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House of Representatives

The House met at 2 p.m. and was called to order by the Speaker pro tempore (Mr. WOMACK).

DESIGNATION OF THE SPEAKER PRO TEMPORE

The SPEAKER pro tempore laid before the House the following communication from the Speaker:

WASHINGTON, DC,
June 3, 2013.

I hereby appoint the Honorable STEVE WOMACK to act as Speaker pro tempore on this day.

JOHN A. BOEHNER,
Speaker of the House of Representatives.

PRAYER

The Chaplain, the Reverend Patrick J. Conroy, offered the following prayer: We give You thanks, God of the universe, for giving us another day.

As the various Members of this people's House return, we ask Your blessing upon each as they resume the difficult responsibilities that await them. Give each the wisdom and good judgment needed to give credit to the office they have been honored by their constituencies to fill.

Bless the work of all who serve in their various capacities here in the United States Capitol.

Bless all those who visit the Capitol this day, be they American citizens or visitors or guests of our Nation. May they be inspired by this monument to the noble idea of human freedom and its guarantee by the democratic experiment that is the United States.

God, bless America, and may all that is done this day be for Your greater honor and glory.

Amen.

THE JOURNAL

The SPEAKER pro tempore. The Chair has examined the Journal of the

last day's proceedings and announces to the House his approval thereof.

Pursuant to clause 1, rule I, the Journal stands approved.

PLEDGE OF ALLEGIANCE

The SPEAKER pro tempore. Will the gentlewoman from North Carolina (Ms. FOXX) come forward and lead the House in the Pledge of Allegiance.

Ms. FOXX led the Pledge of Allegiance as follows:

I pledge allegiance to the Flag of the United States of America, and to the Republic for which it stands, one nation under God, indivisible, with liberty and justice for all.

GOD BLESS OUR TROOPS

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

Mr. WILSON of South Carolina. Mr. Speaker, during the Memorial Day work period, I was grateful to participate on a congressional delegation visiting with servicemembers and our allies. We went to thank them, but the reality is our new greatest generation has inspired us.

We began at Pristina, Kosovo, where NATO personnel are nurturing a 5-year-old nation with a Muslim majority while respecting the rights of a Christian minority.

In Germany, we thanked the dedicated personnel of Landstuhl Regional Medical Center for lifesaving care of courageous warriors for freedom. At Kaiserslautern, the American City of Germany, we were reassured of Germany's appreciation of America's promoting peace through strength.

Across Afghanistan, we witnessed a developing civil society from the rubble of a Soviet occupation. Our heroic personnel have trained 352,000 Afghans into an effective force to protect the civilian population from cowardly terrorists.

To protect American families at home, we must deny safe havens from terrorists overseas.

In conclusion, God bless our troops, and we will never forget September the 11th in the global war on terrorism.

AMNESTY IS NOT THE ANSWER

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

Mr. BURGESS. Mr. Speaker, both the President and the Senate have immigration plans with a central component of amnesty for those who are in the country without the benefit of citizenship.

Past experience has shown us that amnesty hinders us from creating the actual solution to our problems. Remember Congress, in 1986, allowed amnesty during the Reagan administration. We were then promised solutions, but those have not been met.

But let's focus for just a minute on the reality and forget the rhetoric. Which country has been the most welcoming to new citizens? Which country has offered the oath of citizenship to more people who chose to legally enter that country? If you look at this chart, you see it on the far end. It's the United States of America, where, in 2010, 1 million new residents were offered the oath of citizenship. That's better than Turkey, better than Belgium, better than Germany.

Look, amnesty will not solve the problems of drug violence and firearms. In Texas, increased border patrol has been asked for but not delivered, and fencing along the southwest border has been canceled.

We already do a good job allowing new citizens into our country. Perhaps if we focus on securing our borders instead of rewarding or offering amnesty, some of the problems would become more manageable.

□ This symbol represents the time of day during the House proceedings, e.g., □ 1407 is 2:07 p.m.

Matter set in this typeface indicates words inserted or appended, rather than spoken, by a Member of the House on the floor.



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H2967

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. 1. Short title.

Sec. 2. Pharmaceutical distribution supply chain.

Sec. 3. Enhanced drug distribution security.

Sec. 4. National standards for wholesale distributors.

Sec. 5. National licensure standards for third-party logistics providers.

Sec. 6. Penalties.

Sec. 7. Uniform national policy.

Sec. 8. Electronic labeling.

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 manufactures 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 manufactures 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 non-saleable 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 TRACKING.—

“(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 that 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 TRACKING.—

“(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 distributor 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 TRACKING.—

“(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 para-

graph 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 TRACKING.—

“(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 pro-

vide 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 non-saleable 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 miti-

gate 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.

□ 1610

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' Asso-

ciation 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 coun-

terpart—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—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 regu-

late 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 re-sale 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 legislation 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 AS-
SOCIATION, 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, Wash-
ington, 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 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 Rep-
resentatives, Washington, DC.

Hon. HENRY WAXMAN,
Ranking Member, Committee on Energy and
Commerce, House of Representatives, Wash-
ington, 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 organiza-
tions representing cancer patients, physi-
cians, and researchers are writing in support
of efforts to develop legislation to protect
the security of the pharmaceutical distribu-
tion supply chain.

Cancer patients and physicians have experi-
enced the adverse effects of disruptions in
the supply chain and the counterfeiting of
cancer drugs, occurrences which can com-
promise the quality of care they receive and
the effectiveness of their treatments. Pa-
tients and their physicians must be able to
trust that the drugs they prescribe and re-
ceive are consistent with their labeling. In
the past, cancer patients have received coun-
terfeit drugs that were ineffective. In those
circumstances, cancer patients were harmed
by time wasted receiving therapies that pro-
vided no medical benefit.

As you continue your work on supply chain
protections, we urge that you develop a sup-
ply 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 pedi-
gree laws not be preempted until a strong
national system is implemented. Elimina-
ting 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 ac-
companied 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 ad-
dress 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 diver-
sion are great, as patients may be harmed
by unsafe or ineffective medications.

We commend your commitment to address-
ing the safety of the pharmaceutical dis-
tribution system and urge you to develop
protections that are adequate to meet the
needs of cancer patients and their physi-
cians.

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 Al-
liance

MAY 7, 2013.

Re Energy and Commerce Health Sub-
committee markup to amend the Federal
Food, Drug, and Cosmetic Act with re-
spect 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, Ray-
burn House Office Building, Washington,
DC.

DEAR CHAIRMAN PITTS AND RANKING MEM-
BER PALLONE: We, the undersigned, thank
the Health Subcommittee for the oppor-
tunity to provide feedback on the pharma-
ceutical distribution supply chain legisla-
tion being marked up on May 8.

