I

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

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A BILL

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

Be it enacted by the Senate and House of Representatives of the United States of America in Congress assembled,

SECTION 1. SHORT TITLE.

This Act may be cited as the ''Safeguarding America's Pharmaceuticals Act of 2008''.

SEC. 2. TABLE OF CONTENTS.

The table of contents of this Act is as follows:

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Sec. 6. Prescription drug identification and tracking system.
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Sec. 11. Injunctions; civil penalties.
Sec. 12. State enforcement of Federal requirements.
Sec. 13. Study on threats to domestic prescription drug supply chain.

SEC. 3. DESTRUCTION OF COUNTERFEIT DRUGS OFFERED FOR IMPORT.

Section 801(a) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 381(a)) is amended—

(1) in the third sentence—

(A) by striking ''or (3) such'' and inserting ''(3) such''; and

(B) by inserting '', or (4) such article is a counterfeit drug,'' before ''then such article shall be refused admission''; and

(2) by striking ''Clause (2) of the third sentence of this paragraph'' and inserting ''Notwithstanding the preceding sentence, the Secretary of the Treasury shall cause the destruction of any such article refused admission if (1) the article is a drug, the article appears to be adulterated, misbranded, or in violation of section 505, and the article has a value less than $2,000 or such amount as the Secretary of Health and Human Services may determine by regulation; or (2) the article appears to be

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

SEC. 4. INTERIM PROVISIONS TO ASSURE THE SAFETY OF THE WHOLESALE DISTRIBUTION OF PRESCRIPTION DRUGS.

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

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

(2) by redesignating paragraph (2) as paragraph (4); and

(3) by inserting before paragraph (4), as so redesignated by paragraph (2) of this subsection, the following:

''(e) REGULATION OF WHOLESALE DISTRIBUTORS OF PRESCRIPTION DRUGS.—

''(1) INTERIM PROVISIONS.—

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

''(i) for purposes of this paragraph and subsection (d) only, the term 'authorized distributor of record' with respect to a prescription drug means a wholesale distributor that has a written agreement for such drug currently in effect with the

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

"(ii) the term 'co-licensed partner' means one of two or more persons who has the right to engage in the manufacturing or marketing of a prescription drug;

"(iii) the term 'dispenser' means a retail pharmacy, hospital pharmacy, or any other person authorized by law to dispense or administer prescription drugs;

"(iv) for purposes of this paragraph and subsection (d) only, the term 'manufacturer' means, with respect to a prescription drug—

"(I) the person that holds the application approved under section 505 or the license issued under section 351 of the Public Health Service Act for the drug, or if the drug is not the subject of an approved application or license, the person identified on the original label of the drug as the manufacturer, distributor, or both;

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

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

''(III) a person that manufactures the prescription drug for the person identified in subclause (I) or (II);

''(IV) a third-party logistics provider operating on behalf of the person identified in subclause (I) or (II) that obtains the drug directly from the person identified in subclause (I), (II), or (III); or

''(V) the exclusive distributor of the person identified in subclause (I) or (II) that obtains the drug directly from the person identified in subclause (I), (II), or (III);

''(v) the term 'exclusive distributor' means any person who contracts with another person to provide or coordinate warehousing, distribution, or other services on behalf of such person and who takes title to that person's prescription drug, but who does not have general responsibility to

direct the sale or disposition of that person's prescription drug;

"(vi) the term 'prescription drug' means a drug subject to subsection (b);

"(vii) the term 'third party logistics provider' means a person that, by agreement with another person, is responsible for providing or coordinating distribution, warehousing, and related services with respect to a prescription drug on behalf of that person, but that does not take title to such drug and does not have general responsibility to direct the sale or distribution of the prescription drug;

"(viii) for purposes of subsection (d) and this subsection, the term 'wholesale distribution' means the sale, purchase, trade, or delivery of a prescription drug between and within any State, but does not include—

"(I) intracompany sales, purchases, trades, or transfers of any prescription drug between members of an affiliated group (as that term is

defined in section 1504 of the Internal Revenue Code);

''(II) the purchase or other acquisition by a hospital or other health care entity that is a member of a group purchasing organization of a drug for its own use from the group purchasing organization or from other hospitals or health care entities that are members of such organizations;

