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REPORT
113–93

SAFEGUARDING AMERICA'S PHARMACEUTICALS ACT OF 2013

JUNE 3, 2013.—Committed to the Committee of the Whole House on the State of the Union and ordered to be printed

Mr. UPTON, from the Committee on Energy and Commerce, submitted the following

R E P O R T

together with

DISSENTING VIEWS

[To accompany H.R. 1919]

[Including cost estimate of the Congressional Budget Office]

The Committee on Energy and Commerce, to whom was referred the bill (H.R. 1919) to amend the Federal Food, Drug, and Cosmetic Act with respect to the pharmaceutical distribution supply chain, and for other purposes, having considered the same, report favorably thereon with an amendment and recommend that the bill as amended do pass.

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29–006

The amendment is as follows:

Strike all after the enacting clause and insert the following:

SECTION 1. SHORT TITLE.

(a) SHORT TITLE.—This Act may be cited as the "Safeguarding America's Pharmaceuticals Act of 2013".

(b) TABLE OF CONTENTS.—The table of contents of this Act is as follows:

SEC. 2. PHARMACEUTICAL DISTRIBUTION SUPPLY CHAIN.

Chapter V of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 351 et seq.) is amended by adding at the end the following:

"Subchapter H—Pharmaceutical Distribution Supply Chain

"SEC. 581. DEFINITIONS.

"In this subchapter:

"(1) AUTHORIZED.—The term 'authorized' means—

"(A) in the case of a manufacturer or repackager, having a valid registration in accordance with section 510; and

"(B) in the case of a wholesale distributor, third-party logistics provider, or dispenser, licensed (as defined in this section).

"(2) DISPENSER.—The term 'dispenser'—

"(A) subject to subparagraph (C), means a retail pharmacy, hospital pharmacy, a group of chain pharmacies under common ownership and control, or any other person authorized by law to dispense or administer prescription drugs, to the extent such pharmacy, group, or person does not act as a wholesale distributor;

"(B) includes warehouses and distribution centers under common ownership or control of entities described in subparagraph (A) that are members of an affiliated group pursuant to section 1504(a) of the Internal Revenue Code of 1986, to the extent such warehouses and distribution centers do not act as a wholesale distributor; and

"(C) does not include a person who only dispenses prescription drug product to be used in animals in accordance with section 512(a)(5).

"(3) DISPOSITION.—The term 'disposition', with respect to a prescription drug product within the possession and control of an entity—

"(A) means the removal of such prescription drug product, or taking measures to prevent the introduction of such prescription drug product, from the pharmaceutical distribution supply chain; and

"(B) may include disposal, return of the prescription drug product for disposal, or other appropriate handling and other actions such as retaining a sample of the prescription drug product for additional physical examination or laboratory analysis by a manufacturer or regulatory or law enforcement agency.

"(4) DISTRIBUTE OR DISTRIBUTION.—The terms 'distribute' and 'distribution' mean the sale, purchase, trade, delivery, handling, or storage of a prescription drug product.

"(5) ILLEGITIMATE PRESCRIPTION DRUG PRODUCT.—The term 'illegitimate prescription drug product' means a prescription drug product which a manufacturer has confirmed—

"(A) is counterfeit, diverted, or stolen;

"(B) is intentionally adulterated such that the prescription drug product would result in serious adverse health consequences or death to humans; or

"(C) is otherwise unfit for distribution such that the prescription drug product is reasonably likely to cause serious adverse human health consequences or death.

"(6) LICENSED.—The term 'licensed' means—

"(A) in the case of a wholesale distributor, having a valid license to make wholesale distributions consistent with the standards under section 583;

"(B) in the case of a third-party logistics provider, having a valid license to engage in the activities of a third-party logistics provider in accordance with section 584; and

"(C) in the case of a dispenser, having a valid license to dispense prescription drugs under State law.

"(7) MANUFACTURER.—The term 'manufacturer' means, with respect to a prescription drug product—

"(A) a person that holds an application approved under section 505 or a license issued under section 351 of the Public Health Service Act for such prescription drug product, or if such prescription drug product is not the subject of an approved application or license, the person who manufactured the prescription drug product;

"(B) a co-licensed partner of the person described in subparagraph (A) that obtains the prescription drug product directly from the person described in such subparagraph; or

"(C) a person that—

"(i) is a member of an affiliated group (as defined in section 1504(a) of the Internal Revenue Code of 1986) to which a person described in subparagraph (A) or (B) is also a member; and

"(ii) receives the prescription drug product directly from a person described in subparagraph (A) or (B).

"(8) PACKAGE.—

"(A) IN GENERAL.—The term 'package' means the smallest individual saleable unit of prescription drug product for distribution in interstate commerce by a manufacturer or repackager that is intended by the manufacturer for ultimate sale to the dispenser of such prescription drug product.

"(B) INDIVIDUAL SALEABLE UNIT.—The term 'individual saleable unit' means the smallest container of prescription drug product introduced into interstate commerce by the manufacturer or repackager that is intended by the manufacturer for individual sale to a dispenser.

"(9) PRESCRIPTION DRUG.—The term 'prescription drug' means a drug for human use subject to section 503(b)(1).

"(10) PRESCRIPTION DRUG PRODUCT.—The term 'prescription drug product' means a prescription drug in a finished dosage form for administration to a patient without substantial further manufacturing (such as capsules, tablets, and lyophilized prescription drug products before reconstitution).

"(11) PRESCRIPTION DRUG PRODUCT IDENTIFIER.—The term 'prescription drug product identifier' means a standardized graphic that—

"(A) includes the standardized numerical identifier, lot number, and expiration date of a prescription drug product; and

"(B) is in both human-readable form and on a machine-readable data carrier that conforms to the standards developed by a widely recognized international standards development organization.

"(12) QUARANTINE.—The term 'quarantine' means to store or identify a product, for the purpose of preventing distribution or transfer of the product, in a physically separate area clearly identified for such use, or through use of other procedures such as automated designation.

"(13) REPACKAGER.—The term 'repackager' means a person who owns or operates an establishment that repacks and relabels a prescription drug product or package for further sale or distribution.

"(14) RETURN.—The term 'return' means providing prescription drug product to the authorized trading partner or trading partners from which such prescription drug product was purchased or received, or to a returns processor for handling of such prescription drug product.

"(15) RETURNS PROCESSOR.—The terms 'returns processor' mean a person who owns or operates an establishment that provides for the disposition of or otherwise processes saleable and nonsaleable prescription drug product received from an authorized trading partner such that the prescription drug product may be processed for credit to the purchaser, manufacturer, seller, or disposed of for no further distribution.

"(16) SPECIFIC PATIENT NEED.—The term 'specific patient need'—

"(A) means with respect to the transfer of a prescription drug product from one pharmacy to another, to fill a prescription for an identified patient; and

"(B) does not include the transfer of a prescription drug product from one pharmacy to another for the purpose of increasing or replenishing stock in anticipation of a potential need.

"(17) STANDARDIZED NUMERICAL IDENTIFIER.—The term 'standardized numerical identifier' means a set of numbers or characters that—

"(A) is used to uniquely identify each package or homogenous case of the prescription drug product; and

"(B) is composed of the National Drug Code that corresponds to the specific prescription drug product (including the particular package configuration) combined with a unique alphanumeric serial number of up to 20 characters.

"(18) SUSPECT PRESCRIPTION DRUG PRODUCT.—The term 'suspect prescription drug product' means a prescription drug product for which there is reason to believe that such prescription drug product—

"(A) is potentially counterfeit, diverted, or stolen;

"(B) is potentially intentionally adulterated such that the prescription drug product would result in serious adverse health consequences or death to humans; or

"(C) appears otherwise unfit for distribution such that the prescription drug product would result in serious adverse health consequences or death to humans.

"(19) THIRD-PARTY LOGISTICS PROVIDER.—The term 'third-party logistics provider' means an entity that provides or coordinates warehousing, distribution, or other logistics services of a prescription drug product in interstate commerce on behalf of a manufacturer, wholesale distributor, or dispenser of a prescription drug product, but does not take ownership of the prescription drug product, nor have responsibility to direct the sale or disposition of, the prescription drug product.

"(20) TRADING PARTNER.—The term 'trading partner' means—

"(A) a manufacturer, repackager, wholesale distributor, or dispenser from whom a manufacturer, repackager, wholesale distributor, or dispenser accepts ownership of a prescription drug product or to whom a manufacturer, repackager, wholesale distributor, or dispenser transfers ownership of a prescription drug product; or

"(B) a third-party logistics provider from whom a manufacturer, repackager, wholesale distributor, or dispenser accepts possession of a prescription drug product or to whom a manufacturer, repackager, wholesale distributor, or dispenser transfers possession of a prescription drug product.

"(21) TRANSACTION.—

"(A) IN GENERAL.—The term 'transaction' means the transfer in interstate commerce of prescription drug product between persons in which a change of ownership occurs.

"(B) EXEMPTIONS.—The term 'transaction' does not include—

"(i) intracompany distribution of any prescription drug product, including between members of an affiliated group (as defined in section 1504(a) of the Internal Revenue Code of 1986);

"(ii) the distribution of a prescription drug product among hospitals or other health care entities that are under common control;

"(iii) the distribution of a prescription drug product for emergency medical reasons including a public health emergency declaration pursuant to section 319 of the Public Health Service Act, except that a drug shortage not caused by a public health emergency shall not constitute an emergency medical reason;

"(iv) the dispensing of a prescription drug product pursuant to a valid prescription executed in accordance with section 503(b)(1);

"(v) the distribution of prescription drug product samples by a manufacturer or a licensed wholesale distributor in accordance with section 503(d);

"(vi) the distribution of blood or blood components intended for transfusion;

"(vii) the distribution of minimal quantities of prescription drug product by a licensed retail pharmacy to a licensed practitioner for office use;

"(viii) the distribution of a prescription drug product by a charitable organization to a nonprofit affiliate of the organization to the extent otherwise permitted by law;

"(ix) the distribution of a prescription drug product pursuant to the sale or merger of a pharmacy or pharmacies or a wholesale distributor or wholesale distributors, except that any records required to be maintained for the prescription drug product shall be transferred to the new owner of the pharmacy or pharmacies or wholesale distributor or wholesale distributors;

"(x) the dispensing of a prescription drug product approved under section 512(b);

"(xi) the transfer of prescription drug products to or from any facility that is licensed by the Nuclear Regulatory Commission or by a State pursuant to an agreement with such Commission under section 274 of the Atomic Energy Act of 1954 (42 U.S.C. 2021);

"(xii) the distribution of a combination product that consists of—

"(I) a product comprised of two or more components that are each a drug, biological product, or device and that are physically, chemically, or otherwise combined or mixed and produced as a single entity;

"(II) two or more separate products packaged together in a single package or as a unit and comprised of a drug and device or a device and biological product; or

"(III) two or more finished devices plus one or more drug or biological products which are packaged together in a medical convenience kit described in clause (xiv);

"(xiii) the distribution of a medical convenience kit which is a collection of finished products (consisting of devices or drugs) assembled in kit form strictly for the convenience of the purchaser or user if—

"(I) the medical convenience kit is assembled in an establishment that is registered with the Food and Drug Administration as a medical device manufacturer;

"(II) the person who manufacturers the medical convenience kit purchased the prescription drug product directly from the manufacturer or from a wholesale distributor that purchased the prescription drug product directly from the manufacturer;

"(III) the person who manufacturers the medical convenience kit does not alter the primary container or label of the prescription drug product as purchased from the manufacturer or wholesale distributor;

"(IV) the medical convenience kit does not contain a controlled substance (as defined in section 102 of the Controlled Substances Act); and

"(V) the prescription drug products contained in the medical convenience kit are—

"(aa) intravenous solutions intended for the replenishment of fluids and electrolytes;

"(bb) drugs intended to maintain the equilibrium of water and minerals in the body;

"(cc) drugs intended for irrigation or reconstitution;

"(dd) anesthetics;

"(ee) anticoagulants;

"(ff) vasopressors; or

"(gg) sympathicomimetics;

"(xiv) the distribution of an intravenous prescription drug product that, by its formulation, is intended for the replenishment of fluids and electrolytes (such as sodium, chloride, and potassium) or calories (such as dextrose and amino acids);

"(xv) the distribution of an intravenous prescription drug product used to maintain the equilibrium of water and minerals in the body, such as dialysis solutions;

"(xvi) the distribution of a prescription drug product that is intended for irrigation or reconstitution, or sterile water, whether intended for such purposes or for injection;

"(xvii) the distribution of compressed medical gas; or

"(xviii)(I) the distribution of a product by a dispenser, or a wholesale distributor acting at the direction of the dispenser, to a repackager registered under section 510 for the purpose of repackaging the drug for use by that dispenser or another health care entity that is under the dispenser's ownership or control, so long as the dispenser retains ownership of the prescription drug product; and

"(II) the saleable or nonsaleable return by such repackager of such prescription drug product.

"(C) COMPRESSED MEDICAL GAS.—For purposes of subparagraph (B)(xviii), the term 'compressed medical gas' means any substance in its gaseous or cryogenic liquid form that meets medical purity standards and has application in a medical or homecare environment, including oxygen and nitrous oxide.

"(22) TRANSACTION HISTORY.—The term 'transaction history' means a statement that—

"(A) includes the transaction information for each transaction conducted with respect to a prescription drug product beginning with the manufacturer or initial purchase distributor for each prior transaction going back to the manufacturer of the prescription drug product or to the initial purchase distributor; and

"(B) is in paper or electronic form.

"(23) TRANSACTION INFORMATION.—The term 'transaction information' means—

"(A) the proprietary or established name or names of the prescription drug product;

"(B) the strength and dosage form of the prescription drug product;

"(C) the National Drug Code number of the prescription drug product;

"(D) the container size;

"(E) the number of containers;

"(F) the lot number of the prescription drug product;

"(G) the date of the transaction;

"(H) the business name and address of the person from whom ownership is being transferred; and

"(I) the business name and address of the person to whom ownership is being transferred.

"(24) TRANSACTION STATEMENT.—The 'transaction statement' is a statement, which states that the manufacturer, repackager, wholesale distributor, third-party logistics provider, or dispenser transferring ownership in a transaction—

"(A) is authorized;

"(B) received transaction information and a transaction statement as required under section 582 from the prior owner of the prescription drug product;

"(C) did not knowingly and intentionally ship an illegitimate prescription drug product;

"(D) did not knowingly and intentionally provide false transaction information; and

"(E) did not knowingly and intentionally alter the transaction history.

"(25) VERIFICATION AND VERIFY.—The terms 'verification' and 'verify'—

"(A) mean determining whether the prescription drug product identifier affixed to, or imprinted upon, a package or homogeneous case of the prescription drug product corresponds to the standardized numerical identifier or lot number, and expiration date assigned to the prescription drug product by the manufacturer or the repackager, as applicable; and

"(B) include making the determination under subparagraph (A) using human-readable or machine-readable methods.

"(26) WHOLESALE DISTRIBUTOR.—The term 'wholesale distributor'—

"(A) means a person engaged in wholesale distribution (as defined in section 583); and

"(B) excludes—

"(i) a manufacturer, a co-licensed partner of a manufacturer, or a third-party logistics provider, or a dispenser who does not engage in such wholesale distribution;

"(ii) a repackager engaged in such wholesale distribution; or

"(iii) the distribution of prescription drug product or an offer to distribute prescription drug product by an authorized repackager that has taken ownership or possession of the prescription drug product and repacked the prescription drug product in accordance with the requirements of section 582(e).

"SEC. 582. REQUIREMENTS.

"(a) IN GENERAL.—

"(1) COMPLIANCE REQUIRED.—An entity that is a manufacturer, repackager, wholesale distributor, third-party logistics provider, or dispenser shall comply with the requirements of this section. If an entity meets the definition of more than one of the entities referred to in the preceding sentence, such entity shall comply with all applicable requirements of this section, but shall not be required to comply with duplicative requirements.

"(2) STANDARDS.—The Secretary shall, in consultation with other appropriate Federal officials, manufacturers, repackagers, wholesale distributors, third-party logistics providers, and dispensers, establish, by regulation, standards for the exchange of transaction information for purposes of complying with this section. The standards established under this paragraph shall be in accordance

with a form developed by a widely recognized international standards development organization. In establishing such standards, the Secretary shall consider the feasibility of establishing standardized documentation to be used by all members of the pharmaceutical distribution supply chain to convey the transaction history and transaction statement to the subsequent owner of a prescription drug product. The Secretary shall publish such standards not later than 180 days after the date of the enactment of the Safeguarding America's Pharmaceuticals Act of 2013.

"(3) WAIVERS, EXCEPTIONS, AND EXEMPTIONS.—Not later than one year after the date of the enactment of the Safeguarding America's Pharmaceuticals Act of 2013, the Secretary shall promulgate a regulation to—

"(A) establish a process by which the Secretary may grant, at the request of an authorized manufacturer, repackager, wholesale distributor, or dispenser, a waiver from any of the requirements of this section—

"(i) if the Secretary determines that such requirements would result in an undue economic hardship; or

"(ii) for emergency medical reasons, including a public health emergency declaration pursuant to section 319 of the Public Health Service Act;

"(B) establish a process, with respect to the prescription drug product identifier requirement under paragraph (2) of subsections (b), (c), (d), and (e) through which—

"(i) a manufacturer or repackager may request a waiver with respect to prescription drug products that are packaged in a container too small or otherwise unable to accommodate a label with sufficient space to bear the information required for compliance with such requirement; and

"(ii) the Secretary determines whether to waive such requirement; and

"(C) establish a process by which the Secretary may add the prescription drug products or transactions that are exempt from the requirements of this section.

"(4) GRANDFATHERED PERSONS AND PRESCRIPTION DRUG PRODUCTS.—

"(A) IN GENERAL.—Not later than one year after the date of the enactment of the Safeguarding America's Pharmaceuticals Act of 2013, the Secretary shall specify, by regulation, whether and under what circumstances the prescription drug product identifier requirement under paragraph (2) of subsections (b), (c), (d), and (e) shall apply to a prescription drug product that is in the supply chain or in a manufacturer's inventory on the date of the enactment of the Safeguarding America's Pharmaceuticals Act of 2013.

"(B) THIRD-PARTY LOGISTICS PROVIDER LICENSES.—Until the date that is 1 year after the effective date of the third-party logistics provider licensing requirements under section 584, a third-party logistics provider shall be considered 'licensed' under section 581(6)(B) unless the Secretary has made a finding that the third-party logistics provider does not utilize good handling and distribution practices and publishes notice thereof.

"(C) LABEL CHANGES.—Changes made to package labels solely to incorporate the prescription drug product identifier may be submitted to the Secretary in the annual report of an establishment, in accordance with section 314.70(d) of chapter 21, Code of Federal Regulations (or any successor regulation).

"(b) MANUFACTURER REQUIREMENTS.—

"(1) PRESCRIPTION DRUG PRODUCT TRACING.—

"(A) IN GENERAL.—Beginning not later than January 1, 2015, a manufacturer shall—

"(i) prior to, or at the time of, each transaction in which such manufacturer transfers ownership of a prescription drug product, provide the subsequent owner with the transaction history and a transaction statement; and

"(ii) maintain the transaction information for each such transaction for not less than 3 years after the date of the transaction.

"(B) REQUESTS FOR INFORMATION.—Upon a request by the Secretary or other appropriate Federal or State official, in the event of a recall or for the purpose of investigating a suspect prescription drug product or an illegitimate prescription drug product, a manufacturer shall, not later than 2 business days after receiving the request or in such reasonable time as determined by the Secretary, provide to the Secretary or other official, the applicable transaction history and transaction statement for the prescription drug product.

"(2) PRESCRIPTION DRUG PRODUCT IDENTIFIER.—Beginning not later than 5 years after the date of the enactment of the Safeguarding America's Pharmaceuticals Act of 2013, a manufacturer shall affix or imprint a prescription drug product identifier on each package and homogenous case of a prescription drug product intended to be introduced in a transaction. Such manufacturer shall maintain the information in the prescription drug product identifier for such prescription drug product for not less than 3 years after the date of the transaction.

"(3) AUTHORIZED TRADING PARTNERS.—Beginning not later than January 1, 2015, a manufacturer shall ensure that each of its trading partners is authorized.

"(4) LIST OF AUTHORIZED DISTRIBUTORS OF RECORD.—Beginning not later than January 1, 2015, each manufacturer of a prescription drug shall—

"(A) maintain a list of the authorized distributors of record of such drug at the corporate offices of such manufacturer;

"(B) make such list publicly available, including placement on the Internet Website of such manufacturer; and

"(C) update such list not less than once per quarter.

"(5) VERIFICATION.—Beginning not later than January 1, 2015, a manufacturer shall implement systems and processes to enable the manufacturer to comply with the following requirements:

"(A) SUSPECT PRESCRIPTION DRUG PRODUCT.—

"(i) IN GENERAL.—Upon making a determination that a prescription drug product in the possession or control of the manufacturer is a suspect prescription drug product, or upon receiving a request for verification from the Secretary that a prescription drug product within the possession or control of a manufacturer is a suspect prescription drug product, a manufacturer shall promptly conduct an investigation in coordination with trading partners, as applicable, to determine whether the prescription drug product is an illegitimate prescription drug product. Beginning not later than 5 years after the date of the enactment of the Safeguarding America's Pharmaceuticals Act of 2013, such investigation shall include—

"(I) verifying the prescription drug product at the package level;

"(II) validating any applicable transaction history in the possession of the manufacturer; and

"(III) otherwise investigating to determine whether the prescription drug product is an illegitimate prescription drug product.

"(ii) CLEARED PRESCRIPTION DRUG PRODUCT.—If the manufacturer determines that a suspect prescription drug product is not an illegitimate prescription drug product, the manufacturer shall promptly notify the Secretary of such determination and such prescription drug product may be further distributed.

"(iii) RECORDS.—A manufacturer shall keep records of its investigation of a suspect prescription drug product for not less than 3 years after the conclusion of the investigation.