On behalf of millions of consumers, pa-
tients, and public health advocates, we write
in support of a strong national unit-level se-
rialization 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 min-
imum 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 sys-
tem. Furthermore, the proposed legisla-
tion 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 lim-
ited traceability requirements.

In order to justify the preemption of exist-
ing 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 num-
bers.

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 an-
nounced three times over the past year that
it had discovered counterfeit Avastin—a crit-
ical drug used to treat several types of can-
cer—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 South-
ern District of New York charged 48 individ-
uals 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 li-
censed 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 im-

portant 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. PASCARELL. 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:

Sec. 1. Short title.

Sec. 2. Table of contents; references in Act.

TITLE I—FEES RELATING TO ANIMAL DRUGS

Sec. 101. Short title; finding.

Sec. 102. Definitions.

Sec. 103. Authority to assess and use animal drug fees.

Sec. 104. Reauthorization; reporting requirements.

Sec. 105. Savings clause.

Sec. 106. Effective date.

Sec. 107. Sunset dates.

TITLE II—FEES RELATING TO GENERIC ANIMAL DRUGS

Sec. 201. Short title; finding.

Sec. 202. Authority to assess and use generic new animal drug fees.

Sec. 203. Reauthorization; reporting requirements.

Sec. 204. Savings clause.

Sec. 205. Effective date.

Sec. 206. Sunset dates.

(b) REFERENCES IN ACT.—Except as otherwise specified, amendments made by this Act to a section or other provision of law are amendments to such section or other provision of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 301 et seq.).

TITLE I—FEES RELATING TO ANIMAL DRUGS

SEC. 101. SHORT TITLE; FINDING.

(a) SHORT TITLE.—This title may be cited as the “Animal Drug User Fee Amendments of 2013”.

(b) FINDING.—Congress finds that the fees authorized by the amendments made in this title will be dedicated toward expediting the animal drug development process and the review of new and supplemental animal drug applications and investigational animal drug submissions as set forth in the goals identified, for purposes of part 4 of subchapter C of chapter VII of the Federal Food, Drug, and Cosmetic Act, in the letters from the Secretary of Health and Human Services to the Chairman of the Committee on Energy and Commerce of the House of Representatives and the Chairman of the Committee on Health, Education, Labor, and Pensions of the Senate as set forth in the Congressional Record.

SEC. 102. DEFINITIONS.

Section 739 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 379j-11) is amended to read as follows:

“SEC. 739. DEFINITIONS.

“For purposes of this part:

“(1) The term ‘animal drug application’ means an application for approval of any new animal drug submitted under section 512(b)(1). Such term does not include either a new animal drug application submitted under section 512(b)(2) or a supplemental animal drug application.

“(2) The term ‘supplemental animal drug application’ means—

“(A) a request to the Secretary to approve a change in an animal drug application which has been approved; or

“(B) a request to the Secretary to approve a change to an application approved under section 512(c)(2) for which data with respect to safety or effectiveness are required.

“(3) The term ‘animal drug product’ means each specific strength or potency of a particular active ingredient or ingredients in final dosage form marketed by a particular manufacturer or distributor, which is uniquely identified by the labeler code and product code portions of the national drug code, and for which an animal drug application or a supplemental animal drug application has been approved.

“(4) The term ‘animal drug establishment’ means a foreign or domestic place of business which is at one general physical location consisting of one or more buildings all of which are within 5 miles of each other, at which one or more animal drug products are manufactured in final dosage form.

“(5) The term ‘investigational animal drug submission’ means—

“(A) the filing of a claim for an investigational exemption under section 512(j) for a

new animal drug intended to be the subject of an animal drug application or a supplemental animal drug application; or

“(B) the submission of information for the purpose of enabling the Secretary to evaluate the safety or effectiveness of an animal drug application or supplemental animal drug application in the event of their filing.

“(6) The term ‘animal drug sponsor’ means either an applicant named in an animal drug application that has not been withdrawn by the applicant and for which approval has not been withdrawn by the Secretary, or a person who has submitted an investigational animal drug submission that has not been terminated or otherwise rendered inactive by the Secretary.

“(7) The term ‘final dosage form’ means, with respect to an animal drug product, a finished dosage form which is approved for administration to an animal without substantial further manufacturing. Such term includes animal drug products intended for mixing in animal feeds.

“(8) The term ‘process for the review of animal drug applications’ means the following activities of the Secretary with respect to the review of animal drug applications, supplemental animal drug applications, and investigational animal drug submissions:

“(A) The activities necessary for the review of animal drug applications, supplemental animal drug applications, and investigational animal drug submissions.

“(B) The issuance of action letters which approve animal drug applications or supplemental animal drug applications or which set forth in detail the specific deficiencies in animal drug applications, supplemental animal drug applications, or investigational animal drug submissions and, where appropriate, the actions necessary to place such applications, supplements or submissions in condition for approval.

“(C) The inspection of animal drug establishments and other facilities undertaken as part of the Secretary’s review of pending animal drug applications, supplemental animal drug applications, and investigational animal drug submissions.

“(D) Monitoring of research conducted in connection with the review of animal drug applications, supplemental animal drug applications, and investigational animal drug submissions.

“(E) The development of regulations and policy related to the review of animal drug applications, supplemental animal drug applications, and investigational animal drug submissions.

“(F) Development of standards for products subject to review.

“(G) Meetings between the agency and the animal drug sponsor.

“(H) Review of advertising and labeling prior to approval of an animal drug application or supplemental animal drug application, but not after such application has been approved.

“(9) The term ‘costs of resources allocated for the process for the review of animal drug applications’ means the expenses in connection with the process for the review of animal drug applications for—

“(A) officers and employees of the Food and Drug Administration, contractors of the Food and Drug Administration, advisory committees consulted with respect to the review of specific animal drug applications, supplemental animal drug applications, or investigational animal drug submissions, and costs related to such officers, employees, committees, and contractors, including costs for travel, education, and recruitment and other personnel activities;

“(B) management of information and the acquisition, maintenance, and repair of computer resources;

“(C) leasing, maintenance, renovation, and repair of facilities and acquisition, maintenance, and repair of fixtures, furniture, scientific equipment, and other necessary materials and supplies; and

“(D) collecting fees under section 740 and accounting for resources allocated for the review of animal drug applications, supplemental animal drug applications, and investigational animal drug submissions.

“(10) The term ‘adjustment factor’ applicable to a fiscal year refers to the formula set forth in section 735(8) with the base or comparator month being October 2002.

“(11) The term ‘person’ includes an affiliate thereof.

“(12) The term ‘affiliate’ refers to the definition set forth in section 735(11).”

SEC. 103. AUTHORITY TO ASSESS AND USE ANIMAL DRUG FEES.

