I

112TH CONGRESS
1ST SESSION

H. R. 3026

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

IN THE HOUSE OF REPRESENTATIVES

SEPTEMBER 22, 2011

Mr. MATHESON (for himself and Mr. BILBRAY) 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 2011''.

SEC. 2. TABLE OF CONTENTS.

The table of contents of this Act is as follows:

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 (2) such'' and inserting ''(2) such''; and

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

(C) by striking ''or (4) such'' and inserting ''(4) such''; and

(D) by inserting ''or (5) such article is a counterfeit drug,'' before ''then such article shall be refused admission''; and

(2) in the last sentence, 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. Before causing the destruction of an article with a value greater than $2,000 under the preceding sentence, the Secretary shall provide notice and an opportunity for an informal hearing to the owner or consignee. The Secretary of Health and Human Services shall retain a sample of any product destroyed under the seventh sentence of this subsection and shall investigate any counterfeit products so destroyed. 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 ''(e)(1)(A)'' and all that follows through the end of paragraph (1) and inserting the following:

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

(2) by striking paragraph (3);

(3) by redesignating paragraph (2) as paragraph (4) and moving the margin of such paragraph 2 ems to the right; and

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

''(1) INTERIM PROVISIONS.—

''(A) DEFINITIONS.—Except as otherwise provided, 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 distribution 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 au-

thorized 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.—Subject to the succeeding provisions of this subparagraph, 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.

"(ii) DRUGS.—Any return of a drug to a distributor, manufacturer, or other person under clause (i) shall be documented on the same pedigree as the transaction that resulted in the receipt of the drug by the wholesale distributor or dispenser returning it.

"(iii) EXCEPTION.—Clause (i) shall not apply to the sale or transfer from a retail pharmacy, mail order pharmacy, or non-wholesaling pharmacy warehouse of expired, damaged, returned, or recalled prescription drugs to the original manufac-

turer, the originating wholesaler, or to a third party returns processor.

''(iv) TERMS AND CONDITIONS.—A wholesaler or manufacturer shall receive prescription drug returns from a pharmacy or other person authorized to administer or dispense drugs or non-wholesaling pharmacy warehouse pursuant to the terms and condition of the agreement between the wholesaler or manufacturer and the pharmacy or non-wholesaling pharmacy warehouse. Returns of expired, damaged, recalled, or otherwise non-saleable pharmaceutical products shall be distributed by the receiving wholesaler only to either the original manufacturer or a third party returns processor. Returns of prescription drugs, saleable or otherwise, shall not be subject to clause (ii) so long as they are also exempt from the pedigree requirement of the most current applicable prescription drug marketing guidance of the Food and Drug Administration. Both licensees under this Act and pharmacies or other persons authorized to administer or dispense pre-

scription drugs shall be accountable for administering their returns process and ensuring that the aspects of this operation are secure and do not permit the entry of unadulterated, counterfeit, or misbranded product into the prescription drug supply chain.

''(E) LIST OF AUTHORIZED DISTRIBUTORS OF RECORD.—Each manufacturer described in subclause (I) or (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 requirement under paragraph (3) for an effective drug identification and tracking system based on standardized numerical identifiers.''.

(b) EFFECTIVE DATE.—The amendments 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) ANNOUNCEMENT OF DEVELOPMENT OF STANDARDIZED NUMERICAL IDENTIFIER.—Not later than March 27, 2012, 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) REQUIREMENT.—

"(i) IN GENERAL.—Except as provided in subparagraph (C), each manufacturer or repackager of a prescription drug shall apply in accordance with this subparagraph 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—

"(I) to at least 50 percent of its drugs not later than January 1, 2015; and

"(II) to all of its drugs not later than January 1, 2016.

"(ii) APPLICATION OF IDENTIFIER.—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). Each manufacturer shall notify the Food and Drug Administration of the serialized drugs and the measures used in designating its drugs to be serialized and shall include in the notification the technology to be used for the standardized numerical identifier.

"(iii) METHODOLOGY FOR APPLYING 50 PERCENT TEST.—The manufacturer or repackager shall elect, and notify the Secretary, of which of the following 3 methods the manufacturer or repackager will use

for applying the 50 percent requirement of clause (i)(I):

"(I) Unit volume.

"(II) Product package (SKU) type.

"(III) Drug product family.

"(C) EXCEPTION.—The requirement of subparagraph (B) shall not apply to the following classes of prescription drugs:

"(i) Radioactive drugs or radioactive biological products (as defined in section 600.3(ee) of title 21, Code of Federal Regulations) which are regulated by the Nuclear Regulatory Commission.

"(ii) Intravenous products used to maintain the equilibrium of water and minerals in the body.

"(iii) Drugs that are placed in a sealed package with a medical device or medical supplies at the point of first shipment into commerce by the manufacturer if—

"(I) the package remains sealed until the drug or device is used; and

''(II) the drugs and the device or supplies are used only for surgical purposes.

''(iv) Products that are intended for irrigation or reconstitution, as well as sterile water, whether intended for those purposes or for injection.

''(v) Intravenous products that, by their formulation, are intended for the replenishment of fluids and electrolytes, such as sodium, chloride, and potassium, calories, such as dextrose and amino acids, or both.

''(D) SECRETARIAL WAIVER AUTHORITY IN CASE OF PUBLIC HEALTH EMERGENCIES.—The Secretary of Health and Human Services may waive the application of the requirement of subparagraph (B) in the case of a public health emergency.''.

(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;

''(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; and

''(vi) define the circumstances under which participants in the pharmaceutical supply chain may infer the contents of a case, pallet, or other aggregate of individual units, packages, or containers of drugs, from a unique identifier associated with the case, pallet, or other aggregate, without opening each case, pallet, or other aggregate or otherwise individually authenticating each unit.

''(C) ISSUANCE OF REGULATIONS.—

''(i) TIMING.—The Secretary shall issue proposed regulations under subparagraph (A) not later than 18 months after the date of the enactment of this paragraph. In determining such regulations, the Secretary shall provide sufficient time for inventory conversion across the supply chain.

''(ii) REQUIREMENTS.—With regard to any drug, the regulations under subparagraph (A) shall be required for—

''(I) any wholesaler or repackager beginning on July 1, 2016; and

''(II) for any pharmacy beginning on July 1, 2017.

''(D) EXCEPTION.—The tracking system under subparagraph (A) shall not apply to drugs that are transferred between Federal, State, or local governments which are authorized by Federal law to distribute such drugs.

''(E) PRESIDENTIAL WAIVER AUTHORITY IN CASE OF PUBLIC HEALTH EMERGENCIES.—The President may waive the application of the tracking system under subparagraph (A) in the case of a public health emergency.''.

SEC. 7. 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 2011, 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 track-

ing systems for prescription drugs that is different from, or in addition to, any requirement under this subsection.''.

SEC. 8. 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)(3) 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; and

''(vi) 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 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.

SEC. 9. 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) through (9) as paragraphs (6) through (10), respectively;

(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 2012 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), (4),'' each place such term appears and inserting ''paragraph (1), (2), (3), (4), (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. 10. 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. 11. 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 2011, 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 mis-

branded, adulterated, and counterfeit drugs and drugs in violation of section 505 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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