"(B) ILLEGITIMATE PRESCRIPTION DRUG PRODUCT.—

"(i) IN GENERAL.—Upon determining that a prescription drug product in the possession or control of a manufacturer is an illegitimate prescription drug product, the manufacturer shall—

"(I) quarantine such prescription drug product from prescription drug product intended for distribution; and

"(II) provide for the disposition of the illegitimate prescription drug product.

"(ii) TRADING PARTNER.—Upon determining that a prescription drug product in the possession or control of a trading partner is an illegitimate prescription drug product, the manufacturer shall take reasonable steps to assist a trading partner to provide for the disposition of the illegitimate prescription drug product.

"(iii) MAKING A NOTIFICATION.—Upon determining that a prescription drug product in the possession or control of the manufacturer is an illegitimate prescription drug product, the manufacturer shall notify the Secretary of such determination not later than 24 hours after making such determination. The Secretary shall determine whether additional trading partner notification is appropriate.

"(iv) RESPONDING TO A NOTIFICATION.—Upon the receipt of a notification from the Secretary that a determination has been made that a prescription drug product is an illegitimate prescription drug product, a manufacturer shall—

"(I) identify all illegitimate prescription drug products that are subject to such notification and in the possession or control of the manufacturer, including any prescription drug product that is subsequently received; and

"(II) perform the activities described in clause (i).

"(v) RECORDS.—A manufacturer shall keep records of the disposition of an illegitimate prescription drug product for not less than 3 years after the conclusion of the disposition.

"(C) ELECTRONIC DATABASE.—A manufacturer may satisfy the requirements of this paragraph through the use of a secure electronic database developed and operated by the manufacturer or another entity. The owner of such database shall establish the requirements and processes to respond to requests and may provide for data access to other members of the pharmaceutical distribution supply chain, as appropriate. The development and operation of such a database shall not relieve a manufacturer of the requirement under this paragraph to respond to a verification request submitted by means other than a secure electronic database.

"(D) RETURNED PRESCRIPTION DRUG PRODUCT.—Beginning not later than 5 years after the date of the enactment of the Safeguarding America's Pharmaceuticals Act of 2013, upon receipt of a returned prescription drug product that the manufacturer intends to further distribute, before further distributing such prescription drug product, the manufacturer shall—

"(i) verify the prescription drug product identifier for each sealed homogeneous case of such prescription drug product; or

"(ii) if such prescription drug product is not in a sealed homogeneous case, verify the prescription drug product identifier on each package.

"(c) WHOLESALE DISTRIBUTOR REQUIREMENTS.—

"(1) PRESCRIPTION DRUG PRODUCT TRACING.—

"(A) IN GENERAL.—Beginning not later than April 1, 2015, a wholesale distributor shall—

"(i) not accept ownership of a prescription drug product unless the previous owner prior to, or at the time of, the transaction provides the applicable transaction history and a transaction statement for the prescription drug product;

"(ii) prior to, or at the time of, each transaction in which the wholesale distributor transfers ownership of a prescription drug product—

"(I) in the case that the wholesale distributor purchased the prescription drug product directly from the manufacturer, provide the subsequent owner with transaction history and a transaction statement for the prescription drug product; or

"(II) in the case that the wholesale distributor did not purchase the prescription drug product directly from the manufacturer, the exclusive distributor of the manufacturer, or a repackager that purchased directly from the manufacturer, provide the subsequent owner with transaction history beginning with the wholesale distributor that did purchase the product directly from the manufacturer, the exclusive distributor of the manufacturer, or a repackager that purchased directly from the manufacturer;

"(iii) notwithstanding clause (ii), if the wholesale distributor purchased the prescription drug product directly from the manufacturer, its exclusive distributor, or a repackager that purchased directly from the manufacturer or its authorized distributor of record—

"(I) provide an initial purchase transaction statement on the invoice to the customer, stating that the wholesale distributor purchased the prescription drug product package directly from the manufacturer, exclusive distributor, or repackager;

"(II) make available to the immediate subsequent recipient of such prescription drug product the information required under clause (ii) through any combination of self-generated paper, electronic data, or manufacturer-provided information on the prescription drug product package; and

"(III) for purposes of subclauses (I) and (II), need not include any transactions occurring before the transfer of the prescription drug product to the wholesale distributor; and

"(iv) maintain the transaction information for each transaction described in clauses (i) and (ii) for not less than 3 years after the transaction.

"(B) RETURNS EXCEPTION.—

"(i) SALEABLE RETURNS.—Notwithstanding subparagraph (A), a wholesale distributor may—

"(I) accept returned prescription drug product without a transaction history from a dispenser or repackager; and

"(II) distribute such returned prescription drug product with a transaction history that begins with the wholesale distributor that so accepted the returned product.

"(ii) NONSALEABLE RETURNS.—A wholesale distributor may return a nonsaleable prescription drug to the manufacturer or repackager, to the wholesale distributor from whom such prescription drug was purchased, or to a person acting on behalf of such a person, including a returns processor, without providing the information required under subparagraph (A).

"(C) REQUESTS FOR INFORMATION.—Upon a request by the Secretary or other appropriate Federal or State official, in the event of a recall or for the purpose of investigating a suspect prescription drug product or an illegitimate prescription drug product a wholesale distributor shall, not later than 2 business days after receiving the request or in such other reasonable time as determined by the Secretary, provide the applicable transaction history and transaction statements for the prescription drug product.

"(2) PRESCRIPTION DRUG PRODUCT IDENTIFIER.—Beginning not later than 7 years after the date of the enactment of the Safeguarding America's Pharmaceuticals Act of 2013, a wholesale distributor may engage in transactions involving a prescription drug product only if such prescription drug product is encoded with a prescription drug product identifier, except as provided in subsection (a)(4).

"(3) AUTHORIZED TRADING PARTNERS.—Beginning not later than January 1, 2015, a wholesale distributor shall ensure that each of its trading partners is authorized.

"(4) VERIFICATION.—Beginning not later than April 1, 2015, a wholesale distributor shall implement systems to enable the wholesale distributor to comply with the following requirements:

"(A) SUSPECT PRESCRIPTION DRUG PRODUCT.—

"(i) IN GENERAL.—Upon making a determination that a prescription drug product in the possession or control of the wholesale distributor is a suspect prescription drug product, or upon receiving a request for verification from the Secretary that a prescription drug product within the possession or control of a wholesale distributor is a suspect prescription drug product, a wholesale distributor shall promptly conduct an investigation to determine whether the prescription drug product is an illegitimate prescription drug product. Beginning not later than 7 years after the date of the enactment of the Safeguarding America's Pharmaceuticals Act of 2013, such investigation shall include—

"(I) verifying a package of the prescription drug product;

"(II) validating any applicable transaction history in the possession of the wholesale distributor; and

"(III) otherwise investigating to determine whether the prescription drug product is an illegitimate prescription drug product.

"(ii) CLEARED PRESCRIPTION DRUG PRODUCT.—If the wholesale distributor determines that a suspect prescription drug product is not an illegitimate prescription drug product, the wholesale distributor shall promptly notify the Secretary of such determination and such prescription drug product may be further distributed.

"(iii) RECORDS.—A wholesale distributor shall keep records of its investigation of a suspect prescription drug product for not less than 3 years after the conclusion of the investigation.

"(B) ILLEGITIMATE PRESCRIPTION DRUG PRODUCT.—

"(i) IN GENERAL.—Upon receiving notice that a manufacturer of a prescription drug product has determined that a prescription drug product in the possession or control of a wholesale distributor is an illegitimate prescription drug product, the wholesale distributor shall—

"(I) quarantine such prescription drug product within the possession or control of the wholesale distributor from prescription drug product intended for distribution; and

"(II) provide for the disposition of the illegitimate prescription drug product within the possession or control of the wholesale distributor.

"(ii) TRADING PARTNER.—Upon determining that a prescription drug product in the possession or control of a trading partner is an illegit-

imate prescription drug product, the wholesale distributor shall take reasonable steps to assist a trading partner to provide for the disposition of the illegitimate prescription drug product.

"(iii) MAKING A NOTIFICATION.—Upon determining that a prescription drug product in the possession or control of the wholesale distributor is an illegitimate prescription drug product, the wholesale distributor shall notify the Secretary of such determination not later than 24 hours after making such determination. The Secretary shall determine whether additional trading partner notification is appropriate.

"(iv) RESPONDING TO A NOTIFICATION.—Upon the receipt of a notification from the Secretary that a determination has been made that a prescription drug product is an illegitimate prescription drug product, a wholesale distributor shall—

"(I) identify all illegitimate prescription drug product subject to such notification that is in the possession or control of the wholesale distributor, including any prescription drug product that is subsequently received; and

"(II) perform the activities described in clause (i).

"(v) RECORDS.—A wholesale distributor shall keep records of the disposition of an illegitimate prescription drug product for not less than 3 years after the conclusion of the disposition.

"(C) ELECTRONIC DATABASE.—A wholesale distributor may satisfy the requirements of this paragraph through the use of a secure electronic database developed and operated by the manufacturer or another entity. The owner of such database shall establish the requirements and processes to respond to requests and may provide for data access to other members of the pharmaceutical distribution supply chain, as appropriate. The development and operation of such a database shall not relieve a wholesale distributor of the requirement under this paragraph to respond to a verification request submitted by means other than a secure electronic database.

"(D) RETURNED PRESCRIPTION DRUG PRODUCT.—Beginning not later than 7 years after the date of the enactment of the Safeguarding America's Pharmaceuticals Act of 2013, upon receipt of a returned prescription drug product that the wholesale distributor intends to further distribute, before further distributing such prescription drug product, the wholesale distributor shall—

"(i) verify the prescription drug product identifier for each sealed homogeneous case of such prescription drug product; or

"(ii) if such prescription drug product is not in a sealed homogeneous case, verify the prescription drug product identifier on each package.

"(d) DISPENSER REQUIREMENTS.—

"(1) PRESCRIPTION DRUG PRODUCT TRACING.—

"(A) IN GENERAL.—Beginning not later than July 1, 2015, a dispenser—

"(i) shall not accept ownership of a prescription drug product, unless the previous owner prior to, or at the time of, the transaction, provides transaction history and a transaction statement;

"(ii) prior to, or at the time of, each transaction in which the dispenser transfers ownership of a prescription drug product (but not including dispensing to a patient or returns) shall provide the subsequent owner with transaction history and a transaction statement for the prescription drug product, except that the requirements of this clause shall not apply to sales by a dispenser to another dispenser to fulfill a specific patient need; and

"(iii) shall maintain transaction information for a period of not less than 3 years after the date of the transaction.

"(B) AGREEMENTS WITH THIRD PARTIES.—A dispenser may enter into a written agreement with a third party, including an authorized wholesale distributor, under which the third party confidentially maintains the transaction information required to be maintained under this subsection on behalf of the dispenser. If a dispenser enters into such an agreement, the dispenser shall maintain a copy of the written agreement.

"(C) RETURNS EXCEPTION.—

"(i) SALEABLE RETURNS.—Notwithstanding subparagraph (A)(ii), a dispenser may return prescription drug product to the trading partner from which the dispenser obtained the prescription drug product without providing the information required under such subparagraph.

"(ii) NONSALEABLE RETURNS.—Notwithstanding subparagraph (A)(ii), a dispenser may return a nonsaleable prescription drug to the manu-

facturer or repackager, to the wholesale distributor from whom such prescription drug was purchased, to a returns processor, or to a person acting on behalf of such persons without providing the information required under such subparagraph.

"(D) REQUESTS FOR INFORMATION.—Upon a request by the Secretary or other appropriate Federal or State official, in the event of a recall or for the purpose of investigating a suspect prescription drug product or an illegitimate prescription drug product, a dispenser shall, not later than 2 business days after receiving the request or in another such reasonable time as determined by the Secretary, provide lot level transaction information.

"(2) PRESCRIPTION DRUG PRODUCT IDENTIFIER.—Beginning not later than 8 years after the date of the enactment of the Safeguarding America's Pharmaceuticals Act of 2013, a dispenser may engage in transactions involving a prescription drug product only if such prescription drug product is encoded with a prescription drug product identifier, except as provided in subsection (a)(4).

"(3) AUTHORIZED TRADING PARTNERS.—Beginning not later than January 1, 2015, a dispenser shall ensure that each of its trading partners is authorized.

"(4) VERIFICATION.—Beginning not later than January 1, 2015, a dispenser shall implement systems to enable the dispenser to comply with the following requirements:

"(A) SUSPECT PRESCRIPTION DRUG PRODUCT.—

"(i) IN GENERAL.—Upon making a determination that a prescription drug product in the possession or control of the dispenser is a suspect prescription drug product, or upon receiving a request for verification from the Secretary that a prescription drug product within the possession or control of a dispenser is a suspect prescription drug product, a dispenser shall promptly conduct an investigation to determine whether the prescription drug product is an illegitimate prescription drug product. Such investigation shall include—

"(I) verifying whether the lot number of a suspect prescription drug product corresponds with the lot number for such prescription drug product;

"(II) beginning 8 years after the date of the enactment of the Safeguarding America's Pharmaceuticals Act of 2013, verifying that the product identifier of at least 3 packages or 10 percent of such suspect prescription drug product, whichever is greater, or all packages, if there are fewer than 3, corresponds with the prescription drug product identifier for such product;

"(III) validating any applicable transaction history in the possession of the dispenser; and

"(IV) otherwise investigating to determine whether the prescription drug product is an illegitimate prescription drug product.

"(ii) CLEARED PRESCRIPTION DRUG PRODUCT.—If the dispenser makes the determination that a suspect prescription drug product is not an illegitimate prescription drug product, the dispenser shall promptly notify the Secretary of such determination and such prescription drug product may be further dispensed.

"(iii) RECORDS.—A dispenser shall keep records of its investigation of a suspect prescription drug product for not less than 3 years after the conclusion of the investigation.

"(B) ILLEGITIMATE PRESCRIPTION DRUG PRODUCT.—

"(i) IN GENERAL.—Upon receiving notice that a manufacturer of a prescription drug product has determined that a prescription drug product in the possession or control of a dispenser is an illegitimate prescription drug product, the dispenser shall—

"(I) quarantine such prescription drug product within the possession or control of the dispenser from prescription drug product intended for distribution; and

"(II) provide for the disposition of the illegitimate prescription drug product within the possession or control of the dispenser.

"(ii) TRADING PARTNERS.—Upon determining that a prescription drug product in the possession or control of a trading partner is an illegitimate prescription drug product, the dispenser shall take reasonable steps to assist a trading partner to provide for the disposition of the illegitimate prescription drug product.

"(iii) MAKING A NOTIFICATION.—Upon determining that a prescription drug product in the possession or control of the dispenser is an illegitimate prescription drug product, the dispenser shall notify the Secretary of such determination not later than 24 hours after making such

determination. The Secretary shall determine whether additional trading partner notification is appropriate.

"(iv) RESPONDING TO A NOTIFICATION.—Upon the receipt of a notification from the Secretary that a determination has been made that a prescription drug product is an illegitimate prescription drug product, a dispenser shall—

"(I) identify all illegitimate prescription drug products that are subject to such notification and in the possession or control of the dispenser, including any prescription drug product that is subsequently received; and

"(II) perform the activities described in clause (i).

"(v) RECORDS.—A dispenser shall keep records of the disposition of an illegitimate prescription drug product for not less than 3 years after the conclusion of the disposition.

"(C) ELECTRONIC DATABASE.—A dispenser may satisfy the requirements of this paragraph through the use of a secure electronic database developed and operated by the manufacturer or another entity. The owner of such database shall establish the requirements and processes to enable responding to requests and may provide for data access to other members of the pharmaceutical distribution supply chain, as appropriate. The development and operation of such a database shall not relieve a dispenser of the requirement under this paragraph to respond to a verification request submitted by means other than a secure electronic database.

"(e) REPACKAGER REQUIREMENTS.—

"(1) PRESCRIPTION DRUG PRODUCT TRACING.—

"(A) IN GENERAL.—Beginning not later than April 1, 2015, with respect to a prescription drug product received by a repackager from a wholesale distributor, and beginning not later than January 1, 2015, with respect to any other prescription drug product, a repackager shall—

"(i) not accept ownership of a prescription drug product unless the previous owner, prior to, or at the time of, the transaction, provides transaction history and a transaction statement for the prescription drug product;

"(ii) prior to, or at the time of, each transaction in which the repackager transfers ownership of a prescription drug product, provide the subsequent owner with transaction history and a transaction statement;

"(iii) maintain the transaction information for each transaction described in clause (i) or (ii) for not less than 3 years after the transaction; and

"(iv) maintain records that allow the repackager to associate the prescription drug product identifier the repackager affixes or imprints with the prescription drug product identifier assigned by the original manufacturer of the prescription drug product.

"(B) NONSALEABLE RETURNS.—Notwithstanding subparagraph (A)(ii), a repackager may return prescription drug product to the trading partner from whom the repackager obtained the prescription drug product without providing the information required under such subparagraph.

"(C) REQUESTS FOR INFORMATION.—Upon a request by the Secretary or other appropriate Federal or State official, in the event of a recall or for the purpose of investigating a suspect prescription drug product or an illegitimate prescription drug product, a repackager shall, not later than 2 business days after receiving the request or in such other reasonable time as determined by the Secretary, provide the applicable transaction history and transaction statement for the prescription drug product.

"(2) PRESCRIPTION DRUG PRODUCT IDENTIFIER.—Beginning not later than 6 years after the date of the enactment of the Safeguarding America's Pharmaceuticals Act of 2013, a repackager—

"(A) shall affix or imprint a prescription drug product identifier to each package and homogenous case of prescription drug product intended to be introduced in a transaction;

"(B) shall maintain the prescription drug product identifier for such prescription drug product for not less than 3 years after the date of the transaction; and

"(C) may engage in transactions involving a prescription drug product only if such prescription drug product is encoded with a prescription drug product identifier except as provided in subsection (a)(4).

"(3) AUTHORIZED TRADING PARTNERS.—Beginning on January 1, 2015, a repackager shall ensure that each of its trading partners is authorized.

"(4) VERIFICATION.—Beginning not later than January 1, 2015, a repackager shall implement systems to enable the repackager to comply with the following requirements:

"(A) SUSPECT PRESCRIPTION DRUG PRODUCT.—

"(i) IN GENERAL.—Upon making a determination that a prescription drug product in the possession or control of the repackager is a suspect prescription drug product, or upon receiving a request for verification from the Secretary that a prescription drug product within the possession or control of a repackager is a suspect prescription drug product, a repackager shall promptly conduct an investigation to determine whether the prescription drug product is an illegitimate prescription drug product, including—

"(I) beginning not later than 6 years after the date of the enactment of the Safeguarding America's Pharmaceuticals Act of 2013, verifying the prescription drug product at the package level;

"(II) validating any applicable transaction information in the possession of the repackager; and

"(III) otherwise investigating to determine whether the prescription drug product is an illegitimate prescription drug product.

"(ii) CLEARED PRESCRIPTION DRUG PRODUCT.—If the repackager determines that a suspect prescription drug product is not an illegitimate prescription drug product, the repackager shall promptly notify the Secretary of such determination and such prescription drug product may be further distributed.

"(iii) RECORDS.—A repackager shall keep records of its investigation of a suspect prescription drug product for not less than 3 years after the conclusion of the investigation.

"(B) ILLEGITIMATE PRESCRIPTION DRUG PRODUCT.—

"(i) IN GENERAL.—Upon receiving notice that a manufacturer of a prescription drug product has determined that a prescription drug product in the possession or control of a repackager is an illegitimate prescription drug product, the repackager shall—

"(I) quarantine such prescription drug product within the possession or control of the repackager from prescription drug product intended for distribution; and

"(II) provide for the disposition of the illegitimate prescription drug product within the possession or control of the repackager.

"(ii) TRADING PARTNER.—Upon determining that a prescription drug product in the possession or control of a trading partner is an illegitimate prescription drug product, the repackagers shall take reasonable steps to assist the trading partner to provide for the disposition of the illegitimate prescription drug product.

"(iii) MAKING A NOTIFICATION.—Upon determining that a prescription drug product in the possession or control of the repackager is an illegitimate prescription drug product, the repackager shall notify the Secretary of such determination not later than 24 hours after making such determination. The Secretary shall determine whether additional trading partner notification is appropriate.

"(iv) RESPONDING TO A NOTIFICATION.—Upon the receipt of a notification from the Secretary that a determination has been made that a prescription drug product is an illegitimate prescription drug product, a repackager shall—

"(I) identify all illegitimate prescription drug products that are subject to such notification and in the possession or control of the repackager, including any prescription drug product that is subsequently received; and

"(II) perform the activities described in clause (i).

"(v) RECORDS.—A repackager shall keep records of the disposition of an illegitimate prescription drug product for not less than 3 years after the conclusion of the disposition.

"(C) ELECTRONIC DATABASE.—A repackager may satisfy the requirements of this paragraph through the use of a secure electronic database developed and operated by the manufacturer or another entity. The owner of such database shall establish the requirements and processes to respond to requests and may provide for data access to other members of the pharmaceutical distribution supply chain, as appropriate. The development and operation of such a database shall not relieve a repackager of the requirement under this paragraph to respond to a verification request submitted by means other than a secure electronic database.

"(D) RETURNED PRESCRIPTION DRUG PRODUCT.—Beginning not later than 6 years after the date of the enactment of the Safeguarding America's Pharmaceuticals Act of 2013, upon receipt of a returned prescription drug product that the repackager intends to further distribute, before further distributing such prescription drug product, the repackager shall—

"(i) verify the prescription drug product identifier for each sealed homogeneous case of such prescription drug product; or

"(ii) if such prescription drug product is not in a sealed homogeneous case, verify the prescription drug product identifier on each package.

"(f) THIRD-PARTY LOGISTICS PROVIDER REQUIREMENTS.—

"(1) AUTHORIZED TRADING PARTNERS.—Beginning on January 1, 2015, a third-party logistics provider shall ensure that each of its trading partners is authorized.

