STUDENT LOAN RATE HIKES

(Ms. FOXX asked and was given permission to address the House for 1 minute.)

Ms. FOXX. Mr. Speaker, student loan interest rates are scheduled to double July 1 unless the President and Senate act now to remove politics from the rate-setting process.

No amount of White House campaigning will stop the increase. We have to work together. And that shouldn't be hard since House Republicans already share a great deal of common ground with President Obama's own interest rate proposal. He asked for a permanent solution to Washington's interest rate conundrum. He asked that the solution anchor rates in the market and away from election cycles and that it include protections for the most vulnerable. The Smarter Solutions for Students Act, passed by the House with bipartisan support, meets those criteria.

Our solution to stop rates from doubling provides a good starting point for Senate Democrats and President Obama to take action before July 1. The President must not cede this common ground to empty speeches and political posturing.

Let's build on the common ground to keep rates from doubling.

PRESIDENT'S COMPETENCY CALLED INTO QUESTION

(Mr. BRIDENSTINE asked and was given permission to address the House for 1 minute.)

Mr. BRIDENSTINE. Mr. Speaker, the President's Justice Department sold weapons to narcoterrorists south of our border who killed one of our finest.

The President's State Department lied about Benghazi with false information provided by the White House.

The President's Attorney General authorized spying on a Fox News journalist and his family for reporting on a North Korean nuclear test.

The President's Justice Department confiscated phone records of the Associated Press because they reported on a thwarted terrorist attack.

The President's Treasury Department uses the IRS to target political opposition.

The President's Health and Human Services Secretary pressures the insurance companies she is supposed to regulate to promote ObamaCare, which is the same law she uses to force citizens to pay for abortion-inducing drugs against their religious liberties.

Mr. Speaker, the President's dishonesty, incompetence, vengefulness, and lack of moral compass lead many to suggest that he is not fit to lead. The only problem is that his Vice President is equally unfit and even more embarrassing.

The SPEAKER pro tempore. The Chair advises Members to refrain from improper references to the President and Vice President.

TWENTY-FOURTH ANNIVERSARY OF TIANANMEN SQUARE

(Mr. WOLF asked and was given permission to address the House for 1 minute and to revise and extend his remarks.)

Mr. WOLF. Twenty-four years ago, peaceful, pro-democracy demonstrators gathered in Tiananmen Square were brutally crushed by the People's Liberation Army. The Chinese Government remains frightened by the spirit that animated that protest.

I will submit for the RECORD an article from today's Washington Post, which reported that:

> In the 2½ decades since the protests' violent end, China's government has largely scrubbed Tiananmen from history.

In 1991, Congressman CHRIS SMITH and I traveled to China where we visited Beijing Prison Number One, which housed approximately 40 Tiananmen Square protesters. While our request to visit the demonstrators was denied, we left with a pair of socks made by prisoners for export to the West.

The events of the past and the continued repression today are made worse by this administration's failure to prioritize human rights in our relationship with China.

Will President Obama even mention Tiananmen in his summit with the Chinese President this week, or will he abide by the censor's wishes and pretend it never happened?

□ 1410

IT'S 2013

(Mr. MESSER asked and was given permission to address the House for 1 minute.)

Mr. MESSER. Mr. Speaker, it's 2013, and the world is full of successful women, women like my mother, who raised her two sons on her own while working at the Delta Faucet factory in Greensburg.

Some women, like my wife—a successful full-time lawyer and a successful full-time mother—balance career with family and still find time to celebrate good report cards, birthday parties, and family vacations.

Last week, a national debate broke out over reports that 4 out of 10 households now have women as the lead breadwinner. I live in and grew up in two such households.

Strong women are central to today's family, and that is a good thing. I look forward to a time when statistics about the success of women are no longer newsworthy.

COMMUNICATION FROM THE OFFICE OF THE LEGISLATIVE COUNSEL

The SPEAKER pro tempore laid before the House the following communication from Peter Szwec, Senior Systems Analyst, Office of the Legislative Counsel:

HOUSE OF REPRESENTATIVES,
OFFICE OF THE LEGISLATIVE COUNSEL,
Washington, DC, May 28, 2013.

Hon. JOHN A. BOEHNER,
Speaker, House of Representatives,
Washington, DC.

DEAR MR. SPEAKER: This is to notify you formally pursuant to rule VIII of the Rules of the House of Representatives that I have been served with a subpoena, issued by the United States District Court for the District of Arizona, for witness testimony.

After consultation with the Office of General Counsel, I have determined that compliance with the subpoena is consistent with the privileges and rights of the House, except to the extent that questions put to me seek information that is privileged.

Sincerely,

PETER SZWEC,
Senior System Analyst.

ANNOUNCEMENT BY THE SPEAKER PRO TEMPORE

The SPEAKER pro tempore. Pursuant to clause 4 of rule I, the following enrolled bill was signed by Speaker pro tempore WOLF on Friday, May 24, 2013:

H.R. 258, to amend title 18, United States Code, with respect to fraudulent representations about having received military decorations or medals.

RECESS

The SPEAKER pro tempore. Pursuant to clause 12(a) of rule I, the Chair declares the House in recess until approximately 4 p.m. today.

Accordingly (at 2 o'clock and 11 minutes p.m.), the House stood in recess.

□ 1602

AFTER RECESS

The recess having expired, the House was called to order by the Speaker pro tempore (Mr. COLLINS of New York) at 4 o'clock and 2 minutes p.m.

MESSAGE FROM THE PRESIDENT

A message in writing from the President of the United States was communicated to the House by Mr. Brian Pate, one of his secretaries.

ANNOUNCEMENT BY THE SPEAKER PRO TEMPORE

The SPEAKER pro tempore. Pursuant to clause 8 of rule XX, the Chair will postpone further proceedings today on motions to suspend the rules on which a recorded vote or the yeas and nays are ordered, or on which the vote incurs objection under clause 6 of rule XX.

Any record votes on postponed questions will be taken later.

SAFEGUARDING AMERICA'S PHARMACEUTICALS ACT OF 2013

Mr. LATTA. Mr. Speaker, I move to suspend the rules and pass 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, as amended.

The Clerk read the title of the bill.

The text of the bill is as follows:

H.R. 1919

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

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 (xiii);

''(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)(xvii), 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; 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 history and transaction statement (in paper or electronic form) 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—

''(I) until the date than is 5 years after the date of the enactment of the Safeguarding America's Pharmaceuticals Act of 2013, provide the subsequent owner with the transaction history and a transaction statement in a single document in paper or electronic form; and

''(II) on or after such date, provide the subsequent owner with the transaction history and a transaction statement in electronic form; 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) subject to clause (iv), 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, the exclusive distributor of the manufacturer, or a repackager that purchased directly from the manufacturer, provide the subsequent owner with transaction history and a transaction statement for the prescription drug product—

''(aa) if the subsequent owner is a dispenser, on a single document in paper or electronic form; or

''(bb) if the subsequent owner is a wholesale distributor, through any combination of self-generated paper, electronic data, or manufacturer-provided information on the product package;

''(II) in the case that the wholesale distributor did not purchase the prescription drug product as described in subclause (I)—

''(aa) provide the subsequent owner with the transaction history and a transaction statement beginning with the wholesale distributor that did so purchase the prescription drug product in paper or electronic form; or

''(bb) pursuant to a written agreement between the wholesale distributor and a dispenser, maintain the transaction history and transaction statement on behalf of the dispenser and if requested by the dispenser, provide the transaction history and transaction statement to the dispenser in paper or electronic form in a timely manner so as to permit the dispenser to comply with requests pursuant to subsection (d)(1)(D);

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

''(iv) on or after the date that is 5 years after the date of the enactment of the Safeguarding America's Pharmaceuticals Act of 2013, provide the transaction history and transaction statement in electronic form.