''(III) the sale, purchase, or trade of a drug or an offer to sell, purchase, or trade a drug by a charitable organization to a nonprofit affiliate of the organization to the extent otherwise permitted by law;

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

''(V) the sale, purchase, or trade of a drug or an offer to sell, purchase, or trade a drug for emergency medical reasons;

''(VI) the sale, purchase, or trade of a drug, an offer to sell, purchase, or trade a drug, or the dispensing of a drug under a prescription executed in accordance with subsection (b);

''(VII) the distribution of drug samples by a manufacturer's representative or an authorized distributor of record's representative;

''(VIII) the sale, purchase, or trade of blood or blood components intended for transfusion;

''(IX) drug returns, when conducted by a dispenser or wholesale distributor in accordance with the requirements of subparagraph (D);

''(X) the sale of minimal quantities of drugs by retail pharmacies to licensed practitioners for office use; or

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

manufacturer under section 510(c) and such drug was purchased by the kit assembler directly from the manufacturer of such drug; and

"(ix) the term 'wholesale distributor' means any person engaged in wholesale distribution, except a common carrier.

"(B) MANUFACTURER PACKING LIST.—The manufacturer of a prescription drug shall provide to each wholesale distributor or dispenser to whom it delivers such drug a packing list or comparable document, in paper or electronic form, that identifies the proprietary and established names of the drug, the National Drug Code number of the drug, the strength of the drug, the container size of the drug, the number of containers of the drug, the lot number or numbers of the drug, the date of the transaction, and the names and addresses of the manufacturer and the person to whom the drug is being delivered.

"(C) STATEMENT OF DISTRIBUTION HISTORY.—Each person engaged in wholesale distribution of a prescription drug (except a manufacturer that is engaged in the wholesale dis-

tribution of a prescription drug, or a wholesale distributor on whose behalf a manufacturer delivers a prescription drug directly to a dispenser) shall provide to each wholesale distributor or dispenser to whom such person delivers such a drug before, or at the time of, each wholesale distribution, one of the following:

''(i) DIRECT PURCHASE PEDIGREE.—

''(I) If the person providing the statement is an authorized distributor of record for such drug and purchased such drug directly from the manufacturer, a statement on the invoice, whether in paper or electronic form, stating that such person is an authorized distributor of record for such drug; and such person purchased the specific unit of the prescription drug directly from the manufacturer.

''(II) If the person providing the statement is a member of the affiliated group (as that term is defined in section 1504 of the Internal Revenue Code) of an authorized distributor of

record that purchased such drug directly from the manufacturer, and such person obtained such drug from such authorized distributor of record directly or by means of one or more transactions involving only members of such affiliated group, a statement on the invoice, whether in paper or electronic form, identifying such authorized distributor of record; stating that such person is a member of the affiliated group (as that term is defined in section 1504 of the Internal Revenue Code) of such authorized distributor of record; and stating that such authorized distributor of record purchased the specific unit of the prescription drug directly from the manufacturer.

''(ii) STANDARD PEDIGREE.—For all situations not described in clause (i), a statement, whether in paper or electronic form, identifying each wholesale distribution of such drug, back to the authorized distributor of record for such drug or a

member of the affiliated group (as that term is defined in section 1504 of the Internal Revenue Code) of such authorized distributor of record that provided one of the statements described in clause (i), or, if there is no such authorized distributor of record, back to the manufacturer of such drug, and including the following:

''(I) The proprietary and established names of the drug.

''(II) The drug's National Drug Code number.

''(III) Strength.

''(IV) Container size.

''(V) Number of containers.

''(VI) The drug's lot or control number or numbers.

''(VII) The business name and address of all parties to each prior transaction involving the drug, starting with the authorized distributor of record who provided the original statement of distribution history required under clause (i) or, if there is no such authorized distributor of

record, back to the manufacturer of such drug.

''(VIII) The date of each previous transaction involving such drug, back to the authorized distributor of record who provided the original statement of distribution history required under clause (i) or, if there is no such authorized distributor of record, back to the manufacturer of such drug.

''(D) RETURNS.—

''(i) IN GENERAL.—A wholesale distributor or dispenser may return prescription drugs to a wholesale distributor, manufacturer, or a person acting on behalf of the wholesale distributor or the manufacturer, provided the requirements of clauses (ii) and (iii) are met.