"(2) VERIFICATION.—Beginning not later than January 1, 2015, a third-party logistics provider shall implement systems to enable the third-party logistics provider to comply with the following requirements:

"(A) SUSPECT PRESCRIPTION DRUG PRODUCT.—

"(i) IN GENERAL.—Upon making a determination that a prescription drug product in the possession or control of a third-party logistics provider is a suspect prescription drug product, a third-party logistics provider shall promptly notify the owner of such prescription drug product of the need to conduct an investigation to determine whether the prescription drug product is an illegitimate prescription drug product.

"(ii) CLEARED PRESCRIPTION DRUG PRODUCT.—If the owner of the prescription drug product notifies the third-party logistics provider of the determination that a suspect prescription drug product is not an illegitimate prescription drug product, such prescription drug product may be further distributed.

"(iii) RECORDS.—A third-party logistics provider shall keep records of the activities described in clauses (i) and (ii) with respect to a suspect prescription drug product for not less than 3 years after the conclusion of the investigation.

"(B) ILLEGITIMATE PRESCRIPTION DRUG PRODUCT.—

"(i) IN GENERAL.—Upon receiving notice that a manufacturer of a prescription drug product has determined that a prescription drug product in the possession or control of a third-party logistics provider is an illegitimate prescription drug product, the third-party logistics provider shall—

"(I) quarantine such prescription drug product within the possession or control of the third-party logistics provider from prescription drug product intended for distribution;

"(II) promptly notify the owner of such prescription drug product of the need to provide for the disposition of such prescription drug product; and

"(III) promptly transfer possession of the prescription drug product to the owner of such prescription drug product to provide for the disposition of the prescription drug product.

"(ii) MAKING A NOTIFICATION.—Upon determining that a prescription drug product in the possession or control of the third-party logistics provider is an illegitimate prescription drug product, the third-party logistics provider shall notify the Secretary not later than 24 hours after making such determination. The Secretary shall determine whether additional trading partner notification is appropriate.

"(iii) RESPONDING TO A NOTIFICATION.—Upon the receipt of a notification from the Secretary, a third-party logistics provider shall—

"(I) identify all illegitimate prescription drug product subject to such notification that is in the possession or control of the third-party logistics provider, including any prescription drug product that is subsequently received; and

"(II) perform the activities described in clause (i).

"(iv) RECORDS.—A third-party logistics provider shall keep records of the activities described in clauses (i) and (ii) with respect to an illegitimate prescription drug product for not less than 3 years after the conclusion of the disposition.

"(g) DROP SHIPMENTS.—This section does not apply to any entity, notwithstanding its status as a wholesale distributor or repackager, or other status that is not involved in the physical handling, distribution, or storage of a prescription drug product. For purposes of this subsection, facilitating the distribution of a prescription drug product by providing various administrative services, including processing of

orders and payments, shall not, by itself, be construed as being involved in the handling, distribution, or storage of a prescription drug product.".

SEC. 3. ENHANCED DRUG DISTRIBUTION SECURITY.

(a) PILOT PROJECTS.—

(1) IN GENERAL.—Not later than 2 years after the date of the enactment of this Act, the Secretary shall establish one or more pilot projects in coordination with manufacturers, repackagers, wholesale distributors, third-party logistics providers, and dispensers to explore and evaluate methods to enhance the safety and security of the pharmaceutical distribution supply chain.

(2) CONTENT.—

(A) IN GENERAL.—The Secretary shall ensure that the pilot projects under paragraph (1) collectively—

(i) reflect the diversity of the pharmaceutical distribution supply chain; and

(ii) include participants representative of every sector within the pharmaceutical distribution supply chain, including participants representative of small businesses.

(B) PROJECT DESIGN.—The pilot projects shall be designed to—

(i) utilize the prescription drug product identifier for tracing of a prescription drug product, which utilization may include—

(I) verification of the prescription drug product identifier of a prescription drug product; and

(II) the use of aggregation and inference;

(ii) improve the technical capabilities of each sector within the pharmaceutical supply chain to comply with systems and processes needed to utilize the prescription drug product identifiers to enhance tracing of a prescription drug product; and

(iii) conduct such other activities as the Secretary determines appropriate to explore and evaluate methods to enhance the safety and security of the pharmaceutical distribution supply chain.

(b) PUBLIC MEETINGS.—

(1) IN GENERAL.—Not later than 6 months after the date of the enactment of this Act, and at least every 6 months thereafter until the submission of the report required by subsection (e)(2), the Secretary shall hold a public meeting to enhance the safety and security of the pharmaceutical distribution supply chain. In conducting such meetings, the Secretary shall take all measures reasonable and practicable to ensure the protection of confidential commercial information and trade secrets.

(2) CONTENT.—In conducting meetings under this subsection, the Secretary shall seek to address, in at least one such meeting, each of the following topics:

(A) Best practices in each of the sectors within the pharmaceutical distribution supply chain to implement the requirements of section 582 of the Federal Food, Drug, and Cosmetic Act, as added by section 2.

(B) The costs and benefits of implementation of such section 582, including the impact on each pharmaceutical distribution supply chain sector and on public health.

(C) Whether additional electronic traceability requirements, including tracing of prescription drug product at the package level, are feasible, cost effective, overly burdensome on small businesses, and needed to protect public health.

(D) The systems and processes needed to utilize the prescription drug product identifiers to enhance tracing of prescription drug product at the package level.

(E) The technical capabilities and legal authorities, if any, needed to establish an electronic system that provides for enhanced tracing of prescription drug product at the package level.

(F) The impact that the requirements, systems, processes, capabilities, and legal authorities referred to in subparagraphs (C), (D), and (E) would have on patient safety, the drug supply, cost and regulatory burden, the timeliness of patient access to prescription drugs, and small businesses.

(c) STUDY OF THE PHARMACEUTICAL DISTRIBUTION SUPPLY CHAIN.—

(1) IN GENERAL.—The Comptroller General of the United States shall conduct a study to examine implementation of the requirements established under subchapter H of chapter V of the Federal Food, Drug, and Cosmetic Act, as added by section 2, in order to inform the regulations promulgated under this section.

(2) CONSIDERATION.—In conducting the study under this subsection, the Comptroller General shall provide for stakeholder input and shall consider the following:

(A) The implementation of the requirements established under such subchapter H with respect to—

(i) the ability of the health care system collectively to maintain patient access to medicines;

(ii) the scalability of such requirements, including with respect to prescription drug product lines; and

(iii) the capability of different sectors within the pharmaceutical distribution supply chain, including small businesses, to affix and utilize the prescription drug product identifier.

(B) The need for additional legal authorities and activities to address additional gaps in the pharmaceutical distribution supply chain, if any, after the implementation of the requirements established under such subchapter H with respect to—

(i) the systems and processes needed to enhance tracing of prescription drug product at the package level;

(ii) the impact, feasibility, and cost effectiveness that additional requirements pursuant to this section would have on each pharmaceutical distribution supply chain sector and the public health; and

(iii) the systems and processes needed to enhance interoperability among trading partners.

(C) Risks to the security and privacy of data collected, maintained, or exchanged pursuant to the requirements established under such subchapter H.

(d) SMALL DISPENSERS.—

(1) IN GENERAL.—Not later than 10 years after the date of the enactment of this Act, the Secretary shall enter into a contract with a private, independent consulting firm with relevant expertise to conduct a technology and software study on the feasibility of dispensers that have 25 or fewer full-time employees conducting interoperable, electronic tracing of prescription drug products at the package level.

(2) CONDITION.—As a condition of the award of a contract under paragraph (1), the private independent consulting firm awarded such contract shall agree to consult with dispensers that have 25 or fewer full-time employees when conducting the study under such subparagraph.

(3) STUDY CONTENT.—The study conducted under paragraph (1) shall assess whether, with respect to conducting interoperable, electronic tracing of prescription drug products at the package level, the necessary hardware and software—

(A) is readily accessible to such dispensers;

(B) is not prohibitively expensive to obtain, install, and maintain for such dispensers; and

(C) can be integrated into business practices, such as interoperability with wholesale distributors, for such dispensers.

(4) PUBLICATION.—The Secretary shall publish—

(A) the statement of work for the study conducted under paragraph (1) for public comment not later than 30 days before commencing the study; and

(B) the final version of such study for public comment not later than 30 days after such study is completed.

(5) REPORT TO CONGRESS.—Not later than 30 days after the date on which the study conducted under paragraph (1) is completed, 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 on the findings of the study and any recommendations to improve the technology and software available to small dispensers for purposes of conducting electronic, interoperable tracing of prescription drug products at the package level.

(6) PUBLIC MEETING.—Not later than 180 days after the date on which the study conducted under paragraph (1) is completed, the Secretary shall hold a public meeting at which members of the public, including stakeholders, may present their views on the study.

(e) REPORTS.—

(1) GAO REPORT.—Not later than 12 years after the date of the enactment of this Act, the Comptroller General 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 on the results of the study conducted under subsection (c).

(2) FDA REPORT.—Not later than 12 years after the date of the enactment of this Act, 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 on the results of the pilot program conducted under subsection (a), taking into consideration—

(A) the comments received during the public meetings conducted under subsection (b); and

(B) the results of the study conducted, and the public comments received during the public meeting held, under subsection (d).

(f) ESTABLISHMENT OF ADDITIONAL REQUIREMENTS.—

(1) IN GENERAL.—Notwithstanding any other provision of this Act, including the amendments made by this Act, not earlier than January 1, 2027, and not later than March 1, 2027, the Secretary shall issue proposed regulations that establish additional requirements to prevent a suspect product, illegitimate product, or a product that is counterfeit, stolen, diverted, or otherwise unfit for distribution from entering into or being further distributed in the supply chain, including—

(A) requirements related to the use of interoperable electronic systems and technologies for enhanced tracing of prescription drug product at the package level, which may include verification of the prescription drug product identifier of a package of prescription drug product and enhanced verification of saleable returns;

(B) requirements related to the use of additional prescription drug product identifiers or prescription drug product identifier technology that meet the standards developed under section 582(a)(2) of the Federal Food, Drug, and Cosmetic Act, as added by section 2;

(C) requirements related to the use of aggregation, inference, and other methods, if determined to be necessary components of the systems and technologies referred to in subparagraph (A); and

(D) other data transmission and maintenance requirements and interoperability standards.

(2) FLEXIBILITY.—The requirements described in paragraph (1) shall provide for flexibility for a member of the pharmaceutical supply chain, by—

(A) with respect to dispensers, allowing a dispenser to enter into a written agreement with a third party, including an authorized wholesale distributor, under which—

(i) the third party confidentially maintains any information required to be maintained under such requirements for the dispenser; and

(ii) the dispenser maintains a copy of the written agreement and is not relieved of the other obligations of the dispenser under such requirements;

(B) establishing a process by which an authorized manufacturer, repackager, wholesale distributor, or dispenser may request a waiver from any such requirements if the Secretary determines that such requirements would result in an undue economic hardship on the manufacturer, wholesale distributor, or dispenser;

(C) not requiring the adoption of specific business systems by a member of the pharmaceutical supply chain for the maintenance and transmission of prescription drug product tracing data; and

(D) prescribing alternative methods of compliance for small businesses, as specified in paragraph (4).

(3) CONSIDERATIONS.—In issuing proposed regulations under paragraph (1), the Secretary shall consider—

(A) the results of the pilot project conducted under subsection (a);

(B) the public meetings held under subsection (b);

(C) the studies conducted under subsections (c) and (d);

(D) the reports submitted under subsection (e);

(E) the public health benefits of such regulations compared with the cost of compliance with the requirements contained in such regulations, including with respect to entities of varying sizes and capabilities; and

(F) the diversity of the pharmaceutical distribution supply chain by providing appropriate flexibility for each sector in the supply chain, including small businesses.

(4) SMALL BUSINESS PROTECTION.—The Secretary, taking into consideration the study conducted under paragraph (d), shall, if the Secretary determines that the requirements established pursuant to paragraph (1) would result in an undue economic hardship on small businesses, provide for alternative methods of compliance with any such requirement by small businesses, including—

(A) establishing timelines for such compliance (including compliance by dispensers with 25 or fewer full-time employees) that do not impose undue economic hardship for small businesses, including dispensers with respect to which the study concluded has insufficient hardware and software to con-

duct interoperable, electronic tracing of prescription drug products at the package level; and

(B) establishing a process by which a dispenser may request a waiver from any such requirement.

(5) REGULATIONS.—In issuing regulations to carry out this subsection, the Secretary shall—

(A) issue a notice of proposed rulemaking that includes a copy of the proposed rule;

(B) provide for a period of not less than 60 days for comments on the proposed rule; and

(C) provide for an effective date of the final rule that is 2 years after the date on which such final rule is published.

(6) SUNSET.—The requirements regarding the provision and receipt of transaction history and transaction statements under section 582 of the Federal Food, Drug, and Cosmetic Act, as added by section 2, shall cease to be effective on the date on which the regulations issued under this section are fully implemented.

(g) DEFINITIONS.—In this section:

(1) The terms defined in section 581 of the Federal Food, Drug, and Cosmetic Act, as added by section 2, shall have the same meanings in this section as such terms are given in such section 581.

(2) The term "Secretary" means the Secretary of Health and Human Services, acting through the Commissioner of Food and Drugs.

SEC. 4. NATIONAL STANDARDS FOR WHOLESALE DISTRIBUTORS.

(a) STANDARDS.—Chapter V of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 351 et seq.) is amended—

(1) in section 503 (21 U.S.C. 353), by striking "(e)(1)(A)" and all that follows through "(3) For the purposes of this subsection and subsection (d)—" and inserting the following:

"(e) For purposes of subsection (d)—";

(2) in section 503(e) (21 U.S.C. 353(e)), by redesignating subparagraphs (A) and (B) as paragraphs (1) and (2), respectively; and

(3) in subchapter H, as added by section 2, by adding at the end the following:

"SEC. 583. NATIONAL STANDARDS FOR WHOLESALE DISTRIBUTORS.

"(a) STANDARDS.—

"(1) IN GENERAL.—The Secretary shall establish, by regulation, standards for the licensing of persons that make wholesale distributions.

"(2) REQUIREMENTS.—The standards under paragraph (1) shall, with respect to wholesale distributions, include requirements for—

"(A) the storage and handling of drugs subject to section 503(b)(1), including facility requirements;

"(B) the establishment and maintenance of records of the distributions of such drugs;

"(C) the furnishing of a bond or other equivalent means of security in accordance with paragraph (3);

"(D) mandatory background checks and fingerprinting of facility managers or designated representatives;

"(E) the establishment and implementation of qualifications for key personnel;

"(F) the mandatory physical inspection of any facility to be used in wholesale distribution within a reasonable timeframe from the initial application for licensure of the wholesale distributor; and

"(G) in accordance with paragraph (5), the prohibition of certain persons from engaging in wholesale distribution.

"(3) BOND OR OTHER SECURITY.—The requirements under paragraph (2)(C) shall provide for the following:

"(A) An applicant that is not a government-owned-and-operated wholesale distributor, for the issuance or renewal of a wholesale distributor license, shall submit a surety bond of $100,000 or other equivalent means of security acceptable to the applicable licensing authority.

"(B) For purposes of subparagraph (A), the applicable licensing authority may accept a surety bond less than $100,000 if the annual gross receipts of the previous tax year for the wholesale distributor is $10,000,000 or less, in which case the surety bond may not be less than $25,000.

"(C) If a wholesale distributor can provide evidence that it possesses the required bond in a State, the requirement for a bond in another State is waived.

"(4) INSPECTIONS.—To satisfy the inspection requirement under paragraph (2)(F), the Secretary may conduct the inspection, or may accept an inspection by—

"(A) the government of the State in which the facility is located; or

"(B) a third-party accreditation or inspection service approved by the Secretary.

"(5) PROHIBITED PERSONS.—The requirements under paragraph (2) shall include requirements to prohibit a person from receiving or maintaining licensure for wholesale distribution if the person—

"(A) has been convicted of any felony for conduct relating to wholesale distribution; any felony violation of section 301(i) or 301(k); or any felony violation of section 1365 of title 18, United States Code, relating to prescription drug product tampering; or

"(B) has engaged in a pattern of violating the requirements of this section that presents a threat of serious adverse health consequences or death to humans.

"(b) REPORTING BY LICENSED WHOLESALE DISTRIBUTORS.—

"(1) ANNUAL REPORT.—Beginning not later than 1 year after the date of the enactment of this section, each person engaged in wholesale distribution in interstate commerce shall submit on an annual basis, and update as necessary, a report to the Secretary including—

"(A) the wholesale distributor's name;

"(B) the wholesale distributor's address;

"(C) a listing of each State in which the wholesale distributor is licensed for wholesale distribution; and

"(D) any disciplinary actions taken by a State, the Federal Government, or a foreign government during the reporting period against the wholesale distributor.

"(2) POSTING ON INTERNET.—The Secretary shall post on the public Internet Website of the Food and Drug Administration the name of each wholesale distributor, and the State in which each such distributor is licensed, based on reports under paragraph (1).

"(c) PRESERVATION OF STATE AUTHORITY.—This subchapter does not prohibit a State from—

"(1) licensing wholesale distributors for the conduct of wholesale distribution activities in the State in accordance with this subchapter; and

"(2) collecting fees from wholesale distributors in connection with such licensing,

so long as the State does not require such licensure to the extent to which an entity is engaged in third-party logistics provider activities.

"(d) DEFINITION.—In this section, the term 'wholesale distribution' means the distribution of a drug subject to section 503(b)(1) to a person other than a consumer or patient, but does not include—

"(1) intracompany distribution of any drug between members of an affiliated group (as defined in section 1504(a) of the Internal Revenue Code of 1986);

"(2) the distribution of a drug, or an offer to distribute a drug among hospitals or other health care entities which are under common control;

"(3) the distribution of a drug or an offer to distribute a drug for emergency medical reasons, including a public health emergency declaration pursuant to section 319 of the Public Health Service Act, except that a drug shortage not caused by a public health emergency shall not constitute such an emergency medical reason;

"(4) dispensing of a drug pursuant to a valid prescription executed in accordance with subsection 503(b)(1);

"(5) the distribution of minimal quantities of drug by a licensed retail pharmacy to a licensed practitioner for office use;

"(6) the distribution of a drug or an offer to distribute a drug by a charitable organization to a nonprofit affiliate of the organization to the extent otherwise permitted by law;

"(7) the purchase or other acquisition by a dispenser, hospital, or other health care entity of a drug for use by such dispenser, hospital, or other health care entity;

"(8) the distribution of a drug by the manufacturer of such drug;

"(9) the receipt or transfer of a drug by an authorized third-party logistics provider provided that such third-party logistics provider does not take ownership of the drug;

"(10) the transport of a drug by a common carrier, provided that the common carrier does not take ownership of the drug;

"(11) the distribution of a drug, or an offer to distribute a drug, by an authorized repackager that has taken ownership of the drug and repacked it in accordance with section 582(e);

"(12) saleable drug returns when conducted by a dispenser in accordance with section 203.23 of title 21, Code of Federal Regulations (or any successor regulation);

"(13) the distribution of a combination prescription drug product described in section 581(20)(B)(xiii);

"(14) the distribution of a medical convenience kit described in section 581(21)(B)(xiv);

"(15) the distribution of an intravenous drug that, by its formulation, is intended for the replenishment of fluids and electrolytes (such as sodium, chloride, and potassium) or calories (such as dextrose and amino acids);

"(16) the distribution of an intravenous drug used to maintain the equilibrium of water and minerals in the body, such as dialysis solutions;

"(17) the distribution of a drug that is intended for irrigation or reconstitution, or sterile water, whether intended for such purposes or for injection;

"(18) the distribution of compressed medical gas (as defined in section 581(21)(C));

"(19) facilitating the distribution of a prescription drug product by providing administrative services, such as processing of orders and payments, without physical handling, distribution, or storage of a prescription drug product; or

"(20)(A) the distribution of a product by a dispenser, or a wholesale distributor acting at the direction of the dispenser, to a repackager registered under section 510 for the purpose of repackaging the drug for use by that dispenser or another health care entity that is under the dispenser's ownership or control, so long as the dispenser retains ownership of the prescription drug product; and

"(B) the saleable or nonsaleable return by such repackager of such prescription drug product.

"(e) EFFECTIVE DATE.—The standards required by subsection (a) shall take effect not later than 2 years after the date of the enactment of this section. The Secretary shall issue the regulations required by subsection (a) not later than 1 year after the date of the enactment of this Act.".

(b) CONFORMING AMENDMENT.—Section 804(a)(5)(A) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 384(a)(5)(A)) is amended by striking "503(e)(2)(A)" and inserting "583(a)".

SEC. 5. NATIONAL LICENSURE STANDARDS FOR THIRD-PARTY LOGISTICS PROVIDERS.

Subchapter H of chapter V of the Federal Food, Drug, and Cosmetic Act, as amended by section 4, is further amended by adding at the end the following:

"SEC. 584. NATIONAL LICENSURE STANDARDS FOR THIRD-PARTY LOGISTICS PROVIDERS.

"(a) LICENSE REQUIREMENT.—No facility may engage in the activities of a third-party logistics provider in any State unless—

"(1) the facility is licensed—

"(A) by the State from which the drug is distributed by the third-party logistics provider in accordance with a qualified licensing program, if the State has such a program; or

"(B) by the Secretary under this section, if the State from which the drug is distributed does not have such a program; and

"(2) if the drug is distributed interstate and the facility is not licensed by the Secretary under paragraph (1)(B), registers with the State into which the drug is distributed if such State requires such registration.

"(b) REPORTING BY LICENSED THIRD-PARTY LOGISTICS PROVIDERS.—

"(1) ANNUAL REPORT.—Beginning not later than 1 year after the date of the enactment of this section, each facility engaged in the activities of a third-party logistics provider shall submit on an annual basis, and update as necessary, a report to the Secretary including—

"(A) the facility's name;

"(B) the facility's address;

"(C) a listing of each jurisdiction (whether State or Federal) in which the facility is licensed for third-party logistics provider activities; and

"(D) any disciplinary actions taken by a State or Federal licensing authority during the reporting period against the facility.

"(2) POSTING ON INTERNET.—The Secretary shall post on the public Internet Website of the Food and Drug Administration the name of each third-party logistics provider, and each jurisdiction (whether State or Federal) in which the provider is licensed, based on reports under paragraph (1).