Section 740 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 379j-12) is amended to read as follows:

“SEC. 740. AUTHORITY TO ASSESS AND USE ANIMAL DRUG FEES.

“(a) TYPES OF FEES.—Beginning in fiscal year 2004, the Secretary shall assess and collect fees in accordance with this section as follows:

“(1) ANIMAL DRUG APPLICATION AND SUPPLEMENT FEE.—

“(A) IN GENERAL.—Each person that submits, on or after September 1, 2003, an animal drug application or a supplemental animal drug application shall be subject to a fee as follows:

“(i) A fee established in subsection (c) for an animal drug application, except an animal drug application subject to the criteria set forth in section 512(d)(4).

“(ii) A fee established in subsection (c), in an amount that is equal to 50 percent of the amount of the fee under clause (i), for—

“(I) a supplemental animal drug application for which safety or effectiveness data are required; and

“(II) an animal drug application subject to the criteria set forth in section 512(d)(4).

“(B) PAYMENT.—The fee required by subparagraph (A) shall be due upon submission of the animal drug application or supplemental animal drug application.

“(C) EXCEPTION FOR PREVIOUSLY FILED APPLICATION OR SUPPLEMENT.—If an animal drug application or a supplemental animal drug application was submitted by a person that paid the fee for such application or supplement, was accepted for filing, and was not approved or was withdrawn (without a waiver or refund), the submission of an animal drug application or a supplemental animal drug application for the same product by the same person (or the person’s licensee, assignee, or successor) shall not be subject to a fee under subparagraph (A).

“(D) REFUND OF FEE IF APPLICATION REFUSED FOR FILING.—The Secretary shall refund 75 percent of the fee paid under subparagraph (B) for any animal drug application or supplemental animal drug application which is refused for filing.

“(E) REFUND OF FEE IF APPLICATION WITHDRAWN.—If an animal drug application or a supplemental animal drug application is withdrawn after the application or supplement was filed, the Secretary may refund the fee or portion of the fee paid under subparagraph (B) if no substantial work was performed on the application or supplement after the application or supplement was filed. The Secretary shall have the sole discretion to refund the fee under this paragraph. A determination by the Secretary concerning a refund under this paragraph shall not be reviewable.

“(2) ANIMAL DRUG PRODUCT FEE.—

“(A) IN GENERAL.—Each person—

“(i) who is named as the applicant in an animal drug application or supplemental animal drug application for an animal drug product which has been submitted for listing under section 510; and

“(ii) who, after September 1, 2003, had pending before the Secretary an animal drug application or supplemental animal drug application,

shall pay for each such animal drug product the annual fee established in subsection (c).

“(B) PAYMENT; FEE DUE DATE.—Such fee shall be payable for the fiscal year in which the animal drug product is first submitted for listing under section 510, or is submitted for relisting under section 510 if the animal drug product has been withdrawn from listing and relisted. After such fee is paid for that fiscal year, such fee shall be due each subsequent fiscal year that the product remains listed, upon the later of—

“(i) the first business day after the date of enactment of an appropriations Act providing for the collection and obligation of fees for such fiscal year under this section; or

“(ii) January 31 of each year.

“(C) LIMITATION.—Such fee shall be paid only once for each animal drug product for a fiscal year in which the fee is payable.

“(3) ANIMAL DRUG ESTABLISHMENT FEE.—

“(A) IN GENERAL.—Each person—

“(i) who owns or operates, directly or through an affiliate, an animal drug establishment;

“(ii) who is named as the applicant in an animal drug application or supplemental animal drug application for an animal drug product which has been submitted for listing under section 510; and

“(iii) who, after September 1, 2003, had pending before the Secretary an animal drug application or supplemental animal drug application,

shall be assessed an annual establishment fee as established in subsection (c) for each animal drug establishment listed in its approved animal drug application as an establishment that manufactures the animal drug product named in the application.

“(B) PAYMENT; FEE DUE DATE.—The annual establishment fee shall be assessed in each fiscal year in which the animal drug product named in the application is assessed a fee under paragraph (2) unless the animal drug establishment listed in the application does not engage in the manufacture of the animal drug product during the fiscal year. The fee under this paragraph for a fiscal year shall be due upon the later of—

“(i) the first business day after the date of enactment of an appropriations Act providing for the collection and obligation of fees for such fiscal year under this section; or

“(ii) January 31 of each year.

“(C) LIMITATION.—

“(i) IN GENERAL.—An establishment shall be assessed only one fee per fiscal year under this section, subject to clause (ii).

“(ii) CERTAIN MANUFACTURERS.—If a single establishment manufactures both animal drug products and prescription drug products, as defined in section 735(3), such establishment shall be assessed both the animal drug establishment fee and the prescription drug establishment fee, as set forth in section 736(a)(2), within a single fiscal year.

“(4) ANIMAL DRUG SPONSOR FEE.—

“(A) IN GENERAL.—Each person—

“(i) who meets the definition of an animal drug sponsor within a fiscal year; and

“(ii) who, after September 1, 2003, had pending before the Secretary an animal drug application, a supplemental animal drug ap-

plication, or an investigational animal drug submission,

shall be assessed an annual sponsor fee as established under subsection (c).

“(B) PAYMENT; FEE DUE DATE.—The fee under this paragraph for a fiscal year shall be due upon the later of—

“(i) the first business day after the date of enactment of an appropriations Act providing for the collection and obligation of fees for such fiscal year under this section; or

“(ii) January 31 of each year.

“(C) LIMITATION.—Each animal drug sponsor shall pay only one such fee each fiscal year.

“(b) FEE REVENUE AMOUNTS.—

“(1) IN GENERAL.—Subject to subsections (c), (d), (f), and (g)—

“(A) for fiscal year 2014, the fees required under subsection (a) shall be established to generate a total revenue amount of \$23,600,000; and

“(B) for each of fiscal years 2015 through 2018, the fees required under subsection (a) shall be established to generate a total revenue amount of \$21,600,000.

“(2) TYPES OF FEES.—Of the total revenue amount determined for a fiscal year under paragraph (1)—

“(A) 20 percent shall be derived from fees under subsection (a)(1) (relating to animal drug applications and supplements);

“(B) 27 percent shall be derived from fees under subsection (a)(2) (relating to animal drug products);

“(C) 26 percent shall be derived from fees under subsection (a)(3) (relating to animal drug establishments); and

“(D) 27 percent shall be derived from fees under subsection (a)(4) (relating to animal drug sponsors).

“(c) ANNUAL FEE SETTING; ADJUSTMENTS.—

“(1) ANNUAL FEE SETTING.—The Secretary shall establish, 60 days before the start of each fiscal year beginning after September 30, 2003, for that fiscal year, animal drug application fees, supplemental animal drug application fees, animal drug sponsor fees, animal drug establishment fees, and animal drug product fees based on the revenue amounts established under subsection (b) and the adjustments provided under this subsection.