''(ii) SALEABLE RETURNS.—

''(I) MISTAKEN ORDERS.—A wholesale distributor or dispenser may return to the selling wholesale distributor prescription drugs that are the result of a mistake in ordering or

shipment. For subsequent sales or trades of such returned drugs, the return of such prescription drugs is not required to be reflected in the statement pursuant to clause (i) or (ii) of subparagraph (C) provided—

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

"(bb) the return is accompanied by a certified statement, in written or electronic form, that such drug was received from the wholesale distributor to which it is being returned by mistake or ordered in error and that such drug was stored and handled under proper conditions while in the possession and control of the returning party.

"(II) OTHER RETURNS.—For returns not described in subclause (I), a wholesale distributor or dispenser may

return prescription drugs under the following conditions:

"(aa) If a prescription drug was delivered to a person with a statement in accord with subparagraph (C)(i), the drug may be returned to the wholesale distributor from which it was purchased provided it is accompanied with a certified statement, in written or electronic form, that such drug was purchased from the wholesale distributor and such drug was stored and handled under proper conditions while in the possession and control of the returning party. For subsequent sales or trades of such returned drugs, the return of such prescription drugs is not required to be reflected in the statement of distribution history required under subparagraph (C)(i).

"(bb) If a prescription drug was delivered to a person with a statement pursuant to subparagraph (C)(ii), the drug may be returned to the wholesaler from which it was purchased provided the return is accompanied by the statement that was received pursuant to subparagraph (C)(ii) and a certified statement that such drug was purchased from the wholesale distributor and was stored and handled under proper conditions while in the possession and control of the returning party. For subsequent sales or trades of such returned drugs, the return of such prescription drugs shall be reflected in the statement of distribution history required under subparagraph (C)(ii).

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

distributor or manufacturer may accept a return of a non-saleable prescription drug including, but not limited to, recalled, expired, or damaged drugs without the statement required under subparagraph (C)(i) or (C)(ii). However, such drugs may not be resold and a wholesale distributor, manufacturer, or a person acting on behalf of the wholesale distributor or manufacturer must destroy the drug.

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

''(i) maintain a list of the authorized distributors of record of such drug at its corporate offices;

''(ii) make such list publicly available, including placement on its Internet website; and

''(iii) update such list not less than once a month.

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

quirement under paragraph (3) for an effective drug identification and tracking system based on standardized numerical identifiers.''.

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

SEC. 5. UNIQUE STANDARDIZED NUMERICAL IDENTIFIERS FOR EACH PRESCRIPTION DRUG.

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

''(2) STANDARDIZED DRUG IDENTIFIERS.—

''(A) REPORT; DEVELOPMENT.—

''(i) REPORT ON PROMISING SECURITY TECHNOLOGIES.—Not later than 18 months after the date of enactment of the Safeguarding America's Pharmaceuticals Act of 2008, the Secretary shall submit to the Committee on Energy and Commerce of the House of Representatives and the Committee on Health, Education, Labor, and Pensions of the Senate a report evaluating the feasibility and operational efficiencies of adopting the security tech-

nologies including barcodes, Radio-Frequency Identification Tags, nanotechnology, or other promising track and trace technology throughout the prescription drug supply chain. The report shall assess the cost-effectiveness and benefits of applying such technologies at the pallet, case, unit, and tablet levels, including the ability to defeat repackaging, enhance product identification or validation, and improve the overall security of the prescription drug supply chain.

''(ii) CONSIDERATION.—The Secretary shall consider the findings made in the report submitted under clause (i) when developing a standard numerical identifier under section 505D(b)(2).

''(iii) ANNOUNCEMENT OF DEVELOPMENT OF STANDARDIZED NUMERICAL IDENTIFIER.—Not later than March 27, 2010, the Secretary shall announce the development of a standardized numerical identifier under section 505D(b)(2) by means of a notice published in the Federal Register.

"(B) HIGH-RISK DRUGS.—

"(i) CRITERIA; LIST.—Not later than March 27, 2010, and periodically thereafter, the Secretary shall develop, and shall notify members of the supply chain regarding, the following:

"(I) Criteria the Secretary will use to determine whether a drug is at high risk for counterfeiting or diversion.