"(c) PRESERVATION OF STATE AUTHORITY.—This subchapter does not prohibit a State from—

"(1) licensing third-party logistic providers for the conduct of third-party logistics provider activities in the State in accordance with this subchapter; and

"(2) collecting fees from third-party logistics providers in connection with such licensing,

so long as the State does not require such licensure to the extent to which an entity is engaged in wholesale distribution.

"(d) COSTS.—

"(1) AUTHORIZED LICENSURE FEES.—In the case of a facility engaging in the activities of a third-party logistics provider licensed by the Secretary under this section, the Secretary may assess and collect a reasonable fee in an amount equal to the costs to the Federal Government of establishing and administering the licensure program established, and conducting period inspections, under this section.

"(2) ADJUSTMENT.—The Secretary shall adjust the amount of the fee under paragraph (1) on an annual basis, if necessary, to generate an amount of revenue equal to the costs referred to in such paragraph.

"(3) AVAILABILITY.—Fees assessed and collected under this subsection shall be available for obligation only to the extent and in the amount provided in advance in appropriations Acts. Such fees shall remain available until expended.

"(e) LICENSE REGULATIONS.—

"(1) IN GENERAL.—The Secretary shall establish, by regulation, standards, terms, and conditions for licensing persons to engage in third-party logistics provider activities.

"(2) CONTENT.—The regulations under paragraph (1) shall—

"(A) include standards relating to eligibility for, and revocation and reissuance of, licenses;

"(B) establish a process by which the applicable licensing authority will, upon request by a third-party logistics provider that is accredited by a third-party accreditation program approved by the Secretary, issue a license to the provider;

"(C) establish a process by which the Secretary shall issue a license to a third-party logistics provider if the Secretary is not able to approve a third-party accreditation program because no such program meets the Secretary's requirements necessary for approval of such a third-party accreditation program;

"(D) require that the third-party logistics provider comply with storage practices, as determined by the Secretary, at the provider's facilities, including—

"(i) maintaining access to warehouse space of suitable size to facilitate safe operations, including a suitable area to quarantine suspect prescription drug product;

"(ii) maintaining adequate security; and

"(iii) having written policies and procedures to—

"(I) address receipt, security, storage, inventory, shipment, and distribution of a prescription drug product;

"(II) identify, record, and report confirmed losses or thefts in the United States;

"(III) correct errors and inaccuracies in inventories;

"(IV) provide support for manufacturer recalls;

"(V) prepare for, protect against, and address any reasonably foreseeable crisis that affects security or operation at the facility, such as a strike, fire, or flood;

"(VI) ensure that any expired prescription drug product is segregated from other prescription drug products and returned to the manufacturer or repackager or destroyed;

"(VII) maintain the capability to electronically trace the receipt and outbound distribution of a prescription drug product, and supplies and records of inventory; and

"(VIII) quarantine or destroy a suspect prescription drug product if directed to do so by the respective manufacturer, wholesale distributor, dispenser, or an authorized government agency;

"(E) provide for periodic inspection, as determined by the Secretary, of such facility warehouse space to ensure compliance with this section;

"(F) prohibit a facility from having as a manager or designated representative anyone convicted of any felony violation of section 301(i) or 301(k) or any felony violation of section 1365 of title 18, United States Code, relating to prescription drug product tampering;

"(G) perform mandatory background checks of the provider's facility managers or designated representatives of such managers;

"(H) require a third-party logistics provider to provide to the applicable licensing authority, upon the authority's request, a list of all prescription drug product manufacturers, wholesale distributors, and dispensers for whom the third-party logistics provider provides services at the provider's facilities; and

"(I) include procedures under which any third-party logistics provider license—

"(i) will expire on the date that is 3 years after issuance of the license; and

"(ii) may be renewed for additional 3-year periods.

"(f) VALIDITY OF LICENSE.—A license issued under this section shall remain valid as long as such third-party logistics provider remains accredited by the Secretary, subject to renewal under subsection (d). If the Secretary finds that the third-party accreditation program demonstrates that all applicable requirements for licensure under this section are met, the Secretary shall issue a license under this section to a third-party logistics provider receiving accreditation.

"(g) QUALIFIED LICENSING PROGRAM DEFINED.—In this section, the term 'qualified licensing program' means a program meeting the requirements of this section and the regulations thereunder.

"(h) EFFECTIVE DATE.—The requirements of this section shall take effect not later than 1 year after the date of the enactment of this section. The Secretary shall issue the regulations required by subsection (d) not later than 180 days after the date of the enactment of this section.".

SEC. 6. PENALTIES.

(a) PROHIBITED ACTS.—Section 301(t) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 331(t)) is amended by striking "or the distribution of drugs in violation of section 503(e) or the failure to otherwise comply with the requirements of section 503(e)" and inserting "the failure to comply with any requirement of section 582, engaging in the wholesale distribution of a drug in violation of section 583 or the failure to otherwise comply with the requirements of section 583, or engaging in the activities of a third-party logistics provider in violation of section 584 or the failure to otherwise comply with the requirements of section 584".

(b) ENHANCED PENALTY FOR KNOWING UNLICENSED ACTIVITIES.—Section 303(b)(1)(D) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 333(b)(1)(D)) is amended by striking "503(e)(2)(A)" and inserting "583 or 584".

(c) MISBRANDING.—Section 502 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 352) is amended by adding at the end the following:

"(bb) If it is a drug and it fails to bear a prescription drug product identifier as required by section 582.".

SEC. 7. UNIFORM NATIONAL POLICY.

Subchapter H of chapter V of the Federal Food, Drug, and Cosmetic Act, as amended by section 5, is further amended by adding at the end the following:

"SEC. 585. UNIFORM NATIONAL POLICY.

"(a) PREEMPTION OF STATE PRESCRIPTION DRUG PRODUCT TRACING AND OTHER REQUIREMENTS.—Beginning on the date of the enactment of the Safeguarding America's Pharmaceuticals Act of 2013, no State or political subdivision of a State may establish or continue in effect any requirements for tracing drugs through the distribution system (including any requirements with respect to paper or electronic pedigrees, track and trace, statements of distribution history, transaction history, or transaction statements, or verification, investigation, disposition, alerts, or recordkeeping relating to the pharmaceutical distribution supply chain system) that—

"(1) are inconsistent with, more stringent than, or in addition to any requirements applicable under this Act; or

"(2) are inconsistent with any applicable waiver, exception, or exemption issued by the Secretary under section 582(a).

"(b) STANDARDS OR LICENSURE.—

"(1) IN GENERAL.—Beginning on the date of the enactment of Safeguarding America's Pharmaceuticals Act of 2013, no State or political subdivision of a State may establish or continue any standards, requirements, or regulations with respect to wholesale drug distributor or third-party logistics provider licensure which are inconsistent with, less stringent than, in addition to, or more stringent than, the standards and requirements under this Act.

"(2) LICENSING FEES.—Paragraph (1) does not affect the authority of a State to collect fees from wholesale drug distributors or third-party logistics providers

in connection with State licensing under section 583 or 584 pursuant to a licensing program meeting the requirements of such sections.

"(3) ENFORCEMENT, SUSPENSION, AND REVOCATION OF LICENSES.—Notwithstanding paragraph (1), a State—

"(A) may take administrative action, including fines, to enforce a licensure requirement promulgated by the State in accordance with this Act;

"(B) may provide for the suspension or revocation of licenses issued by the State for violations of the laws of such State;

"(C) upon conviction of a person for a violation of Federal, State, or local controlled substance laws or regulations, may provide for fines, imprisonment, or civil penalties; and

"(D) may regulate activities of entities licensed pursuant to section 583 or 584 in a manner that is consistent with the provisions of this subchapter.".

SEC. 8 ELECTRONIC LABELING.

(a) IN GENERAL.—Section 502(f) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 352(f)) is amended by adding at the end the following new sentence: "Required labeling (other than immediate container or carton labels) that is intended for use by a physician, a pharmacist, or another health care professional, and that provides directions for human use of a drug subject to section 503(b)(1), may (except as necessary to mitigate a safety risk, as specified by the Secretary in regulation) be made available by electronic means instead of paper form, provided that such labeling complies with all applicable requirements of law, the manufacturer or distributor, as applicable, affords health care professionals and authorized dispensers (as defined in section 581) the opportunity to request the labeling in paper form, and after such a request the manufacturer or distributor promptly provides the requested information without additional cost.".

(b) REGULATIONS.—The Secretary of Health and Human Services shall promulgate regulations implementing the amendment made by subsection (a).

(c) APPLICATION.—The last sentence of section 502(f) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 352(f)), as added by subsection (a), shall apply beginning on the earlier of—

(1) the effective date of final regulations promulgated under subsection (b); or

(2) the day that is 180 days after the date of enactment of this Act.

PURPOSE AND SUMMARY

H.R. 1919, the "Safeguarding America's Pharmaceuticals Act of 2013," was introduced on May 9, 2013, by Reps. Bob Latta (OH–05) and Jim Matheson (UT–04) and referred to the Committee on Energy and Commerce.

This legislation would amend the Federal Food, Drug, and Cosmetic Act, with respect to the pharmaceutical distribution supply chain.

BACKGROUND AND NEED FOR LEGISLATION

H.R. 1919 would strengthen the security of the United States' prescription drug supply chain in order to protect Americans against counterfeit drugs. Further, H.R. 1919 would help prevent increases in drug prices, help avoid additional drug shortages, and eliminate hundreds of millions of dollars worth of duplicative government regulation by replacing the patchwork of State requirements imposed on American drug manufacturers, wholesale distributors, and pharmacies with a uniform national standard.[1]

The American prescription drug supply chain is increasingly vulnerable to counterfeit drugs. This vulnerability exists, in large part, due to a patchwork of inconsistent State regulations. According to recent reports, the number of counterfeit prescription drugs is

[1] Grace-Marie Turner. "Secure The Pharmaceutical Supply Chain From Risky Counterfeiters" *Forbes*, 20 May 2013, *http://www.forbes.com/sites/gracemarieturner/2013/05/20/secure-the-pharmaceutical-supply-chain-from-risky-counterfeiters/* (accessed May 28, 2013).

growing across the country. Experts have commented that the counterfeiting of prescription drugs has grown even more lucrative than trafficking illegal drugs, such as heroin or cocaine.[2] These counterfeit prescription drugs have reached our nation's sickest patients, including those with cancer. Cancer drugs are highly targeted due to their high cost.[3]

Some States, including California, have taken steps or implemented regulations for their States in an attempt to secure the supply chain. While well-intentioned, these State solutions will not increase the security of the U.S. prescription drug supply. For example, California's e-pedigree law will burden businesses in the drug supply chain by requiring them to implement costly and infeasible electronic systems for tracking and tracing prescription drugs at the unit-level in an unreasonable timeframe.

According to the Pharmaceutical Distribution Security Alliance (a consortium of supply chain actors), California's law could impose up to $3.5 billion in costs on manufacturers. Smaller distributors would be forced to potentially "restrict operations" and "some may be forced out of business." A study from Accenture, commissioned by the National Association of Chain Drug Stores and National Community Pharmacists Association, found that startup costs from the California law would impose $84,000 to $112,000 per store, with additional costs to maintain and operate the system in subsequent years.

Small businesses will be hardest hit. By some estimates, California compliance costs could swallow two-thirds of the net annual profit of pharmacies. The Pharmaceutical Distribution Security Alliance reports that after expenses, the new regulations will wipe out more than 100 percent of income for smaller distributors.[4]

If the California law takes effect, these costs would have dramatically negative impacts on patients. For example, the price of prescription drugs would increase. The burden of the California law would also potentially worsen drug shortages for American patients. Additionally, the California law also would impose massive costs on businesses across the nation because the prescription drug industry is a nationwide market.

H.R. 1919 would secure the United States supply chain in a reasonable, common sense way. This system would save our nation's businesses millions of dollars and negate other negative consequences of the onerous, infeasible California e-pedigree law from spreading across the country. Additionally, H.R. 1919 would ensure the Food and Drug Administration (FDA) and industry work together in a transparent and collaborative process to develop a unit-level tracing system. H.R. 1919, is a pragmatic and effective solution to secure the United States supply chain, which will ensure patients receive safe and effective FDA approved drugs.

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[2] Weaver, Christopher. "More Lucrative Than Cocaine: Fake Medicine On The Rise," *Wall Street Journal*, 13 Feb 2013, *http://blogs.wsj.com/corporate-intelligence/2013/02/13/more-lucrative-than-cocaine-fake-medicine-on-the-rise/* (accessed 28 May 2013).

[3] Whalen, Jeanne; Faucon, Benoit. "Counterfeit Cancer Medicines Multiply," *Wall Street Journal*, 31 Dec. 2013. *http://online.wsj.com/article/SB10001424127887323320404578211492452353034.html* (accessed 28 May, 2013).

[4] Grace-Marie Turner. "Secure The Pharmaceutical Supply Chain From Risky Counterfeiters" *Forbes*, 20 May 2013, *http://www.forbes.com/sites/gracemarieturner/2013/05/20/secure-the-pharmaceutical-supply-chain-from-risky-counterfeiters/* (accessed May 28, 2013).

HEARINGS

The Subcommittee on Health held a hearing on legislation to secure the American prescription drug supply chain on April 25, 2013. The Subcommittee received testimony from: Dr. Janet Woodcock, Director, Center for Drug Evaluation and Research, Food and Drug Administration; Elizabeth A. Gallenagh, Vice President, Government Affairs and General Counsel, Healthcare Distribution Management Association; Christine M. Simmon, Senior Vice President, Policy and Strategic Alliances, Generic Pharmaceutical Association; Michael Rose, Vice President, Supply Chain Visability, Johnson and Johnson Health Care Systems, Inc.; Tim Davis, Owner, Beaver Health Mart Pharmacy, on behalf of the National Community Pharmacist Association; Allan Coukell, Director, Medical Programs, Pew Health Group, the Pew Cheritable Trusts; Carmet A. Catizone, Executive Director and Secretary, National Association of Boards of Pharamcy; and Walter Berghahn, President, SmartRmeds for Life, Executive Director, Healthcare Compliance Packaging Council.

COMMITTEE CONSIDERATION

On May 8, 2013, the Subcommittee on Health met in open markup session and approved H.R. 1919 for full Committee consideration, as amended, by a voice vote. On May 15, 2013, the full Committee met in open markup session and approved H.R. 1919, as amended, by voice vote.

COMMITTEE VOTES

Clause 3(b) of rule XIII of the Rules of the House of Representatives requires the Committee to list the record votes on the motion to report legislation and amendments thereto. A motion by Mr. Upton to order H.R. 1919 reported to the House, with amendment, was agreed to by a voice vote. The following reflects the recorded votes taken during the Committee consideration:

COMMITTEE ON ENERGY AND COMMERCE -- 113TH CONGRESS
ROLL CALL VOTE # 13

BILL: H.R. 1919, the "Safeguarding America's Pharmaceuticals Act of 2013"

AMENDMENT: An amendment offered by Mr. Pallone, No. 2, allowing the FDA to implement the "Phase II" unit-level requirement without a rule making process.

DISPOSITION: NOT AGREED TO, by a roll call vote of 19 yeas and 28 nays.

REPRESENTATIVE	YEAS	NAYS	PRESENT	REPRESENTATIVE	YEAS	NAYS	PRESENT
Mr. Upton		X		Mr. Waxman	X		
Mr. Hall		X		Mr. Dingell	X		
Mr. Barton				Mr. Markey			
Mr. Whitfield		X		Mr. Pallone	X		
Mr. Shimkus		X		Mr. Rush			
Mr. Pitts		X		Ms. Eshoo	X		
Mr. Walden		X		Mr. Engel	X		
Mr. Terry		X		Mr. Green	X		
Mr. Rogers		X		Ms. DeGette	X		
Mr. Murphy		X		Mrs. Capps	X		
Mr. Burgess		X		Mr. Doyle	X		
Mrs. Blackburn		X		Ms. Schakowsky	X		
Mr. Gingrey				Mr. Matheson		X	
Mr. Scalise		X		Mr. Butterfield	X		
Mr. Latta		X		Mr. Barrow		X	
Mrs. McMorris Rodgers		X		Ms. Matsui			
Mr. Harper		X		Ms. Christensen	X		
Mr. Lance		X		Ms. Castor	X		
Mr. Cassidy		X		Mr. Sarbanes	X		
Mr. Guthrie		X		Mr. McNerney	X		
Mr. Olson		X		Mr. Braley	X		
Mr. McKinley		X		Mr. Welch	X		
Mr. Gardner		X		Mr. Lujan	X		
Mr. Pompeo		X		Mr. Tonko	X		
Mr. Kinzinger							
Mr. Griffith		X					
Mr. Bilirakis		X					
Mr. Johnson		X					
Mr. Long		X					
Mrs. Ellmers							

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COMMITTEE ON ENERGY AND COMMERCE -- 113TH CONGRESS
ROLL CALL VOTE # 14

BILL: H.R. 1919, the "Safeguarding America's Pharmaceuticals Act of 2013"

AMENDMENT: An amendment offered by Mr. Engel, No. 3, to require a distributor note on a returned product, and prohibit distributors from selling returned products without a transaction statement.

DISPOSITION: NOT AGREED TO, by a roll call vote of 20 yeas and 29 nays.

REPRESENTATIVE	YEAS	NAYS	PRESENT	REPRESENTATIVE	YEAS	NAYS	PRESENT
Mr. Upton		X		Mr. Waxman	X		
Mr. Hall		X		Mr. Dingell	X		
Mr. Barton		X		Mr. Markey			
Mr. Whitfield		X		Mr. Pallone	X		
Mr. Shimkus		X		Mr. Rush	X		
Mr. Pitts		X		Ms. Eshoo	X		
Mr. Walden		X		Mr. Engel	X		
Mr. Terry		X		Mr. Green	X		
Mr. Rogers		X		Ms. DeGette	X		
Mr. Murphy		X		Mrs. Capps	X		
Mr. Burgess		X		Mr. Doyle	X		
Mrs. Blackburn		X		Ms. Schakowsky	X		
Mr. Gingrey				Mr. Matheson		X	
Mr. Scalise		X		Mr. Butterfield	X		
Mr. Latta		X		Mr. Barrow		X	
Mrs. McMorris Rodgers		X		Ms. Matsui			
Mr. Harper		X		Ms. Christensen	X		
Mr. Lance		X		Ms. Castor	X		
Mr. Cassidy		X		Mr. Sarbanes	X		
Mr. Guthrie		X		Mr. McNerney	X		
Mr. Olson		X		Mr. Braley	X		
Mr. McKinley		X		Mr. Welch	X		
Mr. Gardner		X		Mr. Lujan	X		
Mr. Pompeo		X		Mr. Tonko	X		
Mr. Kinzinger							
Mr. Griffith		X					
Mr. Bilirakis		X					
Mr. Johnson		X					
Mr. Long		X					
Mrs. Ellmers							

05/15/2013

COMMITTEE OVERSIGHT FINDINGS

Pursuant to clause 3(c)(1) of rule XIII of the Rules of the House of Representatives, the Committee made findings that are reflected in this report.

STATEMENT OF GENERAL PERFORMANCE GOALS AND OBJECTIVES

H.R. 1919 will secure the United States supply chain by creating a national standard for tracking all prescription drug products and establishing a process to move to a unit level system.

NEW BUDGET AUTHORITY, ENTITLEMENT AUTHORITY, AND TAX EXPENDITURES

In compliance with clause 3(c)(2) of rule XIII of the Rules of the House of Representatives, the Committee finds that H.R. 1919, Safeguarding America's Pharmaceuticals Act of 2013, would result in no new or increased budget authority, entitlement authority, or tax expenditures or revenues.

EARMARKS, LIMITED TAX BENEFITS, AND LIMITED TARIFF BENEFITS

In compliance with clause 9(e), 9(f), and 9(g) of rule XXI of the Rules of the House of Representatives, the Committee finds that H.R. 1919, Safeguarding America's Pharmaceuticals Act of 2013, contains no earmarks, limited tax benefits, or limited tariff benefits.

COMMITTEE COST ESTIMATE

The Committee adopts as its own the cost estimate prepared by the Director of the Congressional Budget Office pursuant to section 402 of the Congressional Budget Act of 1974.

CONGRESSIONAL BUDGET OFFICE ESTIMATE

Pursuant to clause 3(c)(3) of rule XIII of the Rules of the House of Representatives, the following is the cost estimate provided by the Congressional Budget Office pursuant to section 402 of the Congressional Budget Act of 1974:

MAY 31, 2013.

Hon. FRED UPTON,
Chairman, Committee on Energy and Commerce,
U.S. House of Representatives, Washington, DC.

DEAR MR. CHAIRMAN: The Congressional Budget Office has prepared the enclosed cost estimate for H.R. 1919, the Safeguarding America's Pharmaceuticals Act of 2013.

If you wish further details on this estimate, we will be pleased to provide them. The CBO staff contact is Ellen Werble.

Sincerely,

DOUGLAS W. ELMENDORF,
Director.

Enclosure.

H.R. 1919—Safeguarding America's Pharmaceuticals Act of 2013

Summary: H.R. 1919 would require the Food and Drug Administration (FDA) to establish national standards for monitoring the

movement of prescription drugs through the drug distribution system. The "drug distribution system" encompasses the network of companies that produce, handle, distribute, and dispense drug products. The legislation would impose new regulatory requirements on such companies relating to the handling of drug products and recordkeeping of transactions, and would create notification rules concerning drugs that are potentially unsuitable for distribution.

The bill also would require the FDA to establish a licensing program for certain third parties that provide logistic services to support pharmaceutical manufacturers, wholesalers, and dispensers. The bill would authorize FDA to collect and spend fees to cover the costs of the licensing program.

CBO estimates that enacting H.R. 1919 would increase federal revenues by $19 million over the 2015–2018 period and by $24 million over the 2015–2023 period. Pay-as-you-go procedures apply because enacting the legislation would affect revenues.