''(B) INCLUSION OF LOT NUMBER IN TRANSACTION HISTORY.—Until the date that is 5 years after the date of the enactment of the Safeguarding America's Pharmaceuticals Act of 2013, the transaction history provided by a wholesale distributer under this paragraph shall not be required to include the lot number of the product or the initial date of the transaction from the manufacturer (as such terms are used in subparagraphs (F) and (G) of section 581(23)).

''(C) 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).

''(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 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 products subject to such notification that are in the possession or control of the wholesale distributor, including any such 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—

''(i) 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 the applicable transaction history and transaction statement which the dispenser received from the previous owner;

''(ii) the information provided by the dispenser under clause (i) is not required to include the lot number of the product, the initial date of the transaction, or the initial date of the shipment from the manufacturer unless such information was provided electronically by the previous owner, manufacturer, or wholesale distributor to the dispenser; and

''(iii) a dispenser may respond to the request by providing the paper documentation received from the previous owner or by providing electronic 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 such 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) RETURNS EXCEPTION.—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 such 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 products subject to such notification that are in the possession or control of the third-party logistics provider, including any such 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, including allowing for verification, aggregation, and inference by each sector within the pharmaceutical distribution supply chain for cases, pallets, totes, and other containers of aggregated prescription drug product as necessary.

(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, including the use and evaluation of verification, aggregation, and inference by each sector within the pharmaceutical distribution supply chain as necessary;

(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, which shall permit the use of aggregation and inference for cases, pallets, totes, and other containers of aggregated prescription drug products by each sector of the pharmaceutical distribution supply chain, 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, and public comments resulting from, the pilot project conducted under subsection (a);

(B) the public meetings held under subsection (b) and public comments from such meetings;

(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 conduct 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 of 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—

''(i) any felony for conduct relating to wholesale distribution;

''(ii) any felony violation of section 301(i) or 301(k); or

''(iii) 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)(xii);

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

''(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.

The SPEAKER pro tempore. Pursuant to the rule, the gentleman from Ohio (Mr. LATTA) and the gentleman from California (Mr. WAXMAN) each will control 20 minutes.

The Chair recognizes the gentleman from Ohio.

GENERAL LEAVE

Mr. LATTA. Mr. Speaker, I ask unanimous consent that all Members may have 5 legislative days in which to revise and extend their remarks and insert extraneous matters in the RECORD on the bill.

The SPEAKER pro tempore. Is there objection to the request of the gentleman from Ohio?

There was no objection.

Mr. LATTA. Mr. Speaker, I yield myself such time as I may consume.

I rise today in support of H.R. 1919, the Safeguarding America's Pharmaceuticals Act of 2013. This legislation is the culmination of many years of hard work by legislators and stakeholders alike, and I'm honored to have introduced this legislation, along with Congressman MATHESON.

This is an issue that was brought to my attention when I was first elected to Congress 5½ years ago by concerned stakeholders in Ohio, and I am pleased that the legislation is being considered on the House floor today. Securing our Nation's pharmaceutical supply chain is an extremely important issue, and passage of this bill will be an important step forward to protecting America's families.

The pharmaceutical supply chain touches every part of the health care system, and it is imperative that we get the structure and segments of it connected in a safe, secure, and effective manner that provides the best protection for patients.

H.R. 1919 will make improvements to the current supply chain while providing a clear path for industry stakeholders towards enhanced supply chain protections.

Pharmaceutical distribution occurs nationwide, and it is estimated that within the United States there are more than 4 billion prescriptions filled each year. By replacing the current patchwork of multiple State laws with a uniform national standard, we improve safety, eliminate duplicative regulations, and create certainty for all members of the pharmaceutical supply chain.

When anyone takes a prescribed medication, he or she should have full confidence that the medication is as prescribed and will do no harm. It is of utmost importance that we implement commonsense solutions to safeguard our distribution supply chain against counterfeit and adulterated drugs, as well as improve security and integrity throughout the supply chain. This legislation is an important step forward to ensure greater patient safety for all Americans.

I was pleased to receive a support letter for H.R. 1919 from the United States Deputy Sheriffs' Association, which also recognizes that a national system will help curb criminal activity surrounding prescription drug diversion and criminal counterfeiting.

In the letter, it discusses how a national system could deter opportunists' ability to focus their efforts on differing State laws, or those States that have no laws or regulations, thereby allowing for criminal infiltration.

Specifically, the letter states that ''tracking packages destined for patients is a good defense against criminals who would profit from contaminating or stealing those medicines, and put patients at risk.''

To protect patient safety, this bill would replace multiple State laws and create a uniform national standard for securing the pharmaceutical distribution supply chain, thereby preventing duplicative State and Federal requirements.

It would increase security of the supply chain by establishing tracing requirements for manufacturers, wholesale distributors, pharmacies, and repackagers based on changes in ownership.

The bill also establishes a collaborative, transparent process between the Food and Drug Administration and stakeholders to study ways to even further secure the pharmaceutical supply chain.

Finally, the bill puts in place a requirement for the FDA to issue proposed regulations on unit-level traceability. The timeline put forth in this bill for all those steps is reasonable and will allow enough time for stakeholders to comply with these new national standards and ensure that, through feedback from these same stakeholders, phase two is done efficiently and correctly.

As I stated earlier, this issue has been worked on for many years, and setting up a track and trace process is complicated.

Chairman UPTON, I appreciate your leadership in moving the Safeguarding America's Pharmaceuticals Act to the floor today. We made a number of changes in the Energy and Commerce

Committee to improve the language of the bill as we work to create a safer pharmaceutical distribution system to protect against the threat of counterfeit drugs.

This is a highly complex area, and I understand that additional changes were made to the language in the version we are considering today. Further changes are necessary to ensure that the wholesale distribution system meets the highest standards of safety and consumer protection. In order to achieve those high standards, I am committed to ensuring that language is included in the conference report brought back to the House that establishes a direct purchase pedigree for those wholesalers who only purchase pharmaceuticals directly from the manufacturers.

I know you share my goal of creating the strongest supply chain system, and I look forward to working with you as we move forward.

There has been much work done on this issue over the many years, and I am appreciative of all the input I have received on this bill from stakeholders and interested parties. And I again want to specifically thank Chairman UPTON and Subcommittee Chairman PITTS for all their assistance in advancing this legislation. I urge full support of my colleagues for H.R. 1919.

I reserve the balance of my time.

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Mr. WAXMAN. Mr. Speaker, I yield myself such time as I may consume.