“(2) INFLATION ADJUSTMENT.—For fiscal year 2015 and subsequent fiscal years, the revenue amounts established in subsection (b) shall be adjusted by the Secretary by notice, published in the Federal Register, for a fiscal year, by an amount equal to the sum of—

“(A) one;

“(B) the average annual percent change in the cost, per full-time equivalent position of the Food and Drug Administration, of all personnel compensation and benefits paid with respect to such positions for the first 3 of the preceding 4 fiscal years for which data are available, multiplied by the average proportion of personnel compensation and benefits costs to total Food and Drug Administration costs for the first 3 years of the preceding 4 fiscal years for which data are available; and

“(C) the average annual percent change that occurred in the Consumer Price Index for urban consumers (Washington-Baltimore, DC-MD-VA-WV; not seasonally adjusted; all items less food and energy; annual index) for the first 3 years of the preceding 4 years for which data are available multiplied by the average proportion of all costs other than personnel compensation and benefits costs to total Food and Drug Administration costs for the first 3 years of the preceding 4 fiscal years for which data are available.

The adjustment made each fiscal year under this paragraph shall be added on a com-

pounded basis to the sum of all adjustments made each fiscal year after fiscal year 2014 under this paragraph.

“(3) WORKLOAD ADJUSTMENT.—For fiscal year 2015 and subsequent fiscal years, after the revenue amounts established in subsection (b) are adjusted for inflation in accordance with paragraph (2), the revenue amounts shall be further adjusted for such fiscal year to reflect changes in the workload of the Secretary for the process for the review of animal drug applications. With respect to such adjustment—

“(A) such adjustment shall be determined by the Secretary based on a weighted average of the change in the total number of animal drug applications, supplemental animal drug applications for which data with respect to safety or effectiveness are required, manufacturing supplemental animal drug applications, investigational animal drug study submissions, and investigational animal drug protocol submissions submitted to the Secretary;

“(B) the Secretary shall publish in the Federal Register the fees resulting from such adjustment and the supporting methodologies; and

“(C) under no circumstances shall such adjustment result in fee revenues for a fiscal year that are less than the fee revenues for that fiscal year established in subsection (b), as adjusted for inflation under paragraph (2).

“(4) FINAL YEAR ADJUSTMENT.—For fiscal year 2018, the Secretary may, in addition to other adjustments under this subsection, further increase the fees under this section, if such an adjustment is necessary, to provide for up to 3 months of operating reserves of carryover user fees for the process for the review of animal drug applications for the first 3 months of fiscal year 2019. If the Food and Drug Administration has carryover balances for the process for the review of animal drug applications in excess of 3 months of such operating reserves, then this adjustment will not be made. If this adjustment is necessary, then the rationale for the amount of the increase shall be contained in the annual notice setting fees for fiscal year 2018.

“(5) LIMIT.—The total amount of fees charged, as adjusted under this subsection, for a fiscal year may not exceed the total costs for such fiscal year for the resources allocated for the process for the review of animal drug applications.

“(d) FEE WAIVER OR REDUCTION.—

“(1) IN GENERAL.—The Secretary shall grant a waiver from or a reduction of one or more fees assessed under subsection (a) where the Secretary finds that—

“(A) the assessment of the fee would present a significant barrier to innovation because of limited resources available to such person or other circumstances;

“(B) the fees to be paid by such person will exceed the anticipated present and future costs incurred by the Secretary in conducting the process for the review of animal drug applications for such person;

“(C) the animal drug application or supplemental animal drug application is intended solely to provide for use of the animal drug in—

“(i) a Type B medicated feed (as defined in section 558.3(b)(3) of title 21, Code of Federal Regulations (or any successor regulation)) intended for use in the manufacture of Type C free-choice medicated feeds; or

“(ii) a Type C free-choice medicated feed (as defined in section 558.3(b)(4) of title 21, Code of Federal Regulations (or any successor regulation));

“(D) the animal drug application or supplemental animal drug application is intended solely to provide for a minor use or minor species indication; or

“(E) the sponsor involved is a small business submitting its first animal drug application to the Secretary for review.

“(2) USE OF STANDARD COSTS.—In making the finding in paragraph (1)(B), the Secretary may use standard costs.

“(3) RULES FOR SMALL BUSINESSES.—

“(A) DEFINITION.—In paragraph (1)(E), the term ‘small business’ means an entity that has fewer than 500 employees, including employees of affiliates.

“(B) WAIVER OF APPLICATION FEE.—The Secretary shall waive under paragraph (1)(E) the application fee for the first animal drug application that a small business or its affiliate submits to the Secretary for review. After a small business or its affiliate is granted such a waiver, the small business or its affiliate shall pay application fees for all subsequent animal drug applications and supplemental animal drug applications for which safety or effectiveness data are required in the same manner as an entity that does not qualify as a small business.

“(C) CERTIFICATION.—The Secretary shall require any person who applies for a waiver under paragraph (1)(E) to certify their qualification for the waiver. The Secretary shall periodically publish in the Federal Register a list of persons making such certifications.

“(e) EFFECT OF FAILURE TO PAY FEES.—An animal drug application or supplemental animal drug application submitted by a person subject to fees under subsection (a) shall be considered incomplete and shall not be accepted for filing by the Secretary until all fees owed by such person have been paid. An investigational animal drug submission under section 739(5)(B) that is submitted by a person subject to fees under subsection (a) shall be considered incomplete and shall not be accepted for review by the Secretary until all fees owed by such person have been paid. The Secretary may discontinue review of any animal drug application, supplemental animal drug application or investigational animal drug submission from a person if such person has not submitted for payment all fees owed under this section by 30 days after the date upon which they are due.

“(f) ASSESSMENT OF FEES.—

“(1) LIMITATION.—Fees may not be assessed under subsection (a) for a fiscal year beginning after fiscal year 2003 unless appropriations for salaries and expenses of the Food and Drug Administration for such fiscal year (excluding the amount of fees appropriated for such fiscal year) are equal to or greater than the amount of appropriations for the salaries and expenses of the Food and Drug Administration for the fiscal year 2003 (excluding the amount of fees appropriated for such fiscal year) multiplied by the adjustment factor applicable to the fiscal year involved.

“(2) AUTHORITY.—If the Secretary does not assess fees under subsection (a) during any portion of a fiscal year because of paragraph (1) and if at a later date in such fiscal year the Secretary may assess such fees, the Secretary may assess and collect such fees, without any modification in the rate, for animal drug applications, supplemental animal drug applications, investigational animal drug submissions, animal drug sponsors, animal drug establishments and animal drug products at any time in such fiscal year notwithstanding the provisions of subsection (a) relating to the date fees are to be paid.

