

110TH CONGRESS
2D SESSION

H. R. 5839

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

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

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.

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