Mr. Speaker, I rise to discuss a number of concerns I have about H.R. 1919, the Safeguarding America's Pharmaceuticals Act of 2013. It's a bill designed to improve the integrity of our drug supply chain. Unfortunately, this bill falls far short of achieving that goal.

Throughout last year, Members on a bipartisan, bicameral basis engaged in extensive discussions on legislation to protect our drug supply chain. During those months of discussion last year—and at the Health Subcommittee's hearing this past April—we repeatedly heard loud and clear from FDA, the National Boards of Pharmacy, and many others, that if we want a secure drug supply chain, we will ultimately need an electronic interoperable system that tracks each package of drugs at the unit level and that involves the entire supply chain. This kind of system would enable us to identify illegitimate product in real-time and prevent it from ending up in patients' hands. We also heard repeatedly that creating this kind of system is doable. Unfortunately, the bill we are considering today will not create that kind of system. The bill does not require the establishment of an electronic, interoperable unit-level system.

By 2027, 14 years from now, FDA will be required to issue proposed regulations for such a system. But there's no requirement that these regulations ever be finalized. And if they are ever finalized, they cannot go into effect for at least 2 more years. Almost certainly we are looking at 2030 or beyond under this proposed legislation; and, in fact, it may never be done.

This bill also has a number of additional deficiencies. It fails to adequately address the potential for bad actors to introduce illegitimate product into the supply chain through supposed returns from pharmacies to wholesale distributors. In the meantime, it will prevent States from responding to particular needs they may have in regulating their wholesale distributors, and it preempts important existing State safeguards against the entry into the supply chain of unsafe counterfeit drugs before any adequate substitute will be in place.

Two weeks ago, Mr. Speaker, the Senate HELP Committee unanimously approved a bill sponsored by Senators BURR, BENNET, HARKIN, and ALEXANDER that requires the establishment of a unit-level, electronic, interoperable system within 10 years and is not dependent upon FDA issuing regulations. But the Senate bill still provides plenty of notice, input, and guidance for industry stakeholders. FDA is required to hold public meetings, one or more pilot projects, and to issue draft and final guidances and, as needed, regulations. Because they will not be able to delay or prevent implementation of the system, stakeholders will have the incentive to work with FDA to see that the guidances and any needed regulations are developed and released.

Our fundamental goal in establishing a Federal system should be to prevent Americans from being harmed by counterfeit and substandard medicines. If we cannot assure the public that legislation will establish a system that will protect them and that will do so by a date certain, then, in my view, it's not worth doing. The House bill needs significant improvement as it moves forward if our goal is to enact legislation that will truly protect the American public.

Mr. Speaker, I reserve the balance of my time.

Mr. LATTA. I yield 2 minutes to the chairman of the full committee, the gentleman from Michigan (Mr. UPTON).

Mr. UPTON. Certainly, this afternoon I rise today in strong support of H.R. 1919, the Safeguarding America's Pharmaceutical Act of 2013. I want to thank the bill's authors, including Mr. LATTA, for their bipartisan leadership on this very important issue.

This bill strengthens the prescription drug supply chain in order to protect American families against counterfeit drugs. The bill also would help prevent increases in drug prices, avoid additional drug shortages, and literally eliminate hundreds of millions of dollars worth of duplicative government red tape on American businesses that is harming job growth.

As Mr. LATTA said, supporters of the Federal track and trace legislation include the U.S. Deputy Sheriffs' Association and also those in the supply chain, including the National Community Pharmacists Association. According to the CBO, the bill would reduce the deficit by $24 million.

Last Congress, we spent a significant amount of time working on this very important issue as we successfully moved the Food and Drug Administration Safety and Innovation Act through the legislative process, and our efforts continued beyond enactment and into the 113th Congress. During that entire process, we also sought input from stakeholders like Pfizer and Perrigo, in my district in Michigan, as well as our smaller pharmacies, too. This hard work allowed us to better understand the issue, and this bill reflects that understanding.

At the Energy and Commerce Committee, we held a legislative hearing on the bill last April. We approved the bill in both subcommittee and full committee by voice vote. We certainly did have a spirited debate at the committee, but we stand here united in our belief that the prescription drug supply chain has to be strengthened.

We look forward to working with our Senate colleagues on H.R. 1919 on a bipartisan basis to improve the bill, including how it addresses issues related to wholesale distributors during phase one. Because of the hard work that has already been put in on this issue and the importance of protecting our Nation's families from counterfeit drugs, I am hopeful we can get a product to the President's desk by the August recess.

Mr. WAXMAN. Mr. Speaker, I yield 3 minutes to the gentleman from Utah (Mr. MATHESON), one of the original sponsors of this legislation.

Mr. MATHESON. I thank the gentleman for yielding, and I thank Mr. LATTA for his work on this issue as well.

This bill before us today is a product of several years of collaboration. It's a really complicated issue, and it's important that you have a lot of collaboration to address something of this complexity.

This legislation that Mr. LATTA and I have introduced together will provide what I think are important steps for the security of our prescription drug supply chain from counterfeiters and other bad actors. We've seen in recent press reports about fake drugs slipping into the supply chain, so the threat of counterfeit drugs is a growing problem in this country. In fact, when you think about it, the counterfeit drug trade may be a more lucrative opportunity than the illegal drug trade, since the United States, overall, spends roughly $325 billion a year on prescription drugs. This bill is an effort to try to keep those bad actors from entering the drug supply.

Since we've had some of these problems, some States have, rightly, tried to take action to deal with this. What this legislation is going to do, however,

is establish more of a national standard to create some certainty for everyone in the supply chain so there's an opportunity to work effectively in a national way. Without such action, everyone in the supply chain could be forced to comply with a never-ending patchwork of different and complex State laws. That patchwork will force stakeholders to step up multiple State systems, and it could still open the door for bad actors to exploit security gaps through some States that may have weaker laws.

This bill also establishes a collaborative process between the FDA and the industry in establishing protocols for unit-level traceability. The bill stipulates the FDA will hold regular meetings and conduct pilot programs with stakeholders to better inform the agency as to the feasibility of unit-level traceability and the processes needed to achieve that goal. This is critical to ensure that the unit-level traceability regulation is achievable, does not increase prescription drug costs for consumers, and ultimately protects patients from counterfeit and adulterated prescription drug products. What we do not want to see are regulations that are not technologically achievable by industry stakeholders, causing a delay in implementation, as we've seen in some States' circumstances.

□ 1620

Now, there's no question that this legislation has been an effort of several years, and there's still perhaps some work to be done. I'm hopeful that as this legislation moves through the process, as the House and the Senate go to conference, that there are some other outstanding issues that can be addressed and we can build even greater consensus as we go to a final product that goes to the President's desk.

I urge my colleagues to support this bipartisan bill.

Mr. LATTA. Mr. Speaker, at this time I yield 2 minutes to the gentleman from Pennsylvania (Mr. PITTS), the chairman of the subcommittee.

Mr. PITTS. Mr. Speaker, the bill before us today is important and necessary legislation to strengthen the prescription drug supply chain and to provide greater safety for our Nation's patients.