"(II) A list identifying prescription drugs that are at high risk of diversion or counterfeiting. In developing or updating such list, the Secretary shall consult with the manufacturer of each drug involved, as well as with members of the supply chain and relevant Federal enforcement agencies, and, at least 1 year before including any drug in the list, provide the manufacturer of the drug and members of the supply chain notice of the Secretary's intent to include the drug in the list.

"(ii) REQUIREMENT.—Not later than 18 months after the date of notice in the Federal Register described in subparagraph (A)(iii), each manufacturer or repackager of a prescription drug that appears on the list of high risk drugs established under clause (i) shall apply a standardized numerical identifier that is unique to each unit (namely, a package from which the drug may be repackaged or dispensed) of the drug. The identifier shall be applied by the manufacturer or repackager (in which case the serialized number shall be linked to the numerical identifiers applied by the manufacturer).

"(C) OTHER DRUGS.—

"(i) IN GENERAL.—Each manufacturer or repackager of a prescription drug not described in subparagraph (B) shall apply a standardized numerical identifier that is unique to each unit of the drug, in accordance with a compliance timetable established by the Secretary through rulemaking under section 553 of title 5, United States Code. Such timetable may

establish different compliance dates for different types of drugs. The identifier shall be applied by the manufacturer or repackager (in which case the serialized number shall be linked to the numerical identifiers applied by the manufacturer).

''(ii) REGULATIONS.—The Secretary shall issue proposed regulations to implement this subparagraph not later than the date that is 1 year after the date of the notice in the Federal Register described in subparagraph (A)(iii), and promulgate final regulations not later than 2 years after the date of such Federal Register notice. In proposing or promulgating such regulations, the Secretary shall consult with members of the supply chain and take into account the economic and technical feasibility of compliance by manufacturers, repackagers, wholesale distributors, and dispensers and for different types of drugs. Such regulations shall not establish a compliance date for any drug that is earlier than the date that is 3 years after the date

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

''(iii) EXEMPTION FROM IDENTIFICATION REQUIREMENT.—The regulations under clause (ii) shall include a process under which a manufacturer or repackager may request an exemption from the identification requirement if it can demonstrate to the Secretary's satisfaction that—

''(I) the requirement would adversely affect the safety, effectiveness, purity, or potency of the drug or would not be technologically feasible; and

''(II) the concerns underlying the request could not reasonably be addressed by measures such as package redesign or use of overwraps.''.

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

SEC. 6. PRESCRIPTION DRUG IDENTIFICATION AND TRACKING SYSTEM.

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

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

"(3) EFFECTIVE DRUG IDENTIFICATION AND TRACKING SYSTEM.—

"(A) IN GENERAL.—The Secretary shall issue regulations to establish an effective drug identification and tracking system through which drug manufacturers, repackagers, wholesale distributors, and dispensers may authenticate the wholesale distribution history of any prescription drug that is subject to a requirement for a standardized numerical identifier under paragraph (2).

"(B) CONTENT OF REGULATIONS.—The regulations under subparagraph (A) shall—

"(i) establish standards for electronically accessible and interoperable databases through which drug manufacturers, repackagers, wholesale distributors, and dispensers may authenticate the wholesale distribution history of prescription drugs using the numerical identifiers required under paragraph (2), while maintaining the proprietary information of each entity;

"(ii) require the manufacturer or repackager of a prescription drug to apply such numerical identifier in at least 1 standardized form that is electronically readable;

"(iii) require the repackager of a prescription drug to link electronically within such databases the numerical identifier applied to the drug by the repackager to the numerical identifiers applied to the drug by the manufacturer or previous repackager;

"(iv) require each person that receives a prescription drug in wholesale distribution to authenticate the transaction history of the drug by authenticating the numerical identifier with the appropriate database; and

"(v) require protections to ensure patient privacy, in compliance with the regulations promulgated under section 264(c) of the Health Insurance Portability and Accountability Act of 1996.

"(C) ISSUANCE OF REGULATIONS.—

"(i) CONSIDERATIONS.—In developing the regulations under subparagraph (A), the Secretary shall consider the technical feasibility of compliance—

"(I) by manufacturers, repackagers, wholesale distributors, and dispensers, including small businesses; and

"(II) for different types of drugs.