“(g) CREDITING AND AVAILABILITY OF FEES.—

“(1) IN GENERAL.—Subject to paragraph (2)(C), fees authorized under subsection (a) shall be collected and available for obligation only to the extent and in the amount provided in advance in appropriations Acts. Such fees are authorized to be appropriated to remain available until expended. Such

sums as may be necessary may be transferred from the Food and Drug Administration salaries and expenses appropriation account without fiscal year limitation to such appropriation account for salary and expenses with such fiscal year limitation. The sums transferred shall be available solely for the process for the review of animal drug applications.

“(2) COLLECTIONS AND APPROPRIATION ACTS.—

“(A) IN GENERAL.—The fees authorized by this section—

“(i) subject to subparagraph (C), shall be collected and available in each fiscal year in an amount not to exceed the amount specified in appropriation Acts, or otherwise made available for obligation for such fiscal year, and

“(ii) shall be available to defray increases in the costs of the resources allocated for the process for the review of animal drug applications (including increases in such costs for an additional number of full-time equivalent positions in the Department of Health and Human Services to be engaged in such process) over such costs, excluding costs paid from fees collected under this section, for fiscal year 2003 multiplied by the adjustment factor.

“(B) COMPLIANCE.—The Secretary shall be considered to have met the requirements of subparagraph (A)(ii) in any fiscal year if the costs funded by appropriations and allocated for the process for the review of animal drug applications—

“(i) are not more than 3 percent below the level specified in subparagraph (A)(ii); or

“(ii)(I) are more than 3 percent below the level specified in subparagraph (A)(ii), and fees assessed for the fiscal year following the subsequent fiscal year are decreased by the amount in excess of 3 percent by which such costs fell below the level specified in subparagraph (A)(ii); and

“(II) such costs are not more than 5 percent below the level specified in subparagraph (A)(ii).

“(C) PROVISION FOR EARLY PAYMENTS.—Payment of fees authorized under this section for a fiscal year, prior to the due date for such fees, may be accepted by the Secretary in accordance with authority provided in advance in a prior year appropriations Act.

“(3) AUTHORIZATION OF APPROPRIATIONS.—For each of the fiscal years 2014 through 2018, there is authorized to be appropriated for fees under this section an amount equal to the total revenue amount determined under subsection (b) for the fiscal year, as adjusted or otherwise affected under subsection (c) and paragraph (4).

“(4) OFFSET OF OVERCOLLECTIONS; RECOVERY OF COLLECTION SHORTFALLS.—

“(A) OFFSET OF OVERCOLLECTIONS.—If the sum of the cumulative amount of fees collected under this section for fiscal years 2014 through 2016 and the amount of fees estimated to be collected under this section for fiscal year 2017 (including any increased fee collections attributable to subparagraph (B)), exceeds the cumulative amount appropriated pursuant to paragraph (3) for the fiscal years 2014 through 2017, the excess amount shall be credited to the appropriation account of the Food and Drug Administration as provided in paragraph (1), and shall be subtracted from the amount of fees that would otherwise be authorized to be collected under this section pursuant to appropriation Acts for fiscal year 2018.

“(B) RECOVERY OF COLLECTION SHORTFALLS.—

“(i) FISCAL YEAR 2016.—For fiscal year 2016, the amount of fees otherwise authorized to be collected under this section shall be increased by the amount, if any, by which the

amount collected under this section and appropriated for fiscal year 2014 falls below the amount of fees authorized for fiscal year 2014 under paragraph (3).

“(ii) FISCAL YEAR 2017.—For fiscal year 2017, the amount of fees otherwise authorized to be collected under this section shall be increased by the amount, if any, by which the amount collected under this section and appropriated for fiscal year 2015 falls below the amount of fees authorized for fiscal year 2015 under paragraph (3).

“(iii) FISCAL YEAR 2018.—For fiscal year 2018, the amount of fees otherwise authorized to be collected under this section (including any reduction in the authorized amount under subparagraph (A)), shall be increased by the cumulative amount, if any, by which the amount collected under this section and appropriated for fiscal years 2016 and 2017 (including estimated collections for fiscal year 2017) falls below the cumulative amount of fees authorized under paragraph (3) for fiscal years 2016 and 2017.

“(h) COLLECTION OF UNPAID FEES.—In any case where the Secretary does not receive payment of a fee assessed under subsection (a) within 30 days after it is due, such fee shall be treated as a claim of the United States Government subject to subchapter II of chapter 37 of title 31, United States Code.

“(i) WRITTEN REQUESTS FOR WAIVERS, REDUCTIONS, AND REFUNDS.—To qualify for consideration for a waiver or reduction under subsection (d), or for a refund of any fee collected in accordance with subsection (a), a person shall submit to the Secretary a written request for such waiver, reduction, or refund not later than 180 days after such fee is due.

“(j) CONSTRUCTION.—This section may not be construed to require that the number of full-time equivalent positions in the Department of Health and Human Services, for officers, employees, and advisory committees not engaged in the process of the review of animal drug applications, be reduced to offset the number of officers, employees, and advisory committees so engaged.

“(k) ABBREVIATED NEW ANIMAL DRUG APPLICATIONS.—The Secretary shall—

“(1) to the extent practicable, segregate the review of abbreviated new animal drug applications from the process for the review of animal drug applications; and

“(2) adopt other administrative procedures to ensure that review times of abbreviated new animal drug applications do not increase from their current level due to activities under the user fee program.”.

SEC. 104. REAUTHORIZATION; REPORTING REQUIREMENTS.

Section 740A of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 379j-13) is amended to read as follows:

“SEC. 740A. REAUTHORIZATION; REPORTING REQUIREMENTS.

“(a) PERFORMANCE REPORT.—Beginning with fiscal year 2014, not later than 120 days after the end of each fiscal year during which fees are collected under this part, the Secretary shall prepare and submit to the Committee on Health, Education, Labor, and Pensions of the Senate and the Committee on Energy and Commerce of the House of Representatives a report concerning the progress of the Food and Drug Administration in achieving the goals identified in the letters described in section 101(b) of the Animal Drug User Fee Amendments of 2013 toward expediting the animal drug development process and the review of the new and supplemental animal drug applications and investigational animal drug submissions during such fiscal year, the future plans of the Food and Drug Administration for meeting the goals, the review times for abbreviated new animal drug applications, and the

administrative procedures adopted by the Food and Drug Administration to ensure that review times for abbreviated new animal drug applications are not increased from their current level due to activities under the user fee program.