Safeguarding our prescription drug supply chain is important to protect against counterfeit drugs. It is necessary to help prevent increases in drug prices while also ensuring adequate supplies of much-needed prescription drugs. Equally important, H.R. 1919 includes reforms that will eliminate hundreds of millions of dollars' worth of duplicative government red tape on American drug manufacturers, wholesale distributors, and pharmacies.

Sadly, counterfeit prescription drugs have proven to be a lucrative business, with many of these illegal counterfeit drugs finding their way to some of our sickest patients, including those with cancer.

Additionally, some States have taken draconian actions to safeguard their prescription drug supply chain, but many of these steps will force small and large businesses to implement costly and indefensible electronic systems for tracking such drugs at the unit level.

After hearings in the Health Subcommittee of the Energy and Commerce Committee, which I chair, we heard that a more feasible and practical solution to this serious problem is attainable, and those provisions are included in H.R. 1919.

Mr. Speaker, by approving this legislation, we will be saving our Nation's businesses millions of dollars, protecting our patients from counterfeit drugs, and securing our drug supply chain in a reasonable, commonsense way.

I urge all my colleagues to support this bill and vote for H.R. 1919.

Mr. WAXMAN. Mr. Speaker, I'd like to yield 3 minutes at this time to the gentleman from North Carolina (Mr. BUTTERFIELD) to speak on this legislation.

Mr. BUTTERFIELD. First, let me thank Mr. WAXMAN for yielding time and thank him for his extraordinary leadership on our committee. Let me also thank Mr. LATTA and Mr. MATHESON for working together to try to get this legislation to the floor today.

Mr. Speaker, I rise in support of H.R. 1919 and urge its passage. Since the Prescription Drug Marketing Act was signed into law some 25 years ago, a patchwork of varying State pedigree laws has evolved, leaving our drug supply chain very vulnerable. Resources should focus on up-to-date and adaptable technology using global serialization standards.

In the past 25 years, industry stakeholders have been unable to agree on a uniform Federal solution, but today I'm happy to report that it does exist. The fact that so many members of the industry have finally come together to embrace new, commonsense regulations speaks to the importance of getting this done soon.

If we fail to enact drug distribution safety legislation soon, my fear is, Mr. Speaker, that we will miss the opportunity to significantly enhance patient safety for all Americans.

The House bill has improved since its introduction. And while I strongly support some of the provisions in the Senate companion bill, including a date certain to reach unit-level tracking, the House bill represents a good step forward and advances the ball toward one ultimate goal. Hopefully, some of these concerns can be addressed in conference.

My constituents, like all of yours, deserve to know that the prescription drugs that they use to treat diabetes, high blood pressure, and heart disease are not stolen, misbranded, or counterfeited. This bill—and the Senate counterpart—addresses the very real concerns that spurred the introduction of this legislation.

While the House bill isn't everything many of us want it to be—and Mr. WAXMAN spoke to that earlier—I am hopeful that once the House and Senate bills move to conference, we will see a final version that will protect consumers and better protect the prescription drug supply chain.

Therefore, Mr. Speaker, I urge my colleagues today in the Senate to proceed with deliberate and swift action so that we can pass a workable solution as soon as possible so as to better protect the American people.

I ask my colleagues to support H.R. 1919.

Mr. LATTA. Mr. Speaker, at this time I yield 2 minutes to the gentleman from Texas (Mr. BURGESS).

Mr. BURGESS. I thank the gentleman for yielding.

You know, the United States has the best drug supply chain in the world, but it faces attack each and every day by counterfeiters, thieves, and rogue distributors.

Most Americans would just assume that their prescription drugs that they buy in their drugstore have been tracked rigorously from manufacturer to retail, but that assumption could not be more wrong. In fact, current law leaves a great deal of leeway for counterfeit medications to enter the market, and the punishment for those counterfeiting prescription medication is oftentimes far from adequate. From fake flu vaccines to fake cancer drugs, counterfeit medications have been manufactured and allowed to enter the supply chain and in some cases, unfortunately, even administered to unsuspecting patients. The United States may be the most secure, but we are still at risk.

I believe we have a bill before us today that is guided by the strong principles of patient safety and supply chain integrity. The bill is flexible and does not seek to overly burden States, suppliers, or small businesses. Maintaining the integrity of the United States' prescription drug supply is a compelling national priority.

I want to congratulate Mr. LATTA and Mr. MATHESON, as well as Chairman UPTON and Ranking Member DINGELL, for their leadership on the issue. I appreciate you allowing me to be involved in the development of this bill. I think it is a testament to all the hard work done, including that by our committee staff, Clay Alspach and Paul Edattel, and my personal staff, J.P. Paluskievicz.

I urge my colleagues to support this.

Mr. WAXMAN. Mr. Speaker, at this time I wish to yield 3 minutes to the gentleman from Maine (Mr. MICHAUD).

Mr. MICHAUD. Mr. Speaker, I rise today to express opposition to H.R. 1919.

Specifically, I rise to express concern with section 8 of this bill, which allows prescription drug labeling for physicians, pharmacists, and other health

care professionals to be provided solely by electronic means.

This provision is flawed on multiple levels. First, Internet access in rural States like mine can often be intermittent at best. In an area with low Internet connectivity or reliability, health care providers would not automatically have the necessary information about the drugs to make sure that they're being administered and prescribed appropriately. This is even true in areas that have good Internet connectivity, but may have been hit by a natural disaster like Hurricane Sandy.

Second, eliminating the paper labeling requirement will have repercussions for the industry that it supports. There are more than 10,000 jobs nationwide associated with the printing of this sensitive information.

In Maine, the paper industry supports 7,000 workers, including hundreds in the pharmaceutical paper industry. These workers are part of an important industry that keeps health care professionals, dispensers, and consumers informed about their drugs. Section 8 would jeopardize the jobs of more than 1,000 Mainers.

Finally, legislation passed during the 112th Congress required GAO to conduct a study of the advantages and risks of electronic-only labeling of pharmaceuticals. This study is due to be released next month. Passing this legislation that preempts the finding of this study is bad policy. So I would urge my colleagues to support informed health care professionals and consumers and to fight for more than 10,000 manufacturing jobs across the country. So I would urge a ''no'' vote on H.R. 1919.

Mr. WAXMAN. Will the gentleman yield?

Mr. MICHAUD. I yield to the gentleman from California.

Mr. WAXMAN. I thank you for yielding to me.

You're raising issues that I don't think were really brought to our attention when we were considering the legislation, and I want to look it over carefully.

But I think you raise an interesting point; and as we go into the conference after this bill is passed, I want to pledge to you that I will continue to review this issue with you and others to see what the merits would be of whether this provision should continue in the bill.

I talked to Chairman UPTON, who told me that he would continue to review the issue as well.

Mr. LATTA. Will the gentleman yield?

Mr. MICHAUD. I yield to the gentleman from Ohio.

Mr. LATTA. I thank the gentleman.

As we discussed a little earlier, I will be happy to continue discussing this with you.

Mr. MICHAUD. I thank both gentlemen for your willingness to look at section 8 more closely.

□ 1630

Mr. LATTA. Mr. Speaker, at this time I yield 2 minutes to the gentleman from West Virginia (Mr. MCKINLEY).

Mr. MCKINLEY. Mr. Speaker, I rise today in support of H.R. 1919.