"(ii) TIMING.—The Secretary shall issue proposed regulations under subparagraph (A) not later than March 31, 2010, and shall issue final regulations not later than the date that is 1 year after the date of such proposed regulations.

"(iii) COMPLIANCE DATE.—With regard to any drug, the regulations under subparagraph (A) shall not require compliance on a date that is—

"(I) earlier than 18 months or later than 2 years after the date on which such drug is subject to a requirement for the application of a standardized numerical identifier under paragraph (2)(B); or

"(II) earlier than 6 months or later than 9 months after the date on which such drug is subject to a requirement for the application of a standardized numerical identifier under paragraph (2)(C).

In determining the compliance dates of such regulations, the Secretary shall take into consideration operational and technical feasibility and provide sufficient time for inventory conversion across the supply chain.

"(D) GAO STUDY AND REPORT.—The Comptroller General of the United States shall conduct a study on the availability and cost of technologies to dispensers to comply with this subsection during the 12-month period beginning on the date of the Secretary's notice of proposed regulations under subsection (C)(ii). Not later than the end of such 12-month period, the Comptroller General shall submit to the Secretary and to the Congress a report on such study and shall include in the report recommendations to facilitate the adoption of iden-

tification and tracking system technology by dispensers.''.

SEC. 7. FACILITATING PRESCRIPTION DRUG IDENTIFICATION AND TRACKING SYSTEM FOR SMALL PHARMACIES.

(a) GRANTS FOR ADOPTION OF TECHNOLOGY.—

(1) IN GENERAL.—The Secretary of Health and Human Services shall award grants to eligible entities to facilitate the purchase and enhance the utilization of a drug identification and tracking system to ensure the security and integrity of the drug supply chain.

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

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

(B) agree to provide matching funds in accordance with paragraph (4); and

(C) be an independent pharmacy.

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

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

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

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

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

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

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

(1) a description of the financial costs and benefits of the technology system implemented and of the entities to which such costs and benefits accrue;

(2) an analysis of the impact of the grant on acquiring technology necessary to comply with section 503(e)(3) of the Federal Food, Drug, and Cosmetic Act, as amended by sections 4, 5, and 6 of this Act;

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

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

(d) DEFINITIONS.—

(1) INDEPENDENT PHARMACY.—The term ''independent pharmacy'' means a pharmacy which is not owned (or operated) by a publicly traded company.

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

(3) SECRETARY.—The term ''Secretary'' means the Secretary of Health and Human Services.

(e) AUTHORIZATION OF APPROPRIATIONS.—

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

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

SEC. 8. UNIFORM NATIONAL STANDARDS.

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

''(5) UNIFORM NATIONAL STANDARDS.—Effective 180 days after the date of enactment of the Safeguarding America's Pharmaceuticals Act of 2008, no State or political subdivision of a State may establish or continue in effect any requirement with respect to statements of distribution history, manufacturer packing lists, unique standardized numerical identifiers, or drug identification and tracking systems for prescription drugs that is different

from, or in addition to, any requirement under this subsection.''.

SEC. 9. REPORT TO CONGRESS.

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

SEC. 10. REQUIREMENTS FOR LICENSURE OF WHOLESALE DISTRIBUTORS.

(a) REQUIREMENTS.—Section 503(e)(4) of the Federal Food, Drug, and Cosmetic Act, as so redesignated by section 4(a)(2) of this Act is amended—

(1) in subparagraph (B), by striking the second sentence and inserting the following: ''Such guidelines shall prescribe requirements for—

''(i) the storage and handling of such drugs;

''(ii) the establishment and maintenance of records of the distributions of such drugs;

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

''(iv) the conduct of mandatory background checks and fingerprinting of facility manager and his or her designated representative;

''(v) the establishment and implementation of qualifications for key personnel;

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

''(vii) in accordance with subparagraph (D), the prohibition of certain persons from receiving or maintaining licensure for wholesale distribution.''; and

(2) by adding at the end the following:

''(C) The guidelines under subparagraph (B) shall include requirements for the mandatory physical inspection prior to licensure of any facility to be used, pursuant to such licensure, in wholesale distribution. Such requirements shall allow a State to accept a satisfactory inspection report from a relevant State or Federal inspection authority, or from a third party inspection or accreditation program that meets criteria and standards developed by

an advisory group consisting of representatives of the State, distributors, manufacturers, pharmacies and other stakeholders, in place of the State conducting the inspection.