“(b) FISCAL REPORT.—Beginning with fiscal year 2014, not later than 120 days after the end of each fiscal year during which fees are collected under this part, the Secretary shall prepare and submit to the Committee on Health, Education, Labor, and Pensions of the Senate and the Committee on Energy and Commerce of the House of Representatives a report on the implementation of the authority for such fees during such fiscal year and the use, by the Food and Drug Administration, of the fees collected during such fiscal year for which the report is made.

“(c) PUBLIC AVAILABILITY.—The Secretary shall make the reports required under subsections (a) and (b) available to the public on the Internet Web site of the Food and Drug Administration.

“(d) REAUTHORIZATION.—

“(1) CONSULTATION.—In developing recommendations to present to the Congress with respect to the goals, and plans for meeting the goals, for the process for the review of animal drug applications for the first 5 fiscal years after fiscal year 2018, and for the reauthorization of this part for such fiscal years, the Secretary shall consult with—

“(A) the Committee on Health, Education, Labor, and Pensions of the Senate;

“(B) the Committee on Energy and Commerce of the House of Representatives;

“(C) scientific and academic experts;

“(D) veterinary professionals;

“(E) representatives of patient and consumer advocacy groups; and

“(F) the regulated industry.

“(2) PRIOR PUBLIC INPUT.—Prior to beginning negotiations with the regulated industry on the reauthorization of this part, the Secretary shall—

“(A) publish a notice in the Federal Register requesting public input on the reauthorization;

“(B) hold a public meeting at which the public may present its views on the reauthorization, including specific suggestions for changes to the goals referred to in subsection (a);

“(C) provide a period of 30 days after the public meeting to obtain written comments from the public suggesting changes to this part; and

“(D) publish the comments on the Food and Drug Administration’s Internet Web site.

“(3) PERIODIC CONSULTATION.—Not less frequently than once every 4 months during negotiations with the regulated industry, the Secretary shall hold discussions with representatives of veterinary, patient, and consumer advocacy groups to continue discussions of their views on the reauthorization and their suggestions for changes to this part as expressed under paragraph (2).

“(4) PUBLIC REVIEW OF RECOMMENDATIONS.—After negotiations with the regulated industry, the Secretary shall—

“(A) present the recommendations developed under paragraph (1) to the Congressional committees specified in such paragraph;

“(B) publish such recommendations in the Federal Register;

“(C) provide for a period of 30 days for the public to provide written comments on such recommendations;

“(D) hold a meeting at which the public may present its views on such recommendations; and

“(E) after consideration of such public views and comments, revise such recommendations as necessary.

“(5) TRANSMITTAL OF RECOMMENDATIONS.—Not later than January 15, 2018, the Secretary shall transmit to Congress the revised recommendations under paragraph (4) a summary of the views and comments received under such paragraph, and any changes made to the recommendations in response to such views and comments.

“(6) MINUTES OF NEGOTIATION MEETINGS.—

“(A) PUBLIC AVAILABILITY.—Before presenting the recommendations developed under paragraphs (1) through (5) to Congress, the Secretary shall make publicly available, on the Internet Web site of the Food and Drug Administration, minutes of all negotiation meetings conducted under this subsection between the Food and Drug Administration and the regulated industry.

“(B) CONTENT.—The minutes described under subparagraph (A) shall summarize any substantive proposal made by any party to the negotiations as well as significant controversies or differences of opinion during the negotiations and their resolution.”.

SEC. 105. SAVINGS CLAUSE.

Notwithstanding the amendments made by this title, part 4 of subchapter C of chapter VII of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 379j-11 et seq.), as in effect on the day before the date of the enactment of this title, shall continue to be in effect with respect to animal drug applications and supplemental animal drug applications (as defined in such part as of such day) that on or after October 1, 2008, but before October 1, 2013, were accepted by the Food and Drug Administration for filing with respect to assessing and collecting any fee required by such part for a fiscal year prior to fiscal year 2014.

SEC. 106. EFFECTIVE DATE.

The amendments made by this title shall take effect on October 1, 2013, or the date of enactment of this Act, whichever is later, except that fees under part 4 of subchapter C of chapter VII of the Federal Food, Drug, and Cosmetic Act, as amended by this title, shall be assessed for all animal drug applications and supplemental animal drug applications received on or after October 1, 2013, regardless of the date of the enactment of this Act.

SEC. 107. SUNSET DATES.

(a) AUTHORIZATION.—Section 740 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 379j-12) shall cease to be effective October 1, 2018.

(b) REPORTING REQUIREMENTS.—Section 740A of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 379j-13) shall cease to be effective January 31, 2019.

(c) PREVIOUS SUNSET PROVISION.—

(1) IN GENERAL.—Section 108 of the Animal Drug User Fee Amendments of 2008 (Public Law 110-316) is repealed.

(2) CONFORMING AMENDMENT.—The Animal Drug User Fee Amendments of 2008 (Public Law 110-316) is amended in the table of contents in section 1, by striking the item relating to section 108.

(d) TECHNICAL CLARIFICATION.—Effective November 18, 2003, section 5 of the Animal Drug User Fee Act of 2003 (Public Law 108-130) is repealed.

TITLE II—FEES RELATING TO GENERIC ANIMAL DRUGS

SEC. 201. SHORT TITLE; FINDING.

(a) SHORT TITLE.—This title may be cited as the “Animal Generic Drug User Fee Amendments of 2013”.

(b) FINDING.—The fees authorized by this title will be dedicated toward expediting the generic new animal drug development process and the review of abbreviated applications for generic new animal drugs, supplemental abbreviated applications for generic new animal drugs, and investigational submissions for generic new animal drugs as set

forth in the goals identified in the letters from the Secretary of Health and Human Services to the Chairman of the Committee on Energy and Commerce of the House of Representatives and the Chairman of the Committee on Health, Education, Labor, and Pensions of the Senate as set forth in the Congressional Record.

SEC. 202. AUTHORITY TO ASSESS AND USE GENERIC NEW ANIMAL DRUG FEES.

Section 741 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 379j-21) is amended to read as follows:

“SEC. 741. AUTHORITY TO ASSESS AND USE GENERIC NEW ANIMAL DRUG FEES.

“(a) TYPES OF FEES.—Beginning with respect to fiscal year 2009, the Secretary shall assess and collect fees in accordance with this section as follows:

“(1) ABBREVIATED APPLICATION FEE.—

“(A) IN GENERAL.—Each person that submits, on or after July 1, 2008, an abbreviated application for a generic new animal drug shall be subject to a fee as established in subsection (c) for such an application.

“(B) PAYMENT.—The fee required by subparagraph (A) shall be due upon submission of the abbreviated application.