CBO estimates that implementing H.R. 1919 would have a discretionary cost of $39 million over the 2014–2018 period, assuming annual appropriation actions consistent with the bill.

H.R. 1919 would impose both intergovernmental and private-sector mandates as defined in the Unfunded Mandates Reform Act (UMRA) by requiring public and private-sector entities to comply with standards for monitoring the movement of prescription drugs through the distribution system. Because few public entities manufacture, distribute, or dispense prescription drugs, CBO estimates that the costs to public entities to comply with the mandates in the bill would be small and below the intergovernmental threshold established in UMRA ($75 million in 2013, adjusted annually for inflation). CBO estimates that the costs to private entities would exceed the threshold established in UMRA ($150 million in 2013, adjusted annually for inflation).

Estimated cost to the Federal Government: The estimated budgetary impact of H.R. 1919 is shown in the following table. The costs of this legislation fall within budget function 550 (health).

	By fiscal year, in millions of dollars—					
	2014	2015	2016	2017	2018	2014–2018
CHANGES IN REVENUES [a]						
Collection of Licensing Fees						
Estimated Revenues [b]	0	6	6	6	1	19
Penalties						
Estimated Revenues	0	*	*	*	*	*
Total Changes in Revenues						
Estimated Revenues	0	6	6	6	1	19
CHANGES IN SPENDING SUBJECT TO APPROPRIATION						
Spending of Licensing Fees						
Estimated Authorization Level	0	7	7	8	1	23
Estimated Outlays	0	6	7	8	2	23
Activities not Related to Fees						
Estimated Authorization Level	3	5	5	2	2	17
Estimated Outlays	2	4	5	3	2	16
Total Changes in Discretionary Spending						
Estimated Authorization Level	3	12	12	10	3	40

	By fiscal year, in millions of dollars—					
	2014	2015	2016	2017	2018	2014–2018
Estimated Outlays	2	10	12	11	4	39

Note: * = less than $500,000.
[a] CBO estimates that enacting the bill would increase revenues by $24 million over the 2015–2023 period.
[b] CBO estimates that the assessments in H.R. 1919 would reduce income and payroll taxes because assessments on firms are indirect business charges that reduce the tax base of income and payroll taxes. Numbers here reflect net receipts to the Treasury.

Basis of estimate: For the estimate, CBO assumes that the legislation will be enacted by the end of fiscal year 2013, and that the Congress will take appropriation actions consistent with the bill for the funding of FDA activities. We also assume that outlays will follow historical patterns for similar activities.

H.R. 1919 would authorize FDA to expand its oversight of the drug distribution system in the United States. The legislation aims to improve the safety of the U.S. drug supply by requiring enhanced monitoring of the chain of transactions from the manufacturer of a drug to the party that ultimately dispenses the drug to the consumer.

Key provisions of H.R. 1919 include new requirements on entities in the drug distribution system relating to:

- Storage and handling of prescription drug products,
- Maintenance of records,
- Mandatory inspections of wholesaler facilities,
- Mandatory use of uniform identification numbers (UIDs) on packages or cases,[1] and
- Identification and notification rules concerning products that are potentially counterfeit, diverted, stolen or otherwise appear unfit for distribution.

Revenues: CBO estimates that enacting H.R. 1919 would increase federal revenues by $19 million over the 2015–2018 period and by $24 million over the 2015–2023 period. The legislation would affect revenues in two ways:

- Authorizing the FDA to assess fees on certain third parties to cover the costs of licensing and conducting periodic inspections would increase governmental receipts; and
- Collecting fines associated with violations of certain new requirements imposed by the bill that would be recorded as federal revenues.

Collection of Licensing Fees. H.R. 1919 would require the FDA to license and oversee certain third parties that provide logistic services for a pharmaceutical manufacturer, wholesaler, or distributor. For example, services provided by such entities include warehousing and transporting drug products without taking ownership or responsibility for the sale or disposition of the products. The bill would require all such facilities to be licensed by a state or the FDA. The bill would authorize the collection and spending of fees by FDA to cover the costs of activities related to issuing those licenses such as periodic inspections.

CBO expects FDA would begin licensing facilities in fiscal year 2015, thus we expect fee collections would start in that year. CBO

[1] After 2027, the bill would require that identifiers be applied to individual units of drug products.

expects that FDA would set fees to cover $23 million in estimated gross costs over the 2015–2018 period (as described below under "Spending Subject to Appropriation"). However, because those fees are expected to reduce the tax base for income and payroll taxes, CBO estimates revenues from those sources would be reduced. Overall, CBO estimates net receipts to the Treasury would increase by $19 million over the 2015–2018 period.

Penalties. Civil monetary penalties could be assessed on the facilities in the drug distribution system for violations of new requirements under H.R. 1919. Based on enforcement actions of violations, CBO expects that any additional revenues from the imposition of penalties would not be significant because of the small number of additional cases likely to be affected.

Spending subject to appropriation: Assuming appropriation actions consistent with the bill, CBO estimates that implementing H.R. 1919 would have a discretionary cost of $39 million over the 2014–2018 period.

Spending of Licensing Fees. H.R. 1919 would authorize FDA to collect fees to help defray the costs of establishing a licensure program for third parties that provide logistic services. The spending of fees would be subject to future appropriation action. (CBO expects that the collections from licensing fees would be classified as revenues, as discussed above in the "Revenues" section.)

Based on information on costs of similar oversight programs, CBO estimates the costs to the FDA of implementing those provisions of H.R. 1919 would be $23 million over the 2015–2018 period. CBO expects higher start-up costs through 2017 to fund information technology systems and other activities necessary to implement the program.

Activities Not Related to Fees. H.R. 1919 would require FDA to establish a number of standards to enhance the safety and security of prescription drugs as those drugs are distributed from the manufacturer to the pharmacy, hospital, or other persons authorized to dispense or administer prescription drugs to consumers. In developing those standards the FDA would be required to host numerous public meetings, implement at least one pilot project, and promulgate regulations. CBO estimates the costs to FDA of implementing those provisions would be about $16 million over the 2014–2018 period, subject to appropriation of the necessary amounts.

Pay-As-You-Go considerations: The Statutory Pay-As-You-Go Act of 2010 establishes budget-reporting and enforcement procedures for legislation affecting direct spending or revenues. The net changes in revenues that are subject to those pay-as-you-go procedures are shown in the following table.

CBO ESTIMATE OF PAY-AS-YOU-GO EFFECTS FOR H.R. 1919, AS ORDERED REPORTED BY THE HOUSE COMMITTEE ON ENERGY AND COMMERCE ON MAY 15, 2013

	By fiscal year, in millions of dollars—												
	2013	2014	2015	2016	2017	2018	2019	2020	2021	2022	2023	2013–2018	2013–2023
	NET DECREASE (−) IN THE DEFICIT												
Statutory Pay-As-You-Go Impact	0	0	−6	−6	−6	−1	−1	−1	−1	−1	−1	−19	−24

Intergovernmental and private-sector impact: H.R. 1919 would impose both intergovernmental and private-sector mandates as defined in UMRA by requiring public and private-sector entities to comply with standards for monitoring the movement of prescription drugs through the distribution system.

Effects on the Private Sector: To monitor the movement of prescription drugs, the bill would impose a number of mandates, as defined in UMRA, on drug manufacturers, repackagers, wholesale distributors, dispensers (primarily pharmacies), and third parties that provide logistic services (TPLs). Such entities would be required to:

- Maintain records of the transaction history of all drug products for three years,
- Only accept or transfer ownership of drug products with a UID,
- Identify suspect or illegitimate drug products and notify the FDA of such a discovery,
- Identify, quarantine, dispose, and maintain records of illegitimate drug products, and
- Pay fees to cover the costs of licensing.

Because existing law in California affects nearly all manufacturers, repackagers, wholesale distributors, and TPLs, CBO estimates that the cost of the mandates contained in H.R. 1919 for those private-sector entities would be small. However, independent pharmacies and pharmacies based in hospitals—currently unaffected by existing laws in California—would face new costs to comply with the mandates. According to data from the National Community Pharmacy Association, roughly 20,000 independent pharmacies operate outside of California, most of which would incur new costs in complying with the requirements in H.R. 1919.

The cost of compliance would vary across pharmacies and would depend on the type of data systems developed by manufacturers, wholesale distributors, TPLs, and repackagers. A study by Accenture in 2011 estimated that the cost of complying with a federal standard for tracing prescription drugs would cost the average independent pharmacy roughly $84,000 per pharmacy store in the first year.[2] Even if the first-year costs to independent and hospital-based pharmacies that operate outside of California were half that amount, the costs to comply with the mandate in that year would exceed $800 million. Thus, CBO estimates the costs to those pharmacies of complying with the standards in H.R. 1919 would exceed the threshold established in UMRA ($150 million in 2013, adjusted annually for inflation) in at least one of the first five years in which the mandate would be in effect.

Effects on state, local, and tribal governments: Because few pharmacies are public entities, CBO estimates that the intergovernmental costs of the mandates would be small and below the threshold established in UMRA ($75 million in 2013, adjusted annually for inflation). The bill also would preempt state laws that require tracing prescription drugs through the distribution system. In addition, the legislation would preempt state licensing laws that govern wholesale drug distributors or TPLs if those laws are less stringent

[2] "Current Status of Safety of the U.S. Prescription Drug Distribution System," June 2008, Updated for NACDS March 2011, Accenture.

than the standards established by the bill. Because they would limit the application of state law, those preemptions would be intergovernmental mandates as defined in UMRA; however, they would impose no duty on states that would result in additional spending.

Estimate prepared by: Federal Costs: Ellen Werble, Lisa Ramirez-Branum, and Barbara Edwards; Impact on State, Local, and Tribal Governments: Lisa Ramirez-Branum; Impact on the Private Sector: Michael Levine.

Estimate approved by: Holly Harvey, Deputy Assistant Director for Budget Analysis.

FEDERAL MANDATES STATEMENT

The Committee adopts as its own the estimate of Federal mandates prepared by the Director of the Congressional Budget Office pursuant to section 423 of the Unfunded Mandates Reform Act.

DUPLICATION OF FEDERAL PROGRAMS

No provision of H.R. 1919 establishes or reauthorizes a program of the Federal Government known to be duplicative of another Federal program, a program that was included in any report from the Government Accountability Office to Congress pursuant to section 21 of Public Law 111–139, or a program related to a program identified in the most recent Catalog of Federal Domestic Assistance.

DISCLOSURE OF DIRECTED RULE MAKINGS

The Committee estimates that enacting H.R. 1919 specifically directs to be completed 6 specific rule makings within the meaning of 5 U.S.C. 551.

ADVISORY COMMITTEE STATEMENT

No advisory committees within the meaning of section 5(b) of the Federal Advisory Committee Act were created by this legislation.

APPLICABILITY TO LEGISLATIVE BRANCH

The Committee finds that the legislation does not relate to the terms and conditions of employment or access to public services or accommodations within the meaning of section 102(b)(3) of the Congressional Accountability Act.

SECTION-BY-SECTION ANALYSIS OF THE LEGISLATION

Section 1: Short Title

Section 1 provides the short title of "Safeguarding America's Pharmaceuticals Act of 2013."

Section 2: Pharmaceutical Distribution Supply Chain

This section would increase the security of the supply chain by establishing lot-level tracing requirements for manufacturers, wholesale distributors, pharmacies, and repackagers based on changes in ownership. These requirements would be phased in starting on January 1, 2015. Under the requirements, transaction statements would be passed through the supply chain so those tak-

ing ownership would know where the drug had been. It also would require the members of the supply chain, including third-party logistics providers, to undertake verification and notification activities regarding suspect or illegitimate products. Further, it would require that members of the supply chain only transact with registered or licensed entities. Finally, the section would require manufacturers to serialize prescription drugs at the unit-level starting in five years.

Section 3: Enhanced Drug Distribution Security

This section would require the FDA to establish pilot projects and hold biannual public meetings in order to foster collaboration with stakeholders regarding moving to unit-level traceability. The section also would require that the Government Accountability Office (GAO) and FDA submit reports to Congress on those same subjects. As part of its report, FDA would include the findings of a study by a third-party entity on small dispensers' ability to conduct interoperable tracing at the unit-level. Finally, it would require FDA to issue a proposed regulation on unit-level traceabilty in 2027.

Section 4: National Standards for Wholesale Distributors

This section would establish national standards for wholesale distributors, while continuing State licensing of wholesale distributors and State fee collection.

Section 5: National Licensure Standards for Third-Party Logistics Providers

This section would establish third-party logistics provider licensure standards and allow FDA to charge a user fee. It would not prevent a State from licensing third-party logistics providers in accordance with the section.

Section 6: Penalties

This section would establish penalties for violations of the requirements of the bill to ensure bad actors are held accountable.

Section 7: Uniform National Policy

This section would preempt, upon enactment, State laws on tracing drugs through the distribution system, including California. It also would preempt State laws regarding standards for wholesale drug distributors and third-party logistics providers. This preemption would not affect the authority of States to collect fees from wholesale drug distributors or third-party logistics providers. In addition, State programs related to prescription drug monitoring and controlled substance reporting would not be affected.

Section 8: Electronic Labeling Requirement

This section would allow prescription drug labeling, other than container or container labels, to be provided by electronic means to physician, pharmacists, or other healthcare professionals. The Secretary may exclude drugs subject to section 503(b)(1) in order to mitigate safety risks. Physicians, pharmacists, and healthcare professionals may receive paper labeling by request at no cost to themselves.

CHANGES IN EXISTING LAW MADE BY THE BILL, AS REPORTED

In compliance with clause 3(e) of rule XIII of the Rules of the House of Representatives, changes in existing law made by the bill, as reported, are shown as follows (existing law proposed to be omitted is enclosed in black brackets, new matter is printed in italic, existing law in which no change is proposed is shown in roman):

FEDERAL FOOD, DRUG, AND COSMETIC ACT

* * * * * * *

CHAPTER III—PROHIBITED ACTS AND PENALTIES

PROHIBITED ACTS

SEC. 301. The following acts and the causing thereof are hereby prohibited:

(a) * * *

* * * * * * *

(t) The importation of a drug in violation of section 801(d)(1), the sale, purchase, or trade of a drug or drug sample or the offer to sell, purchase, or trade a drug or drug sample in violation of section 503(c), the sale, purchase, or trade of a coupon, the offer to sell, purchase, or trade such a coupon, or the counterfeiting of such a coupon in violation of section 503(c)(2), the distribution of a drug sample in violation of section 503(d) or the failure to otherwise comply with the requirements of section 503(d), [or the distribution of drugs in violation of section 503(e) or the failure to otherwise comply with the requirements of section 503(e)] *the failure to comply with any requirement of section 582, engaging in the wholesale distribution of a drug in violation of section 583 or the failure to otherwise comply with the requirements of section 583, or engaging in the activities of a third-party logistics provider in violation of section 584 or the failure to otherwise comply with the requirements of section 584.*

* * * * * * *

PENALTIES

SEC. 303. (a) * * *

(b)(1) Notwithstanding subsection (a), any person who violates section 301(t) by—

(A) * * *

* * * * * * *

(D) knowingly distributing drugs in violation of section [503(e)(2)(A)] *583 or 584*,

shall be imprisoned for not more than 10 years or fined not more than $250,000, or both.

* * * * * * *

CHAPTER V—DRUGS AND DEVICES

SUBCHAPTER A—DRUGS AND DEVICES

* * * * * * *

MISBRANDED DRUGS AND DEVICES

SEC. 502. A drug or device shall be deemed to be misbranded—
(a) * * *

* * * * * * *

(f) Unless its labeling bears (1) adequate directions for use; and (2) such adequate warnings against use in those pathological conditions or by children where its use may be dangerous to health, or against unsafe dosage or methods or duration of administration or application, in such manner and form, as are necessary for the protection of users, except that where any requirement of clause (1) of this paragraph, as applied to any drug or device, is not necessary for the protection of the public health, the Secretary shall promulgate regulations exempting such drug or device from such requirement. Required labeling for prescription devices intended for use in health care facilities or by a health care professional and required labeling for in vitro diagnostic devices intended for use by health care professionals or in blood establishments may be made available solely by electronic means, provided that the labeling complies with all applicable requirements of law, and that the manufacturer affords such users the opportunity to request the labeling in paper form, and after such request, promptly provides the requested information without additional cost. *Required labeling (other than immediate container or carton labels) that is intended for use by a physician, a pharmacist, or another health care professional, and that provides directions for human use of a drug subject to section 503(b)(1), may (except as necessary to mitigate a safety risk, as specified by the Secretary in regulation) be made available by electronic means instead of paper form, provided that such labeling complies with all applicable requirements of law, the manufacturer or distributor, as applicable, affords health care professionals and authorized dispensers (as defined in section 581) the opportunity to request the labeling in paper form, and after such a request the manufacturer or distributor promptly provides the requested information without additional cost.*

* * * * * * *

(bb) If it is a drug and it fails to bear a prescription drug product identifier as required by section 582.

EXEMPTIONS AND CONSIDERATION FOR CERTAIN DRUGS, DEVICES, AND BIOLOGICAL PRODUCTS

SEC. 503. (a) * * *

* * * * * * *

[(e)(1)(A) Each person who is engaged in the wholesale distribution of a drug subject to subsection (b) and who is not the manufacturer or an authorized distributor of record of such drug shall, before each wholesale distribution of such drug (including each distribution to an authorized distributor of record or to a retail pharmacy), provide to the person who receives the drug a statement (in such form and containing such information as the Secretary may require) identifying each prior sale, purchase, or trade of such drug (including the date of the transaction and the names and addresses of all parties to the transaction).

[(B) Each manufacturer of a drug subject to subsection (b) shall maintain at its corporate offices a current list of the authorized distributors of record of such drug.

[(2)(A) No person may engage in the wholesale distribution in interstate commerce of drugs subject to subsection (b) in a State unless such person is licensed by the State in accordance with the guidelines issued under subparagraph (B).

[(B) The Secretary shall by regulation issue guidelines establishing minimum standards, terms, and conditions for the licensing of persons to make wholesale distributions in interstate commerce of drugs subject to subsection (b). Such guidelines shall prescribe requirements for the storage and handling of such drugs and for the establishment and maintenance of records of the distributions of such drugs.

[(3) For the purposes of this subsection and subsection (d)—] *(e) For purposes of subsection (d)—*

[(A)] *(1)* the term "authorized distributors of record" means those distributors with whom a manufacturer has established an ongoing relationship to distribute such manufacturer's products, and

[(B)] *(2)* the term "wholesale distribution" means distribution of drugs subject to subsection (b) to other than the consumer or patient but does not include intracompany sales and does not include distributions of drugs described in subsection (c)(3)(B).

* * * * * * *

Subchapter H—Pharmaceutical Distribution Supply Chain

SEC. 581. DEFINITIONS.

In this subchapter:

(1) AUTHORIZED.—The term "authorized" means—

(A) in the case of a manufacturer or repackager, having a valid registration in accordance with section 510; and

(B) in the case of a wholesale distributor, third-party logistics provider, or dispenser, licensed (as defined in this section).

(2) DISPENSER.—The term "dispenser"—

(A) subject to subparagraph (C), means a retail pharmacy, hospital pharmacy, a group of chain pharmacies under common ownership and control, or any other person authorized by law to dispense or administer prescription drugs, to the extent such pharmacy, group, or person does not act as a wholesale distributor;

(B) includes warehouses and distribution centers under common ownership or control of entities described in subparagraph (A) that are members of an affiliated group pursuant to section 1504(a) of the Internal Revenue Code of 1986, to the extent such warehouses and distribution centers do not act as a wholesale distributor; and

(C) does not include a person who only dispenses prescription drug product to be used in animals in accordance with section 512(a)(5).

(3) DISPOSITION.—The term "disposition", with respect to a prescription drug product within the possession and control of an entity—

(A) means the removal of such prescription drug product, or taking measures to prevent the introduction of such prescription drug product, from the pharmaceutical distribution supply chain; and

(B) may include disposal, return of the prescription drug product for disposal, or other appropriate handling and other actions such as retaining a sample of the prescription drug product for additional physical examination or laboratory analysis by a manufacturer or regulatory or law enforcement agency.

(4) DISTRIBUTE OR DISTRIBUTION.—The terms "distribute" and "distribution" mean the sale, purchase, trade, delivery, handling, or storage of a prescription drug product.

(5) ILLEGITIMATE PRESCRIPTION DRUG PRODUCT.—The term "illegitimate prescription drug product" means a prescription drug product which a manufacturer has confirmed—

(A) is counterfeit, diverted, or stolen;

(B) is intentionally adulterated such that the prescription drug product would result in serious adverse health consequences or death to humans; or

(C) is otherwise unfit for distribution such that the prescription drug product is reasonably likely to cause serious adverse human health consequences or death.

(6) LICENSED.—The term "licensed" means—

(A) in the case of a wholesale distributor, having a valid license to make wholesale distributions consistent with the standards under section 583;

(B) in the case of a third-party logistics provider, having a valid license to engage in the activities of a third-party logistics provider in accordance with section 584; and

(C) in the case of a dispenser, having a valid license to dispense prescription drugs under State law.

(7) MANUFACTURER.—The term "manufacturer" means, with respect to a prescription drug product—

(A) a person that holds an application approved under section 505 or a license issued under section 351 of the Public Health Service Act for such prescription drug product, or if such prescription drug product is not the subject of an approved application or license, the person who manufactured the prescription drug product;

(B) a co-licensed partner of the person described in subparagraph (A) that obtains the prescription drug product directly from the person described in such subparagraph; or

(C) a person that—

(i) is a member of an affiliated group (as defined in section 1504(a) of the Internal Revenue Code of 1986) to which a person described in subparagraph (A) or (B) is also a member; and

(ii) receives the prescription drug product directly from a person described in subparagraph (A) or (B).

(8) PACKAGE.—

(A) IN GENERAL.—The term "package" means the smallest individual saleable unit of prescription drug product for distribution in interstate commerce by a manufacturer or repackager that is intended by the manufacturer for ultimate sale to the dispenser of such prescription drug product.