Let me bring attention to a provision in the bill that we were just discussing about electronic distribution of prescription information for health care professionals and pharmacists. Industry and the FDA have been in discussions for years about eliminating the paper attached to bottles of prescription drugs.

Let me show you this. This is what we are talking about—this wad of paper on the top of a prescription bottle. It's a folded up piece of paper. It can be in three and four parts. This is not an efficient way to distribute critical information about prescription drugs. Eliminating this wad of paper would save the consumers millions of dollars in printing and shipping costs.

The House committee recognized the need to allow pharmacists the option of electronic or paper copies, because some rural pharmacies may not have Internet capabilities. Unfortunately, this labeling provision is not in the Senate bill.

So, as the process moves forward into conference, this labeling provision needs to be retained so that we have a final product that assures patient safety and provides uniform national standards to strengthen the national drug supply chain.

I urge my colleagues to support this bill and the labeling provision.

Mr. WAXMAN. Mr. Speaker, I would like to submit for the record three letters from the California State Board of Pharmacy and four letters from dozens of organizations representing consumers, patients, physicians, researchers, and public health advocates. These letters raise serious concerns with H.R. 1919, the track and trace legislation before us today.

I would like to read a few sentences from just one of the letters:

> We are concerned that the legislation as currently written does not contain the minimum safeguards to keep unsafe medicines from reaching patients. The subcommittee's proposal does not create a clear path forward to a meaningful unit-level traceability system. Furthermore, the proposed legislation would eliminate all existing State drug pedigree laws—which provide essential patient safety protections as well as major tools for law enforcement. The bill would leave the U.S. pharmaceutical supply unprotected for a full 2 years before introducing even limited traceability requirements.

I urge my colleagues on both sides of the aisle to read these letters carefully. They provide a detailed critique of the legislation and offer suggestions on how to fix it. I hope we can improve this bill as it moves forward through the legislative process.

COMMENTS OF THE PEW CHARITABLE TRUSTS TO HOUSE COMMITTEE ON ENERGY AND COMMERCE ON H.R. 1919—PROPOSED LEGISLATION TO IMPROVE DRUG DISTRIBUTION SECURITY, MAY 14, 2013

DEAR CHAIRMAN UPTON AND RANKING MEMBER WAXMAN: Thank you for your ongoing interest in measures to secure the drug distribution system in the United States.

We have reviewed H.R. 1919, the legislative proposal that will be considered by the Committee on Energy and Commerce on May 15. As currently drafted, this legislation does not establish meaningful patient protections and does not justify the preemption of state laws. The legislation continues to provide no guarantee that there will be a national drug distribution security system that will involve all members of the supply chain and will track drugs at the unit level within a reasonable time frame.

This bill does not require a proposed regulation until 2027, and does not set a timeline for a final rule. The soonest an enhanced distribution security system could possibly be in place is 2029—assuming FDA could propose and finalize the regulations in one year. This prolonged timeline will eradicate momentum in the supply chain towards unit-level traceability, will halt progress on serialization and data sharing system development, and will seriously undermine investments already being made by stakeholders. We urge the committee to amend this legislation to establish a clear path to a unit-level traceability system, as called for by a majority of the witnesses who testified at your April 25th hearing.

Pharmaceutical manufacturers are already making investments in drug serialization technology. To justify the expense—and the preemption of strong state laws—it is essential that any federal law establish meaningful patient protections through use of this technology. Legislation must achieve the following within a reasonable time frame:

Participation of all members of the supply chain

Traceability of drugs at the package/unit level, and

Routine checking of drug serial numbers.

We attach herewith our comments on the proposed legislation considered by the Energy and Commerce Subcommittee on Health on May 8, 2013.

CALIFORNIA STATE BOARD OF PHARMACY,
Sacramento, CA, May 28, 2013.

Re Federal efforts to secure drug distribution security

Hon. HENRY WAXMAN,
Ranking Member, Energy and Commerce Committee.

Hon. FRANK PALLONE, Jr.,
Ranking Member, Health Subcommittee, Energy and Commerce Committee.

DEAR MR. WAXMAN AND MR. PALLONE: I write on behalf of the California State Board of Pharmacy (Board). We appreciate this opportunity to submit our written comments on H.R. 1919, titled the ''Safeguarding America's Pharmaceuticals Act of 2013.'' Our comments pertain to H.R. 1919 as it was reported out of the Energy & Commerce Committee on or about May 15, 2013. We write to express our concern that this bill, as currently drafted, does not do enough to promise an increase in the security of the drug distribution supply chain, while at the same time preempting the California pedigree law and tying the hands of states like California to regulate wholesalers.

We want to first thank you and the bill's authors and co-sponsors for acknowledging and taking on the challenge of increasing drug supply chain security. We understand

that it is not an easy task to balance the need for increased security against a desire to avoid adding unnecessary costs and possible interruptions to the supply chain. We also recognize and appreciate just how much effort has gone into the bipartisan and bicameral effort to reach agreement on legislation necessary to achieve needed improvements in drug supply chain security. Finally, we agree that it would be ideal for the subject of supply chain security to have a federal legislative solution, as this is a subject that would be more ideally regulated at the federal level than by the states.

However, we believe H.R. 1919 does not promise the kind of robust supply chain security that is necessary to ensure adequate patient protection, and is not an adequate replacement for the California pedigree law that, absent this bill, will go into effect beginning in 2015. Our reasons for this are various; many of these have been covered in our comments on prior legislative drafts. In the interest of brevity, and because we want to get these comments to you in time for them to be considered along with any action that might be taken on H.R. 1919, we will keep this iteration of our comments relatively succinct. Please find enclosed our letters dated April 26, 2013, on the draft of the bipartisan Senate bill released for comment at that time (since introduced in much the same form as S. 957, and combined with S. 959), and November 7, 2012, on the bicameral DDS Draft that was at that time sent out for comment, which we hereby incorporate by reference.

In brief, our primary though by no means only objection to this draft is that it promises no certainty that we will ever see the end-to-end, full participation, electronic track-and-trace system monitoring drug distribution security at the unit (package) level, with trading partner verification and validation and the resulting protections against counterfeit and adulterated products, that has been the recommendation of the FDA since its Counterfeit Drug Task Force convened in 2004. This bill leaves the development of any such system to some future rulemaking, to be published no sooner than 2027, effective 2 years later, and even then this legislation requires no particular outcome of such rulemaking. We have no confidence, given the history of the Prescription Drug Marketing Act of 1987 (PDMA), that this deferral will result in any increase in security. While we have also expressed concern (see April 26, 2013 comments) that Section 3 of the Senate draft should be improved and strengthened, and that it should not take an additional 10 years to get to the system outlined in that section, we far prefer the relative certainty of the Senate model to this draft. There has already been substantial agreement that a uniform track-and-trace infrastructure is needed to ensure supply chain security, and many participants in the supply chain are already well on their way to implementing that infrastructure to comply with the California timeline. We believe that without placing a definite outcome and a date certain into the legislation, all of that momentum will be lost and all of that industry investment will be wasted. We believe the public deserves a robust supply chain security system, and we further believe that the industry needs the certainty of firm deadlines and objectives in order to adequately plan their capital investments.