“(C) EXCEPTIONS.—

“(i) PREVIOUSLY FILED APPLICATION.—If an abbreviated application was submitted by a person that paid the fee for such application, was accepted for filing, and was not approved or was withdrawn (without a waiver or refund), the submission of an abbreviated application for the same product by the same person (or the person’s licensee, assignee, or successor) shall not be subject to a fee under subparagraph (A).

“(ii) CERTAIN ABBREVIATED APPLICATIONS INVOLVING COMBINATION ANIMAL DRUGS.—An abbreviated application which is subject to the criteria in section 512(d)(4) and submitted on or after October 1, 2013 shall be subject to a fee equal to 50 percent of the amount of the abbreviated application fee established in subsection (c).

“(D) REFUND OF FEE IF APPLICATION REFUSED FOR FILING.—The Secretary shall refund 75 percent of the fee paid under subparagraph (B) for any abbreviated application which is refused for filing.

“(E) REFUND OF FEE IF APPLICATION WITHDRAWN.—If an abbreviated application is withdrawn after the application was filed, the Secretary may refund the fee or portion of the fee paid under subparagraph (B) if no substantial work was performed on the application after the application was filed. The Secretary shall have the sole discretion to refund the fee under this subparagraph. A determination by the Secretary concerning a refund under this subparagraph shall not be reviewable.

“(2) GENERIC NEW ANIMAL DRUG PRODUCT FEE.—

“(A) IN GENERAL.—Each person—

“(i) who is named as the applicant in an abbreviated application or supplemental abbreviated application for a generic new animal drug product which has been submitted for listing under section 510; and

“(ii) who, after September 1, 2008, had pending before the Secretary an abbreviated application or supplemental abbreviated application, shall pay for each such generic new animal drug product the annual fee established in subsection (c).

“(B) PAYMENT; FEE DUE DATE.—Such fee shall be payable for the fiscal year in which the generic new animal drug product is first submitted for listing under section 510, or is submitted for relisting under section 510 if the generic new animal drug product has been withdrawn from listing and relisted. After such fee is paid for that fiscal year,

such fee shall be due each subsequent fiscal year that the product remains listed, upon the later of—

“(i) the first business day after the date of enactment of an appropriations Act providing for the collection and obligation of fees for such fiscal year under this section; or

“(ii) January 31 of each year.

“(C) LIMITATION.—Such fee shall be paid only once for each generic new animal drug product for a fiscal year in which the fee is payable.

“(3) GENERIC NEW ANIMAL DRUG SPONSOR FEE.—

“(A) IN GENERAL.—Each person—

“(i) who meets the definition of a generic new animal drug sponsor within a fiscal year; and

“(ii) who, after September 1, 2008, had pending before the Secretary an abbreviated application, a supplemental abbreviated application, or an investigational submission, shall be assessed an annual generic new animal drug sponsor fee as established under subsection (c).

“(B) PAYMENT; FEE DUE DATE.—Such fee shall be due each fiscal year upon the later of—

“(i) the first business day after the date of enactment of an appropriations Act providing for the collection and obligation of fees for such fiscal year under this section; or

“(ii) January 31 of each year.

“(C) AMOUNT OF FEE.—Each generic new animal drug sponsor shall pay only 1 such fee each fiscal year, as follows:

“(i) 100 percent of the amount of the generic new animal drug sponsor fee published for that fiscal year under subsection (c) for an applicant with more than 6 approved abbreviated applications.

“(ii) 75 percent of the amount of the generic new animal drug sponsor fee published for that fiscal year under subsection (c) for an applicant with more than 1 and fewer than 7 approved abbreviated applications.

“(iii) 50 percent of the amount of the generic new animal drug sponsor fee published for that fiscal year under subsection (c) for an applicant with 1 or fewer approved abbreviated applications.

“(b) FEE AMOUNTS.—Subject to subsections (c), (d), (f), and (g), the fees required under subsection (a) shall be established to generate fee revenue amounts as follows:

“(1) TOTAL FEE REVENUES FOR APPLICATION FEES.—The total fee revenues to be collected in abbreviated application fees under subsection (a)(1) shall be \$1,832,000 for fiscal year 2014, \$1,736,000 for fiscal year 2015, \$1,857,000 for fiscal year 2016, \$1,984,000 for fiscal year 2017, and \$2,117,000 for fiscal year 2018.

“(2) TOTAL FEE REVENUES FOR PRODUCT FEES.—The total fee revenues to be collected in generic new animal drug product fees under subsection (a)(2) shall be \$2,748,000 for fiscal year 2014, \$2,604,000 for fiscal year 2015, \$2,786,000 for fiscal year 2016, \$2,976,000 for fiscal year 2017, and \$3,175,000 for fiscal year 2018.

“(3) TOTAL FEE REVENUES FOR SPONSOR FEES.—The total fee revenues to be collected in generic new animal drug sponsor fees under subsection (a)(3) shall be \$2,748,000 for fiscal year 2014, \$2,604,000 for fiscal year 2015, \$2,786,000 for fiscal year 2016, \$2,976,000 for fiscal year 2017, and \$3,175,000 for fiscal year 2018.

“(c) ANNUAL FEE SETTING; ADJUSTMENTS.—

“(1) ANNUAL FEE SETTING.—The Secretary shall establish, 60 days before the start of each fiscal year beginning after September 30, 2008, for that fiscal year, abbreviated application fees, generic new animal drug sponsor fees, and generic new animal drug product fees, based on the revenue amounts es-

tablished under subsection (b) and the adjustments provided under this subsection.

“(2) WORKLOAD ADJUSTMENT.—The fee revenues shall be adjusted each fiscal year after fiscal year 2014 to reflect changes in review workload. With respect to such adjustment:

“(A) This adjustment shall be determined by the Secretary based on a weighted average of the change in the total number of abbreviated applications for generic new animal drugs, manufacturing supplemental abbreviated applications for generic new animal drugs, investigational generic new animal drug study submissions, and investigational generic new animal drug protocol submissions submitted to the Secretary. The Secretary shall publish in the Federal Register the fees resulting from this adjustment and the supporting methodologies.

“(B) Under no circumstances shall this workload adjustment result in fee revenues for a fiscal year that are less than the fee revenues for that fiscal year established in subsection (b).

“(3) FINAL YEAR ADJUSTMENT.—For fiscal year 2018, the Secretary may, in addition to other adjustments under this subsection, further increase the fees under this section, if such an adjustment is necessary, to provide for up to 3 months of operating reserves of carryover user fees for the process for the review of abbreviated applications for generic new animal drugs for the first 3 months of fiscal year 2019. If the Food and Drug Administration has carryover balances for the process for the review of abbreviated applications for generic new animal drugs in excess of 3 months of such operating reserves, then this adjustment shall not be made. If this adjustment is necessary, then the rationale for the amount of the increase shall be contained in the annual notice setting fees for fiscal year 2018.