(B) INDIVIDUAL SALEABLE UNIT.—The term "individual saleable unit" means the smallest container of prescription drug product introduced into interstate commerce by the manufacturer or repackager that is intended by the manufacturer for individual sale to a dispenser.

(9) PRESCRIPTION DRUG.—The term "prescription drug" means a drug for human use subject to section 503(b)(1).

(10) PRESCRIPTION DRUG PRODUCT.—The term "prescription drug product" means a prescription drug in a finished dosage form for administration to a patient without substantial further manufacturing (such as capsules, tablets, and lyophilized prescription drug products before reconstitution).

(11) PRESCRIPTION DRUG PRODUCT IDENTIFIER.—The term "prescription drug product identifier" means a standardized graphic that—

(A) includes the standardized numerical identifier, lot number, and expiration date of a prescription drug product; and

(B) is in both human-readable form and on a machine-readable data carrier that conforms to the standards developed by a widely recognized international standards development organization.

(12) QUARANTINE.—The term "quarantine" means to store or identify a product, for the purpose of preventing distribution or transfer of the product, in a physically separate area clearly identified for such use, or through use of other procedures such as automated designation.

(13) REPACKAGER.—The term "repackager" means a person who owns or operates an establishment that repacks and relabels a prescription drug product or package for further sale or distribution.

(14) RETURN.—The term "return" means providing prescription drug product to the authorized trading partner or trading partners from which such prescription drug product was purchased or received, or to a returns processor for handling of such prescription drug product.

(15) RETURNS PROCESSOR.—The terms "returns processor" mean a person who owns or operates an establishment that provides for the disposition of or otherwise processes saleable and nonsaleable prescription drug product received from an authorized trading partner such that the prescription drug product may be processed for credit to the purchaser, manufacturer, seller, or disposed of for no further distribution.

(16) SPECIFIC PATIENT NEED.—The term "specific patient need"—

(A) means with respect to the transfer of a prescription drug product from one pharmacy to another, to fill a prescription for an identified patient; and

(B) does not include the transfer of a prescription drug product from one pharmacy to another for the purpose of increasing or replenishing stock in anticipation of a potential need.

(17) STANDARDIZED NUMERICAL IDENTIFIER.—The term "standardized numerical identifier" means a set of numbers or characters that—

(A) is used to uniquely identify each package or homogenous case of the prescription drug product; and

(B) is composed of the National Drug Code that corresponds to the specific prescription drug product (including the particular package configuration) combined with a unique alphanumeric serial number of up to 20 characters.

(18) SUSPECT PRESCRIPTION DRUG PRODUCT.—The term "suspect prescription drug product" means a prescription drug product for which there is reason to believe that such prescription drug product—

(A) is potentially counterfeit, diverted, or stolen;

(B) is potentially intentionally adulterated such that the prescription drug product would result in serious adverse health consequences or death to humans; or

(C) appears otherwise unfit for distribution such that the prescription drug product would result in serious adverse health consequences or death to humans.

(19) THIRD-PARTY LOGISTICS PROVIDER.—The term "third-party logistics provider" means an entity that provides or coordinates warehousing, distribution, or other logistics services of a prescription drug product in interstate commerce on behalf of a manufacturer, wholesale distributor, or dispenser of a prescription drug product, but does not take ownership of the prescription drug product, nor have responsibility to direct the sale or disposition of, the prescription drug product.

(20) TRADING PARTNER.—The term "trading partner" means—

(A) a manufacturer, repackager, wholesale distributor, or dispenser from whom a manufacturer, repackager, wholesale distributor, or dispenser accepts ownership of a prescription drug product or to whom a manufacturer, repackager, wholesale distributor, or dispenser transfers ownership of a prescription drug product; or

(B) a third-party logistics provider from whom a manufacturer, repackager, wholesale distributor, or dispenser accepts possession of a prescription drug product or to whom a manufacturer, repackager, wholesale distributor, or dispenser transfers possession of a prescription drug product.

(21) TRANSACTION.—

(A) IN GENERAL.—The term "transaction" means the transfer in interstate commerce of prescription drug product between persons in which a change of ownership occurs.

(B) EXEMPTIONS.—The term "transaction" does not include—

(i) intracompany distribution of any prescription drug product, including between members of an affiliated group (as defined in section 1504(a) of the Internal Revenue Code of 1986);

(ii) the distribution of a prescription drug product among hospitals or other health care entities that are under common control;

(iii) the distribution of a prescription drug product for emergency medical reasons including a public health emergency declaration pursuant to section 319 of the Public Health Service Act, except that a drug shortage not caused by a public health emergency shall not constitute an emergency medical reason;

(iv) the dispensing of a prescription drug product pursuant to a valid prescription executed in accordance with section 503(b)(1);

(v) the distribution of prescription drug product samples by a manufacturer or a licensed wholesale distributor in accordance with section 503(d);

(vi) the distribution of blood or blood components intended for transfusion;

(vii) the distribution of minimal quantities of prescription drug product by a licensed retail pharmacy to a licensed practitioner for office use;

(viii) the distribution of a prescription drug product by a charitable organization to a nonprofit affiliate of the organization to the extent otherwise permitted by law;

(ix) the distribution of a prescription drug product pursuant to the sale or merger of a pharmacy or pharmacies or a wholesale distributor or wholesale distributors, except that any records required to be maintained for the prescription drug product shall be transferred to the new owner of the pharmacy or pharmacies or wholesale distributor or wholesale distributors;

(x) the dispensing of a prescription drug product approved under section 512(b);

(xi) the transfer of prescription drug products to or from any facility that is licensed by the Nuclear Regulatory Commission or by a State pursuant to an agreement with such Commission under section 274 of the Atomic Energy Act of 1954 (42 U.S.C. 2021);

(xii) the distribution of a combination product that consists of—

(I) a product comprised of two or more components that are each a drug, biological product, or device and that are physically, chemically, or otherwise combined or mixed and produced as a single entity;

(II) two or more separate products packaged together in a single package or as a unit and comprised of a drug and device or a device and biological product; or

(III) two or more finished devices plus one or more drug or biological products which are packaged together in a medical convenience kit described in clause (xiv);

(xiii) the distribution of a medical convenience kit which is a collection of finished products (consisting of

devices or drugs) assembled in kit form strictly for the convenience of the purchaser or user if—

(I) the medical convenience kit is assembled in an establishment that is registered with the Food and Drug Administration as a medical device manufacturer;

(II) the person who manufacturers the medical convenience kit purchased the prescription drug product directly from the manufacturer or from a wholesale distributor that purchased the prescription drug product directly from the manufacturer;

(III) the person who manufacturers the medical convenience kit does not alter the primary container or label of the prescription drug product as purchased from the manufacturer or wholesale distributor;

(IV) the medical convenience kit does not contain a controlled substance (as defined in section 102 of the Controlled Substances Act); and

(V) the prescription drug products contained in the medical convenience kit are—

(aa) intravenous solutions intended for the replenishment of fluids and electrolytes;

(bb) drugs intended to maintain the equilibrium of water and minerals in the body;

(cc) drugs intended for irrigation or reconstitution;

(dd) anesthetics;

(ee) anticoagulants;

(ff) vasopressors; or

(gg) sympathicomimetics;

(xiv) the distribution of an intravenous prescription drug product that, by its formulation, is intended for the replenishment of fluids and electrolytes (such as sodium, chloride, and potassium) or calories (such as dextrose and amino acids);

(xv) the distribution of an intravenous prescription drug product used to maintain the equilibrium of water and minerals in the body, such as dialysis solutions;

(xvi) the distribution of a prescription drug product that is intended for irrigation or reconstitution, or sterile water, whether intended for such purposes or for injection;

(xvii) the distribution of compressed medical gas; or

(xviii)(I) the distribution of a product by a dispenser, or a wholesale distributor acting at the direction of the dispenser, to a repackager registered under section 510 for the purpose of repackaging the drug for use by that dispenser or another health care entity that is under the dispenser's ownership or control, so long as the dispenser retains ownership of the prescription drug product; and

(II) the saleable or nonsaleable return by such repackager of such prescription drug product.

(C) COMPRESSED MEDICAL GAS.—For purposes of subparagraph (B)(xviii), the term "compressed medical gas" means any substance in its gaseous or cryogenic liquid form that meets medical purity standards and has application in a medical or homecare environment, including oxygen and nitrous oxide.

(22) TRANSACTION HISTORY.—The term "transaction history" means a statement that—

(A) includes the transaction information for each transaction conducted with respect to a prescription drug product beginning with the manufacturer or initial purchase distributor for each prior transaction going back to the manufacturer of the prescription drug product or to the initial purchase distributor; and

(B) is in paper or electronic form.

(23) TRANSACTION INFORMATION.—The term "transaction information" means—

(A) the proprietary or established name or names of the prescription drug product;

(B) the strength and dosage form of the prescription drug product;

(C) the National Drug Code number of the prescription drug product;

(D) the container size;

(E) the number of containers;

(F) the lot number of the prescription drug product;

(G) the date of the transaction;

(H) the business name and address of the person from whom ownership is being transferred; and

(I) the business name and address of the person to whom ownership is being transferred.

(24) TRANSACTION STATEMENT.—The "transaction statement" is a statement, which states that the manufacturer, repackager, wholesale distributor, third-party logistics provider, or dispenser transferring ownership in a transaction—

(A) is authorized;

(B) received transaction information and a transaction statement as required under section 582 from the prior owner of the prescription drug product;

(C) did not knowingly and intentionally ship an illegitimate prescription drug product;

(D) did not knowingly and intentionally provide false transaction information; and

(E) did not knowingly and intentionally alter the transaction history.

(25) VERIFICATION AND VERIFY.—The terms "verification" and "verify"—

(A) mean determining whether the prescription drug product identifier affixed to, or imprinted upon, a package or homogeneous case of the prescription drug product corresponds to the standardized numerical identifier or lot number, and expiration date assigned to the prescription drug product by the manufacturer or the repackager, as applicable; and

(B) include making the determination under subparagraph (A) using human-readable or machine-readable methods.

(26) WHOLESALE DISTRIBUTOR.—The term "wholesale distributor"—

(A) means a person engaged in wholesale distribution (as defined in section 583); and

(B) excludes—

(i) a manufacturer, a co-licensed partner of a manufacturer, or a third-party logistics provider, or a dispenser who does not engage in such wholesale distribution;

(ii) a repackager engaged in such wholesale distribution; or

(iii) the distribution of prescription drug product or an offer to distribute prescription drug product by an authorized repackager that has taken ownership or possession of the prescription drug product and repacked the prescription drug product in accordance with the requirements of section 582(e).

SEC. 582. REQUIREMENTS.

(a) IN GENERAL.—

(1) COMPLIANCE REQUIRED.—An entity that is a manufacturer, repackager, wholesale distributor, third-party logistics provider, or dispenser shall comply with the requirements of this section. If an entity meets the definition of more than one of the entities referred to in the preceding sentence, such entity shall comply with all applicable requirements of this section, but shall not be required to comply with duplicative requirements.

(2) STANDARDS.—The Secretary shall, in consultation with other appropriate Federal officials, manufacturers, repackagers, wholesale distributors, third-party logistics providers, and dispensers, establish, by regulation, standards for the exchange of transaction information for purposes of complying with this section. The standards established under this paragraph shall be in accordance with a form developed by a widely recognized international standards development organization. In establishing such standards, the Secretary shall consider the feasibility of establishing standardized documentation to be used by all members of the pharmaceutical distribution supply chain to convey the transaction history and transaction statement to the subsequent owner of a prescription drug product. The Secretary shall publish such standards not later than 180 days after the date of the enactment of the Safeguarding America's Pharmaceuticals Act of 2013.

(3) WAIVERS, EXCEPTIONS, AND EXEMPTIONS.—Not later than one year after the date of the enactment of the Safeguarding America's Pharmaceuticals Act of 2013, the Secretary shall promulgate a regulation to—

(A) establish a process by which the Secretary may grant, at the request of an authorized manufacturer, repackager, wholesale distributor, or dispenser, a waiver from any of the requirements of this section—

(i) if the Secretary determines that such requirements would result in an undue economic hardship; or

(ii) for emergency medical reasons, including a public health emergency declaration pursuant to section 319 of the Public Health Service Act;

(B) establish a process, with respect to the prescription drug product identifier requirement under paragraph (2) of subsections (b), (c), (d), and (e) through which—

(i) a manufacturer or repackager may request a waiver with respect to prescription drug products that are packaged in a container too small or otherwise unable to accommodate a label with sufficient space to bear the information required for compliance with such requirement; and

(ii) the Secretary determines whether to waive such requirement; and

(C) establish a process by which the Secretary may add the prescription drug products or transactions that are exempt from the requirements of this section.

(4) GRANDFATHERED PERSONS AND PRESCRIPTION DRUG PRODUCTS.—

(A) IN GENERAL.—Not later than one year after the date of the enactment of the Safeguarding America's Pharmaceuticals Act of 2013, the Secretary shall specify, by regulation, whether and under what circumstances the prescription drug product identifier requirement under paragraph (2) of subsections (b), (c), (d), and (e) shall apply to a prescription drug product that is in the supply chain or in a manufacturer's inventory on the date of the enactment of the Safeguarding America's Pharmaceuticals Act of 2013.

(B) THIRD-PARTY LOGISTICS PROVIDER LICENSES.—Until the date that is 1 year after the effective date of the third-party logistics provider licensing requirements under section 584, a third-party logistics provider shall be considered "licensed" under section 581(6)(B) unless the Secretary has made a finding that the third-party logistics provider does not utilize good handling and distribution practices and publishes notice thereof.

(C) LABEL CHANGES.—Changes made to package labels solely to incorporate the prescription drug product identifier may be submitted to the Secretary in the annual report of an establishment, in accordance with section 314.70(d) of chapter 21, Code of Federal Regulations (or any successor regulation).

(b) MANUFACTURER REQUIREMENTS.—

(1) PRESCRIPTION DRUG PRODUCT TRACING.—

(A) IN GENERAL.—Beginning not later than January 1, 2015, a manufacturer shall—

(i) prior to, or at the time of, each transaction in which such manufacturer transfers ownership of a prescription drug product, provide the subsequent owner with the transaction history and a transaction statement; and

(ii) maintain the transaction information for each such transaction for not less than 3 years after the date of the transaction.

(B) REQUESTS FOR INFORMATION.—Upon a request by the Secretary or other appropriate Federal or State official, in the event of a recall or for the purpose of investigating a suspect prescription drug product or an illegitimate prescription drug product, a manufacturer shall, not later than 2 business days after receiving the request or in such reasonable time as determined by the Secretary, provide to the Secretary or other official, the applicable transaction history and transaction statement for the prescription drug product.

(2) PRESCRIPTION DRUG PRODUCT IDENTIFIER.—Beginning not later than 5 years after the date of the enactment of the Safeguarding America's Pharmaceuticals Act of 2013, a manufacturer shall affix or imprint a prescription drug product identifier on each package and homogenous case of a prescription drug product intended to be introduced in a transaction. Such manufacturer shall maintain the information in the prescription drug product identifier for such prescription drug product for not less than 3 years after the date of the transaction.

(3) AUTHORIZED TRADING PARTNERS.—Beginning not later than January 1, 2015, a manufacturer shall ensure that each of its trading partners is authorized.

(4) LIST OF AUTHORIZED DISTRIBUTORS OF RECORD.—Beginning not later than January 1, 2015, each manufacturer of a prescription drug shall—

(A) maintain a list of the authorized distributors of record of such drug at the corporate offices of such manufacturer;

(B) make such list publicly available, including placement on the Internet Website of such manufacturer; and

(C) update such list not less than once per quarter.

(5) VERIFICATION.—Beginning not later than January 1, 2015, a manufacturer shall implement systems and processes to enable the manufacturer to comply with the following requirements:

(A) SUSPECT PRESCRIPTION DRUG PRODUCT.—

(i) IN GENERAL.—Upon making a determination that a prescription drug product in the possession or control of the manufacturer is a suspect prescription drug product, or upon receiving a request for verification from the Secretary that a prescription drug product within the possession or control of a manufacturer is a suspect prescription drug product, a manufacturer shall promptly conduct an investigation in coordination with trading partners, as applicable, to determine whether the prescription drug product is an illegitimate prescription drug product. Beginning not later than 5 years after the date of the enactment of the Safeguarding America's Pharmaceuticals Act of 2013, such investigation shall include—

(I) verifying the prescription drug product at the package level;

(II) validating any applicable transaction history in the possession of the manufacturer; and

(III) otherwise investigating to determine whether the prescription drug product is an illegitimate prescription drug product.

(ii) CLEARED PRESCRIPTION DRUG PRODUCT.—If the manufacturer determines that a suspect prescription drug product is not an illegitimate prescription drug product, the manufacturer shall promptly notify the Secretary of such determination and such prescription drug product may be further distributed.

(iii) RECORDS.—A manufacturer shall keep records of its investigation of a suspect prescription drug product for not less than 3 years after the conclusion of the investigation.

(B) ILLEGITIMATE PRESCRIPTION DRUG PRODUCT.—

(i) IN GENERAL.—Upon determining that a prescription drug product in the possession or control of a manufacturer is an illegitimate prescription drug product, the manufacturer shall—

(I) quarantine such prescription drug product from prescription drug product intended for distribution; and

(II) provide for the disposition of the illegitimate prescription drug product.

(ii) TRADING PARTNER.—Upon determining that a prescription drug product in the possession or control of a trading partner is an illegitimate prescription drug product, the manufacturer shall take reasonable steps to assist a trading partner to provide for the disposition of the illegitimate prescription drug product.

(iii) MAKING A NOTIFICATION.—Upon determining that a prescription drug product in the possession or control of the manufacturer is an illegitimate prescription drug product, the manufacturer shall notify the Secretary of such determination not later than 24 hours after making such determination. The Secretary shall determine whether additional trading partner notification is appropriate.

(iv) RESPONDING TO A NOTIFICATION.—Upon the receipt of a notification from the Secretary that a determination has been made that a prescription drug product is an illegitimate prescription drug product, a manufacturer shall—

(I) identify all illegitimate prescription drug products that are subject to such notification and in the possession or control of the manufacturer, including any prescription drug product that is subsequently received; and

(II) perform the activities described in clause (i).

(v) RECORDS.—A manufacturer shall keep records of the disposition of an illegitimate prescription drug product for not less than 3 years after the conclusion of the disposition.

(C) ELECTRONIC DATABASE.—A manufacturer may satisfy the requirements of this paragraph through the use of a secure electronic database developed and operated by the manufacturer or another entity. The owner of such database shall establish the requirements and processes to respond to requests and may provide for data access to other members of the pharmaceutical distribution supply chain, as appropriate. The development and operation of such a database shall not relieve a manufacturer of the requirement under this paragraph to respond to a verification request submitted by means other than a secure electronic database.

(D) RETURNED PRESCRIPTION DRUG PRODUCT.—Beginning not later than 5 years after the date of the enactment of the Safeguarding America's Pharmaceuticals Act of 2013, upon receipt of a returned prescription drug product that the manufacturer intends to further distribute, before further distributing such prescription drug product, the manufacturer shall—

(i) verify the prescription drug product identifier for each sealed homogeneous case of such prescription drug product; or

(ii) if such prescription drug product is not in a sealed homogeneous case, verify the prescription drug product identifier on each package.

(c) WHOLESALE DISTRIBUTOR REQUIREMENTS.—

(1) PRESCRIPTION DRUG PRODUCT TRACING.—

(A) IN GENERAL.—Beginning not later than April 1, 2015, a wholesale distributor shall—

(i) not accept ownership of a prescription drug product unless the previous owner prior to, or at the time of, the transaction provides the applicable transaction history and a transaction statement for the prescription drug product;

(ii) prior to, or at the time of, each transaction in which the wholesale distributor transfers ownership of a prescription drug product—

(I) in the case that the wholesale distributor purchased the prescription drug product directly from the manufacturer, provide the subsequent owner with transaction history and a transaction statement for the prescription drug product; or

(II) in the case that the wholesale distributor did not purchase the prescription drug product directly from the manufacturer, the exclusive distributor of the manufacturer, or a repackager that purchased directly from the manufacturer, provide the subsequent owner with transaction history beginning with the wholesale distributor that did purchase the product directly from the manufacturer, the exclusive distributor of the manufacturer, or a repackager that purchased directly from the manufacturer;

(iii) notwithstanding clause (ii), if the wholesale distributor purchased the prescription drug product di-

rectly from the manufacturer, its exclusive distributor, or a repackager that purchased directly from the manufacturer or its authorized distributor of record—

(I) provide an initial purchase transaction statement on the invoice to the customer, stating that the wholesale distributor purchased the prescription drug product package directly from the manufacturer, exclusive distributor, or repackager;

(II) make available to the immediate subsequent recipient of such prescription drug product the information required under clause (ii) through any combination of self-generated paper, electronic data, or manufacturer-provided information on the prescription drug product package; and

(III) for purposes of subclauses (I) and (II), need not include any transactions occurring before the transfer of the prescription drug product to the wholesale distributor; and

(iv) maintain the transaction information for each transaction described in clauses (i) and (ii) for not less than 3 years after the transaction.

(B) RETURNS EXCEPTION.—

(i) SALEABLE RETURNS.—Notwithstanding subparagraph (A), a wholesale distributor may—

(I) accept returned prescription drug product without a transaction history from a dispenser or repackager; and

(II) distribute such returned prescription drug product with a transaction history that begins with the wholesale distributor that so accepted the returned product.

(ii) NONSALEABLE RETURNS.—A wholesale distributor may return a nonsaleable prescription drug to the manufacturer or repackager, to the wholesale distributor from whom such prescription drug was purchased, or to a person acting on behalf of such a person, including a returns processor, without providing the information required under subparagraph (A).

(C) REQUESTS FOR INFORMATION.—Upon a request by the Secretary or other appropriate Federal or State official, in the event of a recall or for the purpose of investigating a suspect prescription drug product or an illegitimate prescription drug product a wholesale distributor shall, not later than 2 business days after receiving the request or in such other reasonable time as determined by the Secretary, provide the applicable transaction history and transaction statements for the prescription drug product.