''(D) The guidelines under subparagraph (B) shall include requirements to prohibit a person from receiving or maintaining licensure for wholesale distribution if the person—

''(i) has been convicted of any felony for conduct relating to wholesale distribution, any felony violation of sections 301(i) or (k) of this Act, or any felony violation of 18 U.S.C. 1365 involving a drug or biologic (relating to product tampering); or

''(ii) the person has engaged in a pattern of violating the requirements of this section, or State requirements for licensure, that presents a threat of serious adverse health consequences or death to humans.''.

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

regulations are promulgated. The Secretary shall by regulation establish conditions under which a person who is licensed by a State to engage in wholesale distribution pursuant to guidelines set forth in part 205 of title 21 of the Code of Federal Regulations, as it existed on the date of amendment of this act, may continue such wholesale distribution if such person is unable to obtain a timely State inspection under section 503(e)(4)(C) of the Federal Food, Drug, and Cosmetic Act, as amended by subsection (a), solely because of the State's resource limitations.

SEC. 11. INJUNCTIONS; CIVIL PENALTIES.

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

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

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

(2) by inserting after paragraph (4) the following:

''(5)(A) Any person who violates paragraph (2) or (3) of section 301(i) shall be subject to a civil monetary penalty of not more than $50,000 in the case of an individual

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

''(B) A civil monetary penalty under this paragraph shall be paid to the United States, except that, in a proceeding brought by a State under section 310(c)(1), 50 percent of a civil monetary penalty under this paragraph shall be paid to the State.

''(C) Amounts paid to the United States under this paragraph shall be—

''(i) deposited in the account providing appropriations for salaries and expenses of the Food and Drug Administration; and

''(ii) subject to the availability of appropriations, used by the Secretary to prevent and address unlawful counterfeiting and diversion of drugs, including through enforcement of paragraphs (2) and (3) of section 301(i) and investigation of potential violations of such paragraphs.

''(D) For fiscal year 2009 and each subsequent fiscal year, there is authorized to be appropriated to the Secretary for the programs and activities described in subparagraph (C)(ii) an amount equal to the total amount paid to the United States under this paragraph during the preceding fiscal year, to remain available until expended.'';

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

(4) in paragraph (7), as so redesignated, by striking ''paragraph (5)(A)'' and inserting ''paragraph (6)(A)''; and

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

SEC. 12. STATE ENFORCEMENT OF FEDERAL REQUIREMENTS.

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

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

''(2) No proceeding may be commenced by a State under paragraph (1)—

''(A) before 30 days after the State has given written notice to the Secretary that the State intends to bring such proceeding;

''(B) before 90 days after the State has given written notice to the Secretary of such intent if the Secretary has, within such 30 days, commenced an informal or formal enforcement action pertaining to the violation which would be the subject of such proceeding; or

''(C) if the Secretary is diligently prosecuting a proceeding in court pertaining to the violation, has settled such proceeding, or has settled the informal or formal enforcement action pertaining to such violation.''.

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

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

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

(2) submit a report to the Congress describing the results of the study and making recommendations for improvement.

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

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

(2) Any additional authorities needed by the Food and Drug Administration and the Department of Homeland Security in order to ensure misbranded, adulterated, counterfeit, and unauthorized drugs are destroyed at the Nation's international mail facilities and express carrier hubs.

(3) New and emerging technologies to assist with screening drug imports in a more efficient manner.

(4) The adequacy of the number of personnel within the Food and Drug Administration and the Department of Homeland Security and room for growth and improvement, including the need for additional personnel and how such additional personnel

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

(5) The potential interface among the Department of Homeland Security targeting systems (including the Automated Targeting System), the Food and Drug Administration targeting system (including the Oasis System), and express carrier targeting systems to create a unified system that—

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

(B) provides for consultation by manufacturers and other private entities actively involved in tracking counterfeit drug enterprises.

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

(7) How the Food and Drug Administration and the Department of Homeland Security can better coordinate with the private sector to provide greater enforcement against counterfeit prescription drugs.

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

(c) CONSULTATION.—In conducting the study required by this section, the Secretary of Health and Human Services, in consultation with the Secretary of Homeland Security, shall consult with technology developers, drug manufacturers, and other interested parties.

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