Of nearly co-equal importance, we also object, for many of the same reasons stated in our November 7, 2012 letter, to the language in Section 585, subdivision (b) (and/or elsewhere), that has the effect of making the proposed national wholesaler licensure standards both a ''floor'' and a ''ceiling'' on the independent authority of states to regulate wholesalers. We support national minimum standards for wholesalers, and also support federal licensure of distributors in states that do not provide such licensure. But we strongly believe that states should remain able to enact and enforce state-specific provisions that go above and beyond national minimums, to respond to more local issues and also to later developments requiring more immediate action. We are happy to work with you further on this topic, and to share examples of why we believe it is so crucial for states to retain flexibility and additional authority with regard to regulating wholesalers.

One such example would be the difficulty experienced in California and other states over the last few years with ''gray market'' purchase and re-sale practices by (secondary) wholesalers. California has seen a dramatic uptick in re-sales of drugs that are in short supply, as wholesalers and their trading partners evade typical drug shortage allocations by purchasing from pharmacies who become de facto ''purchasing agents'' for the secondary wholesalers, acquiring drugs from a primary wholesaler for the purposes of resale to the secondary wholesaler, which in turn re-sells the drugs to another secondary wholesaler or to an end user. These practices can result in further increases in the already-increased prices of shortage drugs, in further distortions in supply, and in supply chain vulnerabilities from the multiple purchases/re-sales. Some of these problems have been documented in a bicameral investigation report by Senators Rockefeller and Harkin, and by Representative Cummings, which addressed the problem and possible solutions. A copy of this report is available at http://cummings.house.gov/cummings-releases-joint-report-gray-market-drug-companies. This kind of unexpected and unprecedented conduct by wholesalers presents a new challenge that has not been anticipated by previous licensing schemes (or the framework in the present draft). California and other states will have to devise new regulatory language that is able to better handle these kinds of market innovations. We must retain the flexibility to do so, and to add to the federal minimums when these kinds of situations come up. Under the language of H.R. 1919, we will not have the necessary flexibility and authority to do so.

CONCLUSION

For these reasons, as well as those spelled out in more detail in the enclosed letters, we cannot support the current draft of H.R. 1919, although we believe and reiterate that a federal model is ideal. We do not believe that additional drug security can await the possible development of future standards some 14 or more years after enactment. We believe the security of the drug supply and the public's trust in that drug supply are threatened, and any further delay simply adds to the scope of these threats..

We also believe that the endpoint should be a national end-to-end track-and-trace system that is worthy of any additional delay, and adequate to replace the California model. We believe the necessary components of any such system include: participation by all industry partners; in passing and receiving electronic drug ''pedigree''/chain-of-custody data as to all prescription drugs; to which data all shipments and deliveries are validated; by tracking and validating shipments at the (saleable) unit level at each stage of distribution. We believe this proposal fails to fully articulate the system first envisioned by the FDA.

Finally, we remain concerned that the hands of California and other states with robust programs to license and regulate wholesale distributors will be tied by the national licensure standards section(s) of the bill. We would encourage you to adopt a model wherein the federal legistaltion sets a floor for wholesaler licensure standards (and provides for federal licensure where states do not offer same) but not a ceiling.

We again commend you for your leadership on these vital issues of national security. Thank you also for your willingness to hear our input. We look forward to our continuing work together to secure the nation's drug supply. Please feel free to contact the Board any time if we can be of assistance.

The best ways to reach me are on my cell phone or by email. You may also communicate with the Board's Executive Officer, Virginia Herold, by telephone or by email.

Thank you again for your efforts. We are grateful to all of you, and hopeful that we are nearing a strong federal system for regaining a strong pharmaceutical supply.

Sincerely,

STANLEY C. WEISSER, R.PH.,
President, California State Board of Pharmacy.

Enclosures: April 26, 2013 Board comment letter, November 7, 2012 Board comment letter.

NATIONAL RESEARCH CENTER FOR WOMEN & FAMILIES, THE TMJ ASSOCIATION, WOODYMATTERS,
May 7, 2013

Re Energy and Commerce Health Subcommittee markup to amend the Federal Food, Drug, and Cosmetic Act with respect to the pharmaceutical distribution supply chain

Hon. FRED UPTON,
Chairman, Committee on Energy and Commerce, Committee on Energy and Commerce, Washington, DC.
Hon. HENRY WAXMAN,
Ranking Member, Committee on Energy and Commerce, Health Committee on Energy and Commerce, Washington, DC.
Hon. JOSEPH R. PITTS,
Chairman, Subcommittee on Health, Committee on Energy and Commerce, Washington, DC.
Hon. FRANK PALLONE,
Ranking Member, Subcommittee on Committee on Energy and Commerce, Washington, DC.

DEAR CHAIRMAN UPTON, CHAIRMAN PITTS, RANKING MEMBER WAXMAN, AND RANKING MEMBER PALLONE: Thank you for the opportunity to provide comments on the pharmaceutical supply chain legislation being marked up on May 7 and May 8.

We are writing on behalf of consumers, patients, scientists, and public health advocates to express our strong support for a drug distribution system that will protect patients and the public's health from unsafe medicines. The ongoing threat to the U.S. drug supply must be addressed through a strong national serialization and traceability system to track and authenticate medicines at the unit level. Without such a system to track and authenticate drugs at the unit level as they move from manufacturer to wholesaler to pharmacy to patient, the public's health continues to be placed at risk from unsafe or counterfeit medicines.

The Subcommittee on Health's proposed legislation, as currently written, lacks necessary and clearly defined elements to guarantee a unit-level serialization and traceability system in a timely manner. This is a serious patient safety concern, and must be rectified. The proposed legislation would also eliminate all existing state drug pedigree laws—major tools for law enforcement—and would leave the U.S. pharmaceutical supply unprotected for a full two years before putting a limited system in place.

We do not support a federal law that preempts existing strong state laws. The federal

law should be a floor, not a ceiling. Any federal law must create a system that includes the following elements within a timely manner:

PARTICIPATION OF ALL MEMBERS OF THE SUPPLY CHAIN

We need full participation of all supply chain stakeholders in a unit-level serialization and traceability system to protect the integrity of the supply chain. Pharmacies are the last step in drug distribution before medicine reaches a patient and are essential for ensuring pharmaceutical integrity.

TRACEABILITY OF DRUGS AT THE SMALLEST SALEABLE UNIT LEVEL

The legislation needs to create a clear, assured path to a unit-level traceability system. The proposal takes away strong existing state drug pedigree requirements, and does not replace them with assurances that unit-level traceability will be achieved. The legislation's requirement for numerous studies and meetings and lack of requirement for a final rule will create years of regulatory uncertainty and will not protect the public's health.

ROUTINE CHECKING AND VERIFICATION OF DRUG SERIAL NUMBERS

The legislation calls for limited verification under an interim system, and does not create a meaningful framework to achieve enhanced verification. A robust system should include proactive verification of drug units in order to prevent stolen and counterfeit drugs that are being distributed as legitimate pharmaceutical products from entering the supply chain.