(2) PRESCRIPTION DRUG PRODUCT IDENTIFIER.—Beginning not later than 7 years after the date of the enactment of the Safeguarding America's Pharmaceuticals Act of 2013, a wholesale distributor may engage in transactions involving a prescription drug product only if such prescription drug product is encoded with a prescription drug product identifier, except as provided in subsection (a)(4).

(3) AUTHORIZED TRADING PARTNERS.—Beginning not later than January 1, 2015, a wholesale distributor shall ensure that each of its trading partners is authorized.

(4) VERIFICATION.—Beginning not later than April 1, 2015, a wholesale distributor shall implement systems to enable the wholesale distributor to comply with the following requirements:

(A) SUSPECT PRESCRIPTION DRUG PRODUCT.—

(i) IN GENERAL.—Upon making a determination that a prescription drug product in the possession or control of the wholesale distributor is a suspect prescription drug product, or upon receiving a request for verification from the Secretary that a prescription drug product within the possession or control of a wholesale distributor is a suspect prescription drug product, a wholesale distributor shall promptly conduct an investigation to determine whether the prescription drug product is an illegitimate prescription drug product. Beginning not later than 7 years after the date of the enactment of the Safeguarding America's Pharmaceuticals Act of 2013, such investigation shall include—

(I) verifying a package of the prescription drug product;

(II) validating any applicable transaction history in the possession of the wholesale distributor; and

(III) otherwise investigating to determine whether the prescription drug product is an illegitimate prescription drug product.

(ii) CLEARED PRESCRIPTION DRUG PRODUCT.—If the wholesale distributor determines that a suspect prescription drug product is not an illegitimate prescription drug product, the wholesale distributor shall promptly notify the Secretary of such determination and such prescription drug product may be further distributed.

(iii) RECORDS.—A wholesale distributor shall keep records of its investigation of a suspect prescription drug product for not less than 3 years after the conclusion of the investigation.

(B) ILLEGITIMATE PRESCRIPTION DRUG PRODUCT.—

(i) IN GENERAL.—Upon receiving notice that a manufacturer of a prescription drug product has determined that a prescription drug product in the possession or control of a wholesale distributor is an illegitimate prescription drug product, the wholesale distributor shall—

(I) quarantine such prescription drug product within the possession or control of the wholesale distributor from prescription drug product intended for distribution; and

(II) provide for the disposition of the illegitimate prescription drug product within the possession or control of the wholesale distributor.

(ii) TRADING PARTNER.—Upon determining that a prescription drug product in the possession or control of a trading partner is an illegitimate prescription drug product, the wholesale distributor shall take reasonable steps to assist a trading partner to provide for the disposition of the illegitimate prescription drug product.

(iii) MAKING A NOTIFICATION.—Upon determining that a prescription drug product in the possession or control of the wholesale distributor is an illegitimate prescription drug product, the wholesale distributor shall notify the Secretary of such determination not later than 24 hours after making such determination. The Secretary shall determine whether additional trading partner notification is appropriate.

(iv) RESPONDING TO A NOTIFICATION.—Upon the receipt of a notification from the Secretary that a determination has been made that a prescription drug product is an illegitimate prescription drug product, a wholesale distributor shall—

(I) identify all illegitimate prescription drug product subject to such notification that is in the possession or control of the wholesale distributor, including any prescription drug product that is subsequently received; and

(II) perform the activities described in clause (i).

(v) RECORDS.—A wholesale distributor shall keep records of the disposition of an illegitimate prescription drug product for not less than 3 years after the conclusion of the disposition.

(C) ELECTRONIC DATABASE.—A wholesale distributor may satisfy the requirements of this paragraph through the use of a secure electronic database developed and operated by the manufacturer or another entity. The owner of such database shall establish the requirements and processes to respond to requests and may provide for data access to other members of the pharmaceutical distribution supply chain, as appropriate. The development and operation of such a database shall not relieve a wholesale distributor of the requirement under this paragraph to respond to a verification request submitted by means other than a secure electronic database.

(D) RETURNED PRESCRIPTION DRUG PRODUCT.—Beginning not later than 7 years after the date of the enactment of the Safeguarding America's Pharmaceuticals Act of 2013, upon receipt of a returned prescription drug product that the wholesale distributor intends to further distribute, before further distributing such prescription drug product, the wholesale distributor shall—

(i) verify the prescription drug product identifier for each sealed homogeneous case of such prescription drug product; or

(ii) if such prescription drug product is not in a sealed homogeneous case, verify the prescription drug product identifier on each package.

(d) DISPENSER REQUIREMENTS.—

(1) PRESCRIPTION DRUG PRODUCT TRACING.—

(A) IN GENERAL.—Beginning not later than July 1, 2015, a dispenser—

(i) shall not accept ownership of a prescription drug product, unless the previous owner prior to, or at the time of, the transaction, provides transaction history and a transaction statement;

(ii) prior to, or at the time of, each transaction in which the dispenser transfers ownership of a prescription drug product (but not including dispensing to a patient or returns) shall provide the subsequent owner with transaction history and a transaction statement for the prescription drug product, except that the requirements of this clause shall not apply to sales by a dispenser to another dispenser to fulfill a specific patient need; and

(iii) shall maintain transaction information for a period of not less than 3 years after the date of the transaction.

(B) AGREEMENTS WITH THIRD PARTIES.—A dispenser may enter into a written agreement with a third party, including an authorized wholesale distributor, under which the third party confidentially maintains the transaction information required to be maintained under this subsection on behalf of the dispenser. If a dispenser enters into such an agreement, the dispenser shall maintain a copy of the written agreement.

(C) RETURNS EXCEPTION.—

(i) SALEABLE RETURNS.—Notwithstanding subparagraph (A)(ii), a dispenser may return prescription drug product to the trading partner from which the dispenser obtained the prescription drug product without providing the information required under such subparagraph.

(ii) NONSALEABLE RETURNS.—Notwithstanding subparagraph (A)(ii), a dispenser may return a nonsaleable prescription drug to the manufacturer or repackager, to the wholesale distributor from whom such prescription drug was purchased, to a returns processor, or to a person acting on behalf of such persons without providing the information required under such subparagraph.

(D) REQUESTS FOR INFORMATION.—Upon a request by the Secretary or other appropriate Federal or State official, in the event of a recall or for the purpose of investigating a suspect prescription drug product or an illegitimate prescription drug product, a dispenser shall, not later than 2 business days after receiving the request or in another such reasonable time as determined by the Secretary, provide lot level transaction information.

(2) PRESCRIPTION DRUG PRODUCT IDENTIFIER.—Beginning not later than 8 years after the date of the enactment of the Safeguarding America's Pharmaceuticals Act of 2013, a dispenser may engage in transactions involving a prescription drug prod-

uct only if such prescription drug product is encoded with a prescription drug product identifier, except as provided in subsection (a)(4).

(3) AUTHORIZED TRADING PARTNERS.—Beginning not later than January 1, 2015, a dispenser shall ensure that each of its trading partners is authorized.

(4) VERIFICATION.—Beginning not later than January 1, 2015, a dispenser shall implement systems to enable the dispenser to comply with the following requirements:

(A) SUSPECT PRESCRIPTION DRUG PRODUCT.—

(i) IN GENERAL.—Upon making a determination that a prescription drug product in the possession or control of the dispenser is a suspect prescription drug product, or upon receiving a request for verification from the Secretary that a prescription drug product within the possession or control of a dispenser is a suspect prescription drug product, a dispenser shall promptly conduct an investigation to determine whether the prescription drug product is an illegitimate prescription drug product. Such investigation shall include—

(I) verifying whether the lot number of a suspect prescription drug product corresponds with the lot number for such prescription drug product;

(II) beginning 8 years after the date of the enactment of the Safeguarding America's Pharmaceuticals Act of 2013, verifying that the product identifier of at least 3 packages or 10 percent of such suspect prescription drug product, whichever is greater, or all packages, if there are fewer than 3, corresponds with the prescription drug product identifier for such product;

(III) validating any applicable transaction history in the possession of the dispenser; and

(IV) otherwise investigating to determine whether the prescription drug product is an illegitimate prescription drug product.

(ii) CLEARED PRESCRIPTION DRUG PRODUCT.—If the dispenser makes the determination that a suspect prescription drug product is not an illegitimate prescription drug product, the dispenser shall promptly notify the Secretary of such determination and such prescription drug product may be further dispensed.

(iii) RECORDS.—A dispenser shall keep records of its investigation of a suspect prescription drug product for not less than 3 years after the conclusion of the investigation.

(B) ILLEGITIMATE PRESCRIPTION DRUG PRODUCT.—

(i) IN GENERAL.—Upon receiving notice that a manufacturer of a prescription drug product has determined that a prescription drug product in the possession or control of a dispenser is an illegitimate prescription drug product, the dispenser shall—

(I) quarantine such prescription drug product within the possession or control of the dispenser

from prescription drug product intended for distribution; and

(II) provide for the disposition of the illegitimate prescription drug product within the possession or control of the dispenser.

(ii) TRADING PARTNERS.—Upon determining that a prescription drug product in the possession or control of a trading partner is an illegitimate prescription drug product, the dispenser shall take reasonable steps to assist a trading partner to provide for the disposition of the illegitimate prescription drug product.

(iii) MAKING A NOTIFICATION.—Upon determining that a prescription drug product in the possession or control of the dispenser is an illegitimate prescription drug product, the dispenser shall notify the Secretary of such determination not later than 24 hours after making such determination. The Secretary shall determine whether additional trading partner notification is appropriate.

(iv) RESPONDING TO A NOTIFICATION.—Upon the receipt of a notification from the Secretary that a determination has been made that a prescription drug product is an illegitimate prescription drug product, a dispenser shall—

(I) identify all illegitimate prescription drug products that are subject to such notification and in the possession or control of the dispenser, including any prescription drug product that is subsequently received; and

(II) perform the activities described in clause (i).

(v) RECORDS.—A dispenser shall keep records of the disposition of an illegitimate prescription drug product for not less than 3 years after the conclusion of the disposition.

(C) ELECTRONIC DATABASE.—A dispenser may satisfy the requirements of this paragraph through the use of a secure electronic database developed and operated by the manufacturer or another entity. The owner of such database shall establish the requirements and processes to enable responding to requests and may provide for data access to other members of the pharmaceutical distribution supply chain, as appropriate. The development and operation of such a database shall not relieve a dispenser of the requirement under this paragraph to respond to a verification request submitted by means other than a secure electronic database.

(e) REPACKAGER REQUIREMENTS.—

(1) PRESCRIPTION DRUG PRODUCT TRACING.—

(A) IN GENERAL.—Beginning not later than April 1, 2015, with respect to a prescription drug product received by a repackager from a wholesale distributor, and beginning not later than January 1, 2015, with respect to any other prescription drug product, a repackager shall—

(i) not accept ownership of a prescription drug product unless the previous owner, prior to, or at the time

of, the transaction, provides transaction history and a transaction statement for the prescription drug product;

(ii) prior to, or at the time of, each transaction in which the repackager transfers ownership of a prescription drug product, provide the subsequent owner with transaction history and a transaction statement;

(iii) maintain the transaction information for each transaction described in clause (i) or (ii) for not less than 3 years after the transaction; and

(iv) maintain records that allow the repackager to associate the prescription drug product identifier the repackager affixes or imprints with the prescription drug product identifier assigned by the original manufacturer of the prescription drug product.

(B) NONSALEABLE RETURNS.—Notwithstanding subparagraph (A)(ii), a repackager may return prescription drug product to the trading partner from whom the repackager obtained the prescription drug product without providing the information required under such subparagraph.

(C) REQUESTS FOR INFORMATION.—Upon a request by the Secretary or other appropriate Federal or State official, in the event of a recall or for the purpose of investigating a suspect prescription drug product or an illegitimate prescription drug product, a repackager shall, not later than 2 business days after receiving the request or in such other reasonable time as determined by the Secretary, provide the applicable transaction history and transaction statement for the prescription drug product.

(2) PRESCRIPTION DRUG PRODUCT IDENTIFIER.—Beginning not later than 6 years after the date of the enactment of the Safeguarding America's Pharmaceuticals Act of 2013, a repackager—

(A) shall affix or imprint a prescription drug product identifier to each package and homogenous case of prescription drug product intended to be introduced in a transaction;

(B) shall maintain the prescription drug product identifier for such prescription drug product for not less than 3 years after the date of the transaction; and

(C) may engage in transactions involving a prescription drug product only if such prescription drug product is encoded with a prescription drug product identifier except as provided in subsection (a)(4).

(3) AUTHORIZED TRADING PARTNERS.—Beginning on January 1, 2015, a repackager shall ensure that each of its trading partners is authorized.

(4) VERIFICATION.—Beginning not later than January 1, 2015, a repackager shall implement systems to enable the repackager to comply with the following requirements:

(A) SUSPECT PRESCRIPTION DRUG PRODUCT.—

(i) IN GENERAL.—Upon making a determination that a prescription drug product in the possession or control of the repackager is a suspect prescription drug product, or upon receiving a request for verification from

the Secretary that a prescription drug product within the possession or control of a repackager is a suspect prescription drug product, a repackager shall promptly conduct an investigation to determine whether the prescription drug product is an illegitimate prescription drug product, including—

(I) beginning not later than 6 years after the date of the enactment of the Safeguarding America's Pharmaceuticals Act of 2013, verifying the prescription drug product at the package level;

(II) validating any applicable transaction information in the possession of the repackager; and

(III) otherwise investigating to determine whether the prescription drug product is an illegitimate prescription drug product.

(ii) CLEARED PRESCRIPTION DRUG PRODUCT.—If the repackager determines that a suspect prescription drug product is not an illegitimate prescription drug product, the repackager shall promptly notify the Secretary of such determination and such prescription drug product may be further distributed.

(iii) RECORDS.—A repackager shall keep records of its investigation of a suspect prescription drug product for not less than 3 years after the conclusion of the investigation.

(B) ILLEGITIMATE PRESCRIPTION DRUG PRODUCT.—

(i) IN GENERAL.—Upon receiving notice that a manufacturer of a prescription drug product has determined that a prescription drug product in the possession or control of a repackager is an illegitimate prescription drug product, the repackager shall—

(I) quarantine such prescription drug product within the possession or control of the repackager from prescription drug product intended for distribution; and

(II) provide for the disposition of the illegitimate prescription drug product within the possession or control of the repackager.

(ii) TRADING PARTNER.—Upon determining that a prescription drug product in the possession or control of a trading partner is an illegitimate prescription drug product, the repackagers shall take reasonable steps to assist the trading partner to provide for the disposition of the illegitimate prescription drug product.

(iii) MAKING A NOTIFICATION.—Upon determining that a prescription drug product in the possession or control of the repackager is an illegitimate prescription drug product, the repackager shall notify the Secretary of such determination not later than 24 hours after making such determination. The Secretary shall determine whether additional trading partner notification is appropriate.

(iv) RESPONDING TO A NOTIFICATION.—Upon the receipt of a notification from the Secretary that a deter-

mination has been made that a prescription drug product is an illegitimate prescription drug product, a repackager shall—

(I) identify all illegitimate prescription drug products that are subject to such notification and in the possession or control of the repackager, including any prescription drug product that is subsequently received; and

(II) perform the activities described in clause (i).

(v) RECORDS.—A repackager shall keep records of the disposition of an illegitimate prescription drug product for not less than 3 years after the conclusion of the disposition.

(C) ELECTRONIC DATABASE.—A repackager may satisfy the requirements of this paragraph through the use of a secure electronic database developed and operated by the manufacturer or another entity. The owner of such database shall establish the requirements and processes to respond to requests and may provide for data access to other members of the pharmaceutical distribution supply chain, as appropriate. The development and operation of such a database shall not relieve a repackager of the requirement under this paragraph to respond to a verification request submitted by means other than a secure electronic database.

(D) RETURNED PRESCRIPTION DRUG PRODUCT.—Beginning not later than 6 years after the date of the enactment of the Safeguarding America's Pharmaceuticals Act of 2013, upon receipt of a returned prescription drug product that the repackager intends to further distribute, before further distributing such prescription drug product, the repackager shall—

(i) verify the prescription drug product identifier for each sealed homogeneous case of such prescription drug product; or

(ii) if such prescription drug product is not in a sealed homogeneous case, verify the prescription drug product identifier on each package.

(f) THIRD-PARTY LOGISTICS PROVIDER REQUIREMENTS.—

(1) AUTHORIZED TRADING PARTNERS.—Beginning on January 1, 2015, a third-party logistics provider shall ensure that each of its trading partners is authorized.

(2) VERIFICATION.—Beginning not later than January 1, 2015, a third-party logistics provider shall implement systems to enable the third-party logistics provider to comply with the following requirements:

(A) SUSPECT PRESCRIPTION DRUG PRODUCT.—

(i) IN GENERAL.—Upon making a determination that a prescription drug product in the possession or control of a third-party logistics provider is a suspect prescription drug product, a third-party logistics provider shall promptly notify the owner of such prescription drug product of the need to conduct an investigation to determine whether the prescription drug product is an illegitimate prescription drug product.

(ii) CLEARED PRESCRIPTION DRUG PRODUCT.—If the owner of the prescription drug product notifies the third-party logistics provider of the determination that a suspect prescription drug product is not an illegitimate prescription drug product, such prescription drug product may be further distributed.

(iii) RECORDS.—A third-party logistics provider shall keep records of the activities described in clauses (i) and (ii) with respect to a suspect prescription drug product for not less than 3 years after the conclusion of the investigation.

(B) ILLEGITIMATE PRESCRIPTION DRUG PRODUCT.—

(i) IN GENERAL.—Upon receiving notice that a manufacturer of a prescription drug product has determined that a prescription drug product in the possession or control of a third-party logistics provider is an illegitimate prescription drug product, the third-party logistics provider shall—

(I) quarantine such prescription drug product within the possession or control of the third-party logistics provider from prescription drug product intended for distribution;

(II) promptly notify the owner of such prescription drug product of the need to provide for the disposition of such prescription drug product; and

(III) promptly transfer possession of the prescription drug product to the owner of such prescription drug product to provide for the disposition of the prescription drug product.

(ii) MAKING A NOTIFICATION.—Upon determining that a prescription drug product in the possession or control of the third-party logistics provider is an illegitimate prescription drug product, the third-party logistics provider shall notify the Secretary not later than 24 hours after making such determination. The Secretary shall determine whether additional trading partner notification is appropriate.

(iii) RESPONDING TO A NOTIFICATION.—Upon the receipt of a notification from the Secretary, a third-party logistics provider shall—

(I) identify all illegitimate prescription drug product subject to such notification that is in the possession or control of the third-party logistics provider, including any prescription drug product that is subsequently received; and

(II) perform the activities described in clause (i).

(iv) RECORDS.—A third-party logistics provider shall keep records of the activities described in clauses (i) and (ii) with respect to an illegitimate prescription drug product for not less than 3 years after the conclusion of the disposition.

(g) DROP SHIPMENTS.—This section does not apply to any entity, notwithstanding its status as a wholesale distributor or repackager, or other status that is not involved in the physical handling, distribution, or storage of a prescription drug product. For purposes of

this subsection, facilitating the distribution of a prescription drug product by providing various administrative services, including processing of orders and payments, shall not, by itself, be construed as being involved in the handling, distribution, or storage of a prescription drug product.

SEC. 583. NATIONAL STANDARDS FOR WHOLESALE DISTRIBUTORS.

(a) STANDARDS.—

(1) IN GENERAL.—The Secretary shall establish, by regulation, standards for the licensing of persons that make wholesale distributions.

(2) REQUIREMENTS.—The standards under paragraph (1) shall, with respect to wholesale distributions, include requirements for—

(A) the storage and handling of drugs subject to section 503(b)(1), including facility requirements;

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

(C) the furnishing of a bond or other equivalent means of security in accordance with paragraph (3);

(D) mandatory background checks and fingerprinting of facility managers or designated representatives;

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

(F) the mandatory physical inspection of any facility to be used in wholesale distribution within a reasonable timeframe from the initial application for licensure of the wholesale distributor; and

(G) in accordance with paragraph (5), the prohibition of certain persons from engaging in wholesale distribution.

(3) BOND OR OTHER SECURITY.—The requirements under paragraph (2)(C) shall provide for the following:

(A) An applicant that is not a government-owned-and-operated wholesale distributor, for the issuance or renewal of a wholesale distributor license, shall submit a surety bond of $100,000 or other equivalent means of security acceptable to the applicable licensing authority.

(B) For purposes of subparagraph (A), the applicable licensing authority may accept a surety bond less than $100,000 if the annual gross receipts of the previous tax year for the wholesale distributor is $10,000,000 or less, in which case the surety bond may not be less than $25,000.

(C) If a wholesale distributor can provide evidence that it possesses the required bond in a State, the requirement for a bond in another State is waived.

(4) INSPECTIONS.—To satisfy the inspection requirement under paragraph (2)(F), the Secretary may conduct the inspection, or may accept an inspection by—

(A) the government of the State in which the facility is located; or

(B) a third-party accreditation or inspection service approved by the Secretary.

(5) PROHIBITED PERSONS.—The requirements under paragraph (2) shall include requirements to prohibit a person from receiving or maintaining licensure for wholesale distribution if the person—

(A) has been convicted of any felony for conduct relating to wholesale distribution; any felony violation of section 301(i) or 301(k); or any felony violation of section 1365 of title 18, United States Code, relating to prescription drug product tampering; or

(B) has engaged in a pattern of violating the requirements of this section that presents a threat of serious adverse health consequences or death to humans.

(b) REPORTING BY LICENSED WHOLESALE DISTRIBUTORS.—

(1) ANNUAL REPORT.—Beginning not later than 1 year after the date of the enactment of this section, each person engaged in wholesale distribution in interstate commerce shall submit on an annual basis, and update as necessary, a report to the Secretary including—

(A) the wholesale distributor's name;

(B) the wholesale distributor's address;

(C) a listing of each State in which the wholesale distributor is licensed for wholesale distribution; and

(D) any disciplinary actions taken by a State, the Federal Government, or a foreign government during the reporting period against the wholesale distributor.

