section shall address the following:

6           (1) How to improve coordination between the  
7           Food and Drug Administration (including the Office  
8           of Criminal Investigations) and the Department of  
9           Homeland Security including at the Nation’s 12  
10          international mail facilities and express carrier hubs.

11          (2) Any additional authorities needed by the  
12          Food and Drug Administration and the Department  
13          of Homeland Security in order to ensure mis-  
14          branded, adulterated, counterfeit, and unauthorized  
15          drugs are destroyed at the Nation’s international  
16          mail facilities and express carrier hubs.

17          (3) New and emerging technologies to assist  
18          with screening drug imports in a more efficient man-  
19          ner.

20          (4) The adequacy of the number of personnel  
21          within the Food and Drug Administration and the  
22          Department of Homeland Security and room for  
23          growth and improvement, including the need for ad-  
24          ditional personnel and how such additional personnel

1 should be employed at the Nation's international  
2 mail facilities and express carrier hubs.

3 (5) The potential interface among the Depart-  
4 ment of Homeland Security targeting systems (in-  
5 cluding the Automated Targeting System), the Food  
6 and Drug Administration targeting system (includ-  
7 ing the Oasis System), and express carrier targeting  
8 systems to create a unified system that—

9 (A) tracks all illegal drug imports arriving  
10 at the Nation's 12 international mail facilities  
11 and express carrier hubs; and

12 (B) provides for consultation by manufac-  
13 turers and other private entities actively in-  
14 volved in tracking counterfeit drug enterprises.

15 (6) Any additional authorities which the Food  
16 and Drug Administration and the Department of  
17 Homeland Security need to provide greater security  
18 at the Nation's borders and within the Nation  
19 against counterfeit and unapproved prescription  
20 drugs.

21 (7) How the Food and Drug Administration  
22 and the Department of Homeland Security can bet-  
23 ter coordinate with the private sector to provide  
24 greater enforcement against counterfeit prescription  
25 drugs.

1           (8) Statistically significant data calculating the  
2           percentage of drugs entering the Nation, including  
3           those entering through the Nation’s 12 international  
4           mail facilities and express carrier hubs, that are  
5           counterfeit, misbranded, adulterated, or otherwise  
6           inadmissible.

7           (c) CONSULTATION.—In conducting the study re-  
8           quired by this section, the Secretary of Health and Human  
9           Services, in consultation with the Secretary of Homeland  
10          Security, shall consult with technology developers, drug  
11          manufacturers, and other interested parties.

○