The risk of counterfeit and diverted medicines in the U.S. drug supply has not abated over the years. The Food and Drug Administration announced three times in the past year that it had discovered counterfeit Avastin—a critical drug used to treat several types of advanced cancer—in the United States. The FDA issued letters to clinical practices in California, Texas, and Illinois warning that they may have knowingly or unknowingly purchased and administered treatments missing active ingredients to cancer patients.

In 2012 in New York, 48 individuals were charged in a huge criminal diversion and fraud scheme to buy prescription drugs ''on the street,'' re-package or re-label them and sell them back into distribution through licensed pharmaceutical wholesalers, who in turn sold the drugs to pharmacies. These ''recycled'' medicines put patients at risk of contaminated or compromised drugs. In addition, authorities estimated the large-scale drug diversion scheme cost the New York state Medicaid program $500 billion. Similar schemes in other states are well documented, including one in Tennessee earlier this year that cost the state Medicaid program more than $58 million.

These incidents represent an unacceptable risk to patients. We urge the Energy and Commerce Subcommittee on Health to consider a strong unit-level serialization and traceability framework that appropriately secures and protects the distribution of medicines in the U.S. in a timely fashion.

Thank you for the opportunity to comment.

NATIONAL RESEARCH CENTER FOR WOMEN & FAMILIES.
THE TMJ ASSOCIATION.
WOODYMATTERS.

CANCER LEADERSHIP COUNCIL,
Washington, DC, May 14, 2013.

Hon. FRED UPTON,
Chairman, Committee on Energy and Commerce, House of Representatives, Washington, DC.
Hon. JOSEPH PITTS,
Chairman, Subcommittee on Health, Committee on Energy and Commerce, House of Representatives, Washington, DC.
Hon. HENRY WAXMAN,
Ranking Member, Committee on Energy and Commerce, House of Representatives, Washington, DC.
Hon. FRANK PALLONE,
Ranking Member, Subcommittee on Health, Committee on Energy and Commerce, House of Representatives, Washington, DC.

DEAR CHAIRMAN UPTON, RANKING MEMBER WAXMAN, CHAIRMAN PITTS, AND RANKING MEMBER PALLONE: The undersigned organizations representing cancer patients, physicians, and researchers are writing in support of efforts to develop legislation to protect the security of the pharmaceutical distribution supply chain.

Cancer patients and physicians have experienced the adverse effects of disruptions in the supply chain and the counterfeiting of cancer drugs, occurrences which can compromise the quality of care they receive and the effectiveness of their treatments. Patients and their physicians must be able to trust that the drugs they prescribe and receive are consistent with their labeling. In the past, cancer patients have received counterfeit drugs that were ineffective. In those circumstances, cancer patients were harmed by time wasted receiving therapies that provided no medical benefit.

As you continue your work on supply chain protections, we urge that you develop a supply chain protection system that: Includes participation by all those involved in the supply chain; requires traceability of drugs at the smallest unit level; and facilitates routine verification of drug serial numbers.

We also urge that existing state drug pedigree laws not be preempted until a strong national system is implemented. Eliminating state protections without a national system to replace them would not be in the best interest of cancer patients and other Americans who trust that the medications they are prescribed are safe and effective.

We understand that developing a strong supply chain protection system will be accompanied by some costs. However, the health care system and patients are already bearing the costs associated with diversion and counterfeiting. Diversion schemes can cost health care payers significant sums. Money is wasted on counterfeit medicines, and additional resources must be spent on the therapies that patients may need to address the harm and/or lack of effectiveness of counterfeit drugs. Companies that have been victims to counterfeiting or diversion may bear significant costs as a result. Finally, the human costs of counterfeiting and diversion are great, as patients may be harmed by unsafe or ineffective medications.

We commend your commitment to addressing the safety of the pharmaceutical distribution system and urge you to develop protections that are adequate to meet the needs of cancer patients and their physicians.

Sincerely,
Cancer Leadership Council:

American Society for Radiation Oncology
Bladder Cancer Advocacy Network
The Children's Cause for Cancer Advocacy
Coalition of Cancer Cooperative Groups
Fight Colorectal Cancer
International Myeloma Foundation
Kidney Cancer Association
Lymphoma Research Foundation
National Coalition for Cancer Survivorship
National Lung Cancer Partnership
Ovarian Cancer National Alliance
Pancreatic Cancer Action Network
Prevent Cancer Foundation
Sarcoma Foundation of America
Susan G. Komen for the Cure Advocacy Alliance

MAY 7, 2013.

Re Energy and Commerce Health Subcommittee markup to amend the Federal Food, Drug, and Cosmetic Act with respect to the pharmaceutical distribution supply chain

Hon. JOSEPH R. PITTS,
Chairman, Subcommittee on Health, Committee on Energy and Commerce, Rayburn House Office Building, Washington, DC.
Hon. FRANK PALLONE,
Ranking Member, Subcommittee on Health, Committee on Energy and Commerce, Rayburn House Office Building, Washington, DC.

DEAR CHAIRMAN PITTS AND RANKING MEMBER PALLONE: We, the undersigned, thank the Health Subcommittee for the opportunity to provide feedback on the pharmaceutical distribution supply chain legislation being marked up on May 8.

On behalf of millions of consumers, patients, and public health advocates, we write in support of a strong national unit-level serialization and traceability system to secure the U.S. pharmaceutical supply. Without such a system to track and authenticate drugs at the unit level as they move from manufacturer to wholesaler to pharmacy to patient, the public's health continues to be placed at risk from diverted or counterfeit medicines.

We are concerned that the legislation as currently written does not contain the minimum safeguards to keep unsafe medicines from reaching patients. The Subcommittee's proposal does not create a clear path forward to a meaningful unit-level traceability system. Furthermore, the proposed legislation would eliminate all existing state drug pedigree laws—which provide essential patient safety protections as well as major tools for law enforcement. The bill would leave the U.S. pharmaceutical supply unprotected for a full two years before introducing even limited traceability requirements.

In order to justify the preemption of existing strong state laws, it is essential that any federal law create a system that includes the following elements within a reasonable time frame: (1) Participation of all members of the supply chain; (2) Traceability of drugs at the smallest saleable unit level; (3) Routine checking and verification of drug serial numbers.

As we have seen over the last several years, the risk of counterfeit and diverted medicines in the U.S. drug supply is real. The Food and Drug Administration announced three times over the past year that it had discovered counterfeit Avastin—a critical drug used to treat several types of cancer—in the United States. The FDA issued letters to clinical practices in California, Texas, and Illinois warning that they may have knowingly or unknowingly purchased and administered treatments missing active ingredients to cancer patients.

Last year the U.S. Attorney for the Southern District of New York charged 48 individuals in a large-scale criminal diversion scheme to buy prescription drugs ''on the street'', re-package and/or re-label them and sell them back into distribution through licensed pharmaceutical wholesalers, who in turn sold the drugs to pharmacies. The scheme included medicines for HIV/AIDS, schizophrenia, and asthma, some of which

were stored under unsafe conditions, or removed from their original packaging and mixed with other medication. Patients receiving these ''recycled'' medicines were at risk of contaminated or compromised drugs. Authorities estimate the large-scale drug diversion scheme cost the New York state Medicaid program almost half-billion dollars. Similar schemes in other states are well documented, including one in Tennessee earlier this year that cost the state Medicaid program more than $58 million.