(2) POSTING ON INTERNET.—The Secretary shall post on the public Internet Website of the Food and Drug Administration the name of each wholesale distributor, and the State in which each such distributor is licensed, based on reports under paragraph (1).

(c) PRESERVATION OF STATE AUTHORITY.—This subchapter does not prohibit a State from—

(1) licensing wholesale distributors for the conduct of wholesale distribution activities in the State in accordance with this subchapter; and

(2) collecting fees from wholesale distributors in connection with such licensing,

so long as the State does not require such licensure to the extent to which an entity is engaged in third-party logistics provider activities.

(d) DEFINITION.—In this section, the term "wholesale distribution" means the distribution of a drug subject to section 503(b)(1) to a person other than a consumer or patient, but does not include—

(1) intracompany distribution of any drug between members of an affiliated group (as defined in section 1504(a) of the Internal Revenue Code of 1986);

(2) the distribution of a drug, or an offer to distribute a drug among hospitals or other health care entities which are under common control;

(3) the distribution of a drug or an offer to distribute a drug for emergency medical reasons, including a public health emergency declaration pursuant to section 319 of the Public Health Service Act, except that a drug shortage not caused by a public health emergency shall not constitute such an emergency medical reason;

(4) dispensing of a drug pursuant to a valid prescription executed in accordance with subsection 503(b)(1);

(5) the distribution of minimal quantities of drug by a licensed retail pharmacy to a licensed practitioner for office use;

(6) the distribution of a drug or an offer to distribute a drug by a charitable organization to a nonprofit affiliate of the organization to the extent otherwise permitted by law;

(7) the purchase or other acquisition by a dispenser, hospital, or other health care entity of a drug for use by such dispenser, hospital, or other health care entity;

(8) the distribution of a drug by the manufacturer of such drug;

(9) the receipt or transfer of a drug by an authorized third-party logistics provider provided that such third-party logistics provider does not take ownership of the drug;

(10) the transport of a drug by a common carrier, provided that the common carrier does not take ownership of the drug;

(11) the distribution of a drug, or an offer to distribute a drug, by an authorized repackager that has taken ownership of the drug and repacked it in accordance with section 582(e);

(12) saleable drug returns when conducted by a dispenser in accordance with section 203.23 of title 21, Code of Federal Regulations (or any successor regulation);

(13) the distribution of a combination prescription drug product described in section 581(20)(B)(xiii);

(14) the distribution of a medical convenience kit described in section 581(21)(B)(xiv);

(15) the distribution of an intravenous drug that, by its formulation, is intended for the replenishment of fluids and electrolytes (such as sodium, chloride, and potassium) or calories (such as dextrose and amino acids);

(16) the distribution of an intravenous drug used to maintain the equilibrium of water and minerals in the body, such as dialysis solutions;

(17) the distribution of a drug that is intended for irrigation or reconstitution, or sterile water, whether intended for such purposes or for injection;

(18) the distribution of compressed medical gas (as defined in section 581(21)(C));

(19) facilitating the distribution of a prescription drug product by providing administrative services, such as processing of orders and payments, without physical handling, distribution, or storage of a prescription drug product; or

(20)(A) the distribution of a product by a dispenser, or a wholesale distributor acting at the direction of the dispenser, to a repackager registered under section 510 for the purpose of repackaging the drug for use by that dispenser or another health care entity that is under the dispenser's ownership or control, so long as the dispenser retains ownership of the prescription drug product; and

(B) the saleable or nonsaleable return by such repackager of such prescription drug product.

(e) EFFECTIVE DATE.—The standards required by subsection (a) shall take effect not later than 2 years after the date of the enactment of this section. The Secretary shall issue the regulations required by subsection (a) not later than 1 year after the date of the enactment of this Act.

SEC. 584. NATIONAL LICENSURE STANDARDS FOR THIRD-PARTY LOGISTICS PROVIDERS.

(a) LICENSE REQUIREMENT.—No facility may engage in the activities of a third-party logistics provider in any State unless—

(1) the facility is licensed—

(A) by the State from which the drug is distributed by the third-party logistics provider in accordance with a qualified licensing program, if the State has such a program; or

(B) by the Secretary under this section, if the State from which the drug is distributed does not have such a program; and

(2) if the drug is distributed interstate and the facility is not licensed by the Secretary under paragraph (1)(B), registers with the State into which the drug is distributed if such State requires such registration.

(b) REPORTING BY LICENSED THIRD-PARTY LOGISTICS PROVIDERS.—

(1) ANNUAL REPORT.—Beginning not later than 1 year after the date of the enactment of this section, each facility engaged in the activities of a third-party logistics provider shall submit on an annual basis, and update as necessary, a report to the Secretary including—

(A) the facility's name;

(B) the facility's address;

(C) a listing of each jurisdiction (whether State or Federal) in which the facility is licensed for third-party logistics provider activities; and

(D) any disciplinary actions taken by a State or Federal licensing authority during the reporting period against the facility.

(2) POSTING ON INTERNET.—The Secretary shall post on the public Internet Website of the Food and Drug Administration the name of each third-party logistics provider, and each jurisdiction (whether State or Federal) in which the provider is licensed, based on reports under paragraph (1).

(c) PRESERVATION OF STATE AUTHORITY.—This subchapter does not prohibit a State from—

(1) licensing third-party logistic providers for the conduct of third-party logistics provider activities in the State in accordance with this subchapter; and

(2) collecting fees from third-party logistics providers in connection with such licensing,

so long as the State does not require such licensure to the extent to which an entity is engaged in wholesale distribution.

(d) COSTS.—

(1) AUTHORIZED LICENSURE FEES.—In the case of a facility engaging in the activities of a third-party logistics provider licensed by the Secretary under this section, the Secretary may assess and collect a reasonable fee in an amount equal to the costs to the Federal Government of establishing and administering the licensure program established, and conducting period inspections, under this section.

(2) ADJUSTMENT.—The Secretary shall adjust the amount of the fee under paragraph (1) on an annual basis, if necessary,

to generate an amount of revenue equal to the costs referred to in such paragraph.

(3) AVAILABILITY.—Fees assessed and collected under this subsection shall be available for obligation only to the extent and in the amount provided in advance in appropriations Acts. Such fees shall remain available until expended.

(e) LICENSE REGULATIONS.—

(1) IN GENERAL.—The Secretary shall establish, by regulation, standards, terms, and conditions for licensing persons to engage in third-party logistics provider activities.

(2) CONTENT.—The regulations under paragraph (1) shall—

(A) include standards relating to eligibility for, and revocation and reissuance of, licenses;

(B) establish a process by which the applicable licensing authority will, upon request by a third-party logistics provider that is accredited by a third-party accreditation program approved by the Secretary, issue a license to the provider;

(C) establish a process by which the Secretary shall issue a license to a third-party logistics provider if the Secretary is not able to approve a third-party accreditation program because no such program meets the Secretary's requirements necessary for approval of such a third-party accreditation program;

(D) require that the third-party logistics provider comply with storage practices, as determined by the Secretary, at the provider's facilities, including—

(i) maintaining access to warehouse space of suitable size to facilitate safe operations, including a suitable area to quarantine suspect prescription drug product;

(ii) maintaining adequate security; and

(iii) having written policies and procedures to—

(I) address receipt, security, storage, inventory, shipment, and distribution of a prescription drug product;

(II) identify, record, and report confirmed losses or thefts in the United States;

(III) correct errors and inaccuracies in inventories;

(IV) provide support for manufacturer recalls;

(V) prepare for, protect against, and address any reasonably foreseeable crisis that affects security or operation at the facility, such as a strike, fire, or flood;

(VI) ensure that any expired prescription drug product is segregated from other prescription drug products and returned to the manufacturer or repackager or destroyed;

(VII) maintain the capability to electronically trace the receipt and outbound distribution of a prescription drug product, and supplies and records of inventory; and

(VIII) quarantine or destroy a suspect prescription drug product if directed to do so by the respec-

tive manufacturer, wholesale distributor, dispenser, or an authorized government agency;

(E) provide for periodic inspection, as determined by the Secretary, of such facility warehouse space to ensure compliance with this section;

(F) prohibit a facility from having as a manager or designated representative anyone convicted of any felony violation of section 301(i) or 301(k) or any felony violation of section 1365 of title 18, United States Code, relating to prescription drug product tampering;

(G) perform mandatory background checks of the provider's facility managers or designated representatives of such managers;

(H) require a third-party logistics provider to provide to the applicable licensing authority, upon the authority's request, a list of all prescription drug product manufacturers, wholesale distributors, and dispensers for whom the third-party logistics provider provides services at the provider's facilities; and

(I) include procedures under which any third-party logistics provider license—

(i) will expire on the date that is 3 years after issuance of the license; and

(ii) may be renewed for additional 3-year periods.

(f) VALIDITY OF LICENSE.—A license issued under this section shall remain valid as long as such third-party logistics provider remains accredited by the Secretary, subject to renewal under subsection (d). If the Secretary finds that the third-party accreditation program demonstrates that all applicable requirements for licensure under this section are met, the Secretary shall issue a license under this section to a third-party logistics provider receiving accreditation.

(g) QUALIFIED LICENSING PROGRAM DEFINED.—In this section, the term "qualified licensing program" means a program meeting the requirements of this section and the regulations thereunder.

(h) EFFECTIVE DATE.—The requirements of this section shall take effect not later than 1 year after the date of the enactment of this section. The Secretary shall issue the regulations required by subsection (d) not later than 180 days after the date of the enactment of this section.

SEC. 585. UNIFORM NATIONAL POLICY.

(a) PREEMPTION OF STATE PRESCRIPTION DRUG PRODUCT TRACING AND OTHER REQUIREMENTS.—Beginning on the date of the enactment of the Safeguarding America's Pharmaceuticals Act of 2013, no State or political subdivision of a State may establish or continue in effect any requirements for tracing drugs through the distribution system (including any requirements with respect to paper or electronic pedigrees, track and trace, statements of distribution history, transaction history, or transaction statements, or verification, investigation, disposition, alerts, or recordkeeping relating to the pharmaceutical distribution supply chain system) that—

(1) are inconsistent with, more stringent than, or in addition to any requirements applicable under this Act; or

(2) are inconsistent with any applicable waiver, exception, or exemption issued by the Secretary under section 582(a).

(b) STANDARDS OR LICENSURE.—

(1) IN GENERAL.—Beginning on the date of the enactment of Safeguarding America's Pharmaceuticals Act of 2013, no State or political subdivision of a State may establish or continue any standards, requirements, or regulations with respect to wholesale drug distributor or third-party logistics provider licensure which are inconsistent with, less stringent than, in addition to, or more stringent than, the standards and requirements under this Act.

(2) LICENSING FEES.—Paragraph (1) does not affect the authority of a State to collect fees from wholesale drug distributors or third-party logistics providers in connection with State licensing under section 583 or 584 pursuant to a licensing program meeting the requirements of such sections.

(3) ENFORCEMENT, SUSPENSION, AND REVOCATION OF LICENSES.—Notwithstanding paragraph (1), a State—

(A) may take administrative action, including fines, to enforce a licensure requirement promulgated by the State in accordance with this Act;

(B) may provide for the suspension or revocation of licenses issued by the State for violations of the laws of such State;

(C) upon conviction of a person for a violation of Federal, State, or local controlled substance laws or regulations, may provide for fines, imprisonment, or civil penalties; and

(D) may regulate activities of entities licensed pursuant to section 583 or 584 in a manner that is consistent with the provisions of this subchapter.

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CHAPTER VIII—IMPORTS AND EXPORTS

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SEC. 804. IMPORTATION OF PRESCRIPTION DRUGS.

(a) DEFINITIONS.—In this section:

(1) * * *

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(5) WHOLESALER.—

(A) IN GENERAL.—The term "wholesaler" means a person licensed as a wholesaler or distributor of prescription drugs in the United States under section **[**503(e)(2)(A)**]** *583(a)*.

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DISSENTING VIEWS

We, the undersigned members of the Committee on Energy and Commerce, oppose passage of H.R. 1919, the Safeguarding America's Pharmaceuticals Act of 2013. Accordingly, we submit the following comments to express our concerns about this inadequate legislation.

INTRODUCTION

Although we share the goals of the supporters of H.R. 1919—to enact legislation that will better secure our drug supply chain—we do not believe that H.R. 1919 will ultimately accomplish that goal. H.R. 1919 does not provide any assurance that an effective system for tracking and tracing drugs through the supply chain will ultimately be put into place. Instead, the bill requires only that Food and Drug Administration (FDA) issue proposed regulations designed to establish such a system—these regulations may never be issued, become final, or go into effect. We believe that any legislation on this issue should give Americans certainty that an effective system will be put into place.

BACKGROUND AND OVERVIEW

There is an increasing prevalence of falsified and substandard drugs in the legitimate drug supply, both in the U.S. and the world over.[1] These drugs pose a public health threat in a variety of ways. Some may contain toxic ingredients, while others may simply not work.[2] Poor quality medicines cause treatment failures, but in many cases, physicians may not suspect medicines as a cause of such failure.[3]

In recent years, there have been several high-profile instances of counterfeit and substandard medicines entering the supply chain. For example:

- In July 2012, federal prosecutors in New York charged 48 people in a fraud involving HIV medications purchased from Medicaid recipients and sold to other patients for cash.[4]
- Between 2012 and 2013, FDA warned about three instances of counterfeit and substandard versions of the cancer drug, Avastin, circulating in the supply chain.[5]

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[1] G. J. Buckley and L. O. Goslin, *Countering the Problem of Falsified and Substandard Drugs.* Institute of Medicine (Feb. 13, 2013) (online at *http://www.iom.edu/Reports/2013/Countering-the-Problem-of-Falsified-and-Substandard-Drugs.aspx*).

[2] *Id.*

[3] *Id.*

[4] C. Boyette, *New York Authorities Charge 48 in Massive Medicaid Fraud,* CNN (July 18, 2012) (online at *http://www.cnn.com/2012/07/18/justice/new-york-drug-scheme*).

[5] *FDA Warns of New Fake Batch of Cancer Drug Avastin,* Associated Press (Feb. 6, 2013) (online at *http://news.yahoo.com/fda-warns-fake-batch-cancer-drug-avastin09155524363-finance.html*).

- In 2009, FDA reported that 129,000 vials of insulin were stolen and were being sold in the U.S. market. FDA indicated that the vials may not have been stored and handled properly which posed a threat for patients who might use them.[6]
- In 2010, $75 million worth of drugs were stolen from an Eli Lilly and Company warehouse in Connecticut.[7]
- In 2003, counterfeit Lipitor from Central America was sold into the U.S. supply chain.[8]
- In 2001, counterfeit Serostim, which is a human growth hormone used to treat AIDS-related wasting, was found in at least seven states and passed through multiple wholesalers.[9]

There is widespread agreement that, if the goal is to protect American patients from substandard and falsified medicines, the best way to protect the supply chain is to establish a unit-level, interoperable system that involves all members of the supply chain. H.R. 1919 fails to assure the establishment of this system and falls short in other significant ways of protecting patients from the entry of unsafe and substandard drugs into the supply chain. The following describes those shortcomings:

A. Section 2 (Pharmaceutical Distribution Supply Chain) Fails To Provide Adequate Assurance That Illegitimate Product Will Not Enter the Supply Chain Through Returns Exemptions

One issue that is reflected in Section 2 is the problem of how to handle "returns," which generally refers to entities in the supply chain having the ability to return unused stock to the previous seller from which they obtained the product. Returns create a significant problem because they create the potential for entry of illegitimate product. For example, pharmacies could obtain counterfeit or substandard medicines and sell them back to the wholesaler at a profit, and then the wholesaler could redistribute that product into the supply chain.

H.R. 1919 provides that upon redistributing returned product, the wholesaler must include a transaction history (which details the drug's trip through the supply chain) that begins with that wholesaler.[10] In other words, upon redistributing the product, the pedigree starts anew with the wholesaler.

We support an alternative approach that would prohibit wholesalers from accepting product from dispensers unless the wholesaler could associate the returned product with the transaction history and information linked to that product. This requirement would ensure that the wholesaler will verify that the returned product from the dispenser was indeed the product that wholesaler sold to that dispenser. As a result, the likelihood of counterfeit or substandard product entering the supply chain is diminished.

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[6] Food and Drug Administration, *FDA Advisory About Levemir Insulin* (June 18, 2009) (online at *http://www.fda.gov/ForConsumers/ConsumerUpdates/ucm167600.htm*).

[7] *Lilly Drugs Stolen in Warehouse Heist,* Wall Street Journal (Mar. 17, 2010) (online at *http://online.wsj.com/article/SB10001424052748704688604575125522684707974.html*).

[8] Pew Health Group, *After Heparin: Protecting Consumers From the Risks of Substandard and Counterfeit Drugs,* 65 (online at: *http://www.pewhealth.org/uploadedFiles/PHG/Content_Level_Pages/Reports/Pew_Heparin_Final_.pdf*).

[9] Pew Health Group, *After Heparin: Protecting Consumers From the Risks of Substandard and Counterfeit Drugs,* 64 (online at *http://www.pewhealth.org/uploadedFiles/PHG/Content_Level_Pages/Reports/Pew_Heparin_Final_.pdf*).

[10] *See* H.R. 1919 at 35, lines 18–36, line 5.

B. Section 3 (Enhanced Drug Distribution Security) Does Not Mandate the Establishment of an Electronic, Interoperable Unit-Level System

In general, section 2 of H.R. 1919 sets up a so-called "phase I" in which certain aspects of an electronic, interoperable unit-level system are gradually put into place.[11] Section 3 represents the so-called "phase II" in which the goal is to establish this system. However, for the following reasons, there is a concern that this goal will not fully be realized based on the current language of the bill.

H.R. 1919 would require FDA to issue *proposed* regulations, no sooner than January 1, 2027 and no later than March 1, 2027.[12] These proposed regulations would establish additional requirements "to prevent a suspect product, illegitimate product, or a product that is counterfeit, stolen, diverted, or otherwise unfit for distribution from entering into or being further distributed in the supply chain."[13] Such requirements would include those "related to the use of interoperable electronic systems and technologies for enhanced tracing of prescription drug product at the package level" among other things.[14]

However, H.R. 1919 does not set a deadline for the issuance of *final* regulations. It also does not explicitly require that the proposed regulations shall establish requirements for the implementation of an electronic, unit-level interoperable system. Further, it mandates that, if and when final regulations are issued, there is an additional two year delay in the effective date of those regulations.[15] Thus, not only is the timeline for issuing proposed regulations inordinately long, but there is no assurance that final regulations will ever be issued. When—or if—final regulations are ever issued, there is even more delay. This kind of delay and uncertainty about whether we will ever get to the best system for protecting consumers is unacceptable to us, and should be unacceptable to all members.

We support an alternative approach that would set a reasonable date-certain for the establishment of a unit-level interoperable tracking and tracing system that includes all entities in the supply chain. This approach would also permit FDA to establish this system based on requirements set forth in the statute; it would not be contingent upon the issuance of FDA regulations. We assume and expect, however, that even though this approach would reflect a self-effectuating system based on the statutory requirements, FDA would still issue guidance to industry stakeholders in the form of regulations and guidance documents.

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[11] *See* H.R. 1919, at 3, line 8.
[12] *See* H.R. 1919, at 71, line 1.
[13] *See* H.R. 1919, at 71, lines 7–12.
[14] *See* H.R. 1919, at 71, lines 13–16.
[15] *See* H.R. 1919, at 75, lines 12–14.

C. Section 4 (National Standards for Wholesale Distributors) Will Prevent States From Responding to the Particular Needs of Their Own States

H.R. 1919 requires FDA to set national standards for the licensing of wholesale distributors[16] and preempts all state laws governing such licensure that are "inconsistent with, less stringent than, in addition to, or more stringent than" the standard that FDA will set.[17] In other words, the draft would make the FDA standards both a "ceiling and a floor" for state licensing laws. This can be a concern for states that have a high number of wholesalers and, consequently, strong licensing schemes. We support an alternative approach of requiring FDA to set standards, but permitting states to go beyond those standards when appropriate.

D. Section 7 (Uniform National Policy) Immediately Preempts Important Safeguards Without Requiring an Acceptable Substitute

On the date of enactment, H.R. 1919 would preempt all state requirements for tracing drugs through the distribution system, as well as current federal requirements that were set forth in Section 503(e) of the Federal Food, Drug, and Cosmetic Act, as part of the Prescription Drug Marketing Act of 1987. For example, Florida requires that a pedigree identifying each previous sale of a drug back to the manufacturer be passed with most drug transactions. Under H.R. 1919, there would be no federal requirement to pass transaction information and history until January 1, 2015 for manufacturers and repackagers,[18] April 1, 2015 for wholesalers,[19] and July 1, 2015 for dispensers.[20] Thus, state and federal requirements would be preempted before any federal requirements to pass transaction information and history have kicked in. Assuming H.R. 1919 were to be enacted during 2013, this would leave a significant gap in the current level of information about a drug's path through the supply chain—information that is important to law enforcement efforts to stop the entry of counterfeit and substandard drugs into the supply chain.

E. FDA Technical Assistance Was Not Addressed in H.R. 1919

FDA provided extensive technical assistance raising additional concerns about the workability of H.R. 1919 and describing various unintended consequences that could pose patient safety concerns. However, H.R. 1919 failed to incorporate much of this technical assistance. We are concerned that the expertise of the regulatory agency that would ultimately be tasked with implementing this legislation was not taken into account.

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[16] See H.R. 1919, at 76, line 6.
[17] See H.R. 1919, at 94, line 16–17.
[18] See H.R. 1919, at 25, lines 21–23; 50, lines 16–51, line 20.
[19] See H.R. 1919, at 33, line 1–35, line 17.
[20] See H.R. 1919, at 42, lines 20–43, line 16.

In sum, we believe that H.R. 1919 will fail to meet the goal of better securing our drug supply chain and protecting Americans from unsafe and substandard drugs. As it moves through the legislative process, significant improvements to this legislation will be necessary in order for it to meet this goal.

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Ranking Member, Subcommittee on Health, Committee on Energy and Commerce.

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