In light of this ongoing and unacceptable risk to patients we urge the Energy and Commerce Subcommittee on Health to consider a strong unit-level serialization and traceability framework that appropriately secures and protects the distribution of medicines in the U.S. in a timely fashion. Thank you again for your work on this important issue.

American Public Health Association (APHA)
American Medical Women's Association
Annie Appleseed Project
Bladder Cancer Advocacy Network
Community Catalyst
Consumers Union
Fight Colorectal Cancer
International Myeloma Foundation
Lymphoma Research Foundation
National Association of County and City Health Officials (NACCHO)
National Women's Health Network
Ovarian Cancer National Alliance
Pancreatic Cancer Action Network
Susan G. Komen
Trust for America's Health
U.S. PIRG

I would like to ask the gentleman from Ohio how many speakers he has?

Mr. LATTA. We have none.

Mr. WAXMAN. Mr. Speaker, I yield back the balance of my time.

Mr. LATTA. Mr. Speaker, we have no further speakers. I ask for support for the bill, and yield back the balance of my time.

Mr. DINGELL. Mr. Speaker, I rise today in support of H.R. 1919, the Safeguarding America's Pharmaceuticals Act of 2013. The American people deserve peace of mind in knowing the pharmaceuticals they take every day are safe and have not been stolen, misbranded, or counterfeited. In last year's Food and Drug Administration Safety and Innovation Act, we took important steps to secure the upstream supply chain by ensuring FDA has accurate information about who is manufacturing and importing drugs, as well as requiring manufacturers to notify FDA if their pharmaceuticals may cause injury or death or have been stolen or counterfeited. That was a good first step, but now Congress must act to secure our downstream drug supply chain.

A strong, national track-and-trace system for our pharmaceutical supply chain will help improve public health and protect the American people from harm. We have seen far too many examples of counterfeit or unsafe pharmaceuticals entering the supply chain and ultimately ending up in the hands of patients. Now is the time to act and implement a system to trace pharmaceuticals as they move through the supply chain to prevent this from ever happening again. This system must be fair, feasible, and provide certainty to industry as to what is required of it. If done properly, a strong track-and-trace system will protect our pharmaceuticals from tampering and ensure their safety for patient use.

I want to thank my friends, Mr. MATHESON and Mr. LATTA, for their hard work on this important issue. I am the first to admit that this is not a perfect bill, and we have more work ahead of us. I also want to acknowledge the concerns of my friend and colleague from Maine, Mr. MICHAUD, about e-labeling. I commit to working with him to address this issue of great importance and ask that my colleagues do the same.

The Senate has also made real, bipartisan progress on this issue and taken a slightly different approach. I urge my colleagues to vote in favor of this legislation today to move the process forward on this matter. Congress has a clear opportunity to pass a bill with major benefits for the American people and must avail itself of the opportunity. I look forward to working with my colleagues on both sides of the aisle and both sides of Capitol Hill to send a strong, bi-partisan bill to President Obama.

Mr. PALLONE. Mr. Speaker, drug distribution security is critical to public health and safety, and I strongly support taking steps to ensure that the final pharmaceutical products patients receive are safe and effective. Although the bill before us today, H.R. 1919, the ''Safeguarding America's Pharmaceuticals Act,'' is well-intentioned, I have a number of concerns and believe the bill must be strengthened before it becomes law in order to truly protect the American people.

There is widespread agreement that the best way to protect the supply chain is to establish a unit-level, interoperable system that involves all members of the supply chain. However, under H.R. 1919, there is no assurance that an effective system for tracking and tracing drugs will ultimately be put into place. The bill only calls on FDA to issue proposed regulations—there is no requirement for final regulations.

In order to protect the drug supply chain, it is also important to ensure that unused drugs that are returned to the previous supplier and then re-enter the supply chain are just as safe as drugs going through the chain for the first time. I am concerned that the provisions in H.R. 1919, which allow the wholesaler to begin a new transaction history when it sells a returned product, create the potential for entry of illegitimate product into the system.

While I am pleased that H.R. 1919 sets national standards for the licensing of wholesale distributors, I am concerned that these standards preempt all state laws, effectively preventing states from having stronger licensing standards if they deem it necessary in their unique circumstance. National licensing standards should act as a floor defining what states must require, not as a floor and a ceiling.

I am also concerned that if H.R. 1919 becomes law, there will be a significant gap in the current level of information about a drug's path through the supply chain. H.R. 1919 preempts all state requirements regarding drug tracing on the date of enactment, but the new federal standards do not go into effect until 2015. This leaves a potentially-long window open for counterfeit or substandard products to enter the supply chain and reach customers.

It is crucial that if we are going to preempt state efforts, we must have a strong federal standard. This standard should serve as a true building block to tracking drugs at the unit level, so that each and every product is authenticated at the lowest unit of sale before they reach patients, and counterfeit or contaminated products are kept out of the drug supply chain or quickly eliminated from it. Unfortunately, H.R. 1919 does not meet these goals.

While I do not want to stop this process from moving forward, I remain concerned about the provisions in H.R. 1919 and look forward to conference with the Senate to strengthen the bill and, ultimately, enacting legislation that will truly protect the nation's drug supply.

Mr. PASCRELL. Mr. Speaker, as the House considers H.R. 1919, the Safeguarding America's Pharmaceuticals Act of 2013, I would like to voice my specific concerns with one provision within the legislation. While the underlying bill seeks to address the issue of preventing counterfeit drugs from reaching consumers, and improving national regulatory standards for pharmaceuticals, Section 8 of the proposed legislation instead mandates an electronic labeling requirement for pharmaceuticals. This serves to eliminate hard copy professional literature, and transition exclusively to electronic only literature. Based on legislation passed by Congress in 2012, GAO was tasked with studying the issue of e-labeling. This study is expected to be issued in July of this year. I urge my colleagues to carefully consider the potential ramifications of exclusive electronic labeling, and be cautious about any premature legislative action on this issue until the GAO report is released. The findings of this Congressionally mandated study should be deliberated before making a change that has the potential to impact consumers and providers.

The SPEAKER pro tempore. The question is on the motion offered by the gentleman from Ohio (Mr. LATTA) that the House suspend the rules and pass the bill, H.R. 1919, as amended.

The question was taken; and (two-thirds being in the affirmative) the rules were suspended and the bill, as amended, was passed.

A motion to reconsider was laid on the table.

ANIMAL DRUG AND ANIMAL GENERIC DRUG USER FEE REAUTHORIZATION ACT OF 2013

Mr. LATTA. Mr. Speaker, I move to suspend the rules and pass the bill (S. 622) to amend the Federal Food, Drug, and Cosmetic Act to reauthorize user fee programs relating to new animal drugs and generic new animal drugs.

The Clerk read the title of the bill.

The text of the bill is as follows:

S. 622

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

SECTION 1. SHORT TITLE.

This Act may be cited as the ''Animal Drug and Animal Generic Drug User Fee Reauthorization Act of 2013''.

SEC. 2. TABLE OF CONTENTS; REFERENCES IN ACT.

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