“(4) LIMIT.—The total amount of fees charged, as adjusted under this subsection, for a fiscal year may not exceed the total costs for such fiscal year for the resources allocated for the process for the review of abbreviated applications for generic new animal drugs.

“(d) FEE WAIVER OR REDUCTION.—The Secretary shall grant a waiver from or a reduction of 1 or more fees assessed under subsection (a) where the Secretary finds that the generic new animal drug is intended solely to provide for a minor use or minor species indication.

“(e) EFFECT OF FAILURE TO PAY FEES.—An abbreviated application for a generic new animal drug submitted by a person subject to fees under subsection (a) shall be considered incomplete and shall not be accepted for filing by the Secretary until all fees owed by such person have been paid. An investigational submission for a generic new animal drug that is submitted by a person subject to fees under subsection (a) shall be considered incomplete and shall not be accepted for review by the Secretary until all fees owed by such person have been paid. The Secretary may discontinue review of any abbreviated application for a generic new animal drug, supplemental abbreviated application for a generic new animal drug, or investigational submission for a generic new animal drug from a person if such person has not submitted for payment all fees owed under this section by 30 days after the date upon which they are due.

“(f) ASSESSMENT OF FEES.—

“(1) LIMITATION.—Fees may not be assessed under subsection (a) for a fiscal year beginning after fiscal year 2008 unless appropriations for salaries and expenses of the Food and Drug Administration for such fiscal year (excluding the amount of fees appropriated for such fiscal year) are equal to or greater than the amount of appropriations for the

salaries and expenses of the Food and Drug Administration for the fiscal year 2003 (excluding the amount of fees appropriated for such fiscal year) multiplied by the adjustment factor applicable to the fiscal year involved.

“(2) AUTHORITY.—If the Secretary does not assess fees under subsection (a) during any portion of a fiscal year because of paragraph (1) and if at a later date in such fiscal year the Secretary may assess such fees, the Secretary may assess and collect such fees, without any modification in the rate, for abbreviated applications, generic new animal drug sponsors, and generic new animal drug products at any time in such fiscal year notwithstanding the provisions of subsection (a) relating to the date fees are to be paid.

“(g) CREDITING AND AVAILABILITY OF FEES.—

“(1) IN GENERAL.—Subject to paragraph (2)(C), fees authorized under subsection (a) shall be collected and available for obligation only to the extent and in the amount provided in advance in appropriations Acts. Such fees are authorized to be appropriated to remain available until expended. Such sums as may be necessary may be transferred from the Food and Drug Administration salaries and expenses appropriation account without fiscal year limitation to such appropriation account for salary and expenses with such fiscal year limitation. The sums transferred shall be available solely for the process for the review of abbreviated applications for generic new animal drugs.

“(2) COLLECTIONS AND APPROPRIATION ACTS.—

“(A) IN GENERAL.—The fees authorized by this section—

“(i) subject to subparagraph (C), shall be collected and available in each fiscal year in an amount not to exceed the amount specified in appropriation Acts, or otherwise made available for obligation for such fiscal year; and

“(ii) shall be available to defray increases in the costs of the resources allocated for the process for the review of abbreviated applications for generic new animal drugs (including increases in such costs for an additional number of full-time equivalent positions in the Department of Health and Human Services to be engaged in such process) over such costs, excluding costs paid from fees collected under this section, for fiscal year 2008 multiplied by the adjustment factor.

“(B) COMPLIANCE.—The Secretary shall be considered to have met the requirements of subparagraph (A)(ii) in any fiscal year if the costs funded by appropriations and allocated for the process for the review of abbreviated applications for generic new animal drugs—

“(i) are not more than 3 percent below the level specified in subparagraph (A)(ii); or

“(ii)(I) are more than 3 percent below the level specified in subparagraph (A)(ii), and fees assessed for the fiscal year following the subsequent fiscal year are decreased by the amount in excess of 3 percent by which such costs fell below the level specified in subparagraph (A)(ii); and

“(II) such costs are not more than 5 percent below the level specified in subparagraph (A)(ii).

“(C) PROVISION FOR EARLY PAYMENTS.—Payment of fees authorized under this section for a fiscal year, prior to the due date for such fees, may be accepted by the Secretary in accordance with authority provided in advance in a prior year appropriations Act.

“(3) AUTHORIZATION OF APPROPRIATIONS.—There are authorized to be appropriated for fees under this section—

“(A) \$7,328,000 for fiscal year 2014;

“(B) \$6,944,000 for fiscal year 2015;

“(C) \$7,429,000 for fiscal year 2016;

“(D) \$7,936,000 for fiscal year 2017; and

“(E) \$8,467,000 for fiscal year 2018;

as adjusted to reflect adjustments in the total fee revenues made under this section and changes in the total amounts collected by abbreviated application fees, generic new animal drug sponsor fees, and generic new animal drug product fees.

“(4) OFFSET.—If the sum of the cumulative amount of fees collected under this section for the fiscal years 2014 through 2016 and the amount of fees estimated to be collected under this section for fiscal year 2017 exceeds the cumulative amount appropriated under paragraph (3) for the fiscal years 2014 through 2017, the excess amount shall be credited to the appropriation account of the Food and Drug Administration as provided in paragraph (1), and shall be subtracted from the amount of fees that would otherwise be authorized to be collected under this section pursuant to appropriation Acts for fiscal year 2018.

“(h) COLLECTION OF UNPAID FEES.—In any case where the Secretary does not receive payment of a fee assessed under subsection (a) within 30 days after it is due, such fee shall be treated as a claim of the United States Government subject to subchapter II of chapter 37 of title 31, United States Code.

“(i) WRITTEN REQUESTS FOR WAIVERS, REDUCTIONS, AND REFUNDS.—To qualify for consideration for a waiver or reduction under subsection (d), or for a refund of any fee collected in accordance with subsection (a), a person shall submit to the Secretary a written request for such waiver, reduction, or refund not later than 180 days after such fee is due.

“(j) CONSTRUCTION.—This section may not be construed to require that the number of full-time equivalent positions in the Department of Health and Human Services, for officers, employees, and advisory committees not engaged in the process of the review of abbreviated applications for generic new animal drugs, be reduced to offset the number of officers, employees, and advisory committees so engaged.

“(k) DEFINITIONS.—In this section and section 742:

“(1) ABBREVIATED APPLICATION FOR A GENERIC NEW ANIMAL DRUG.—The terms ‘abbreviated application for a generic new animal drug’ and ‘abbreviated application’ mean an abbreviated application for the approval of any generic new animal drug submitted under section 512(b)(2). Such term does not include a supplemental abbreviated application for a generic new animal drug.

“(2) ADJUSTMENT FACTOR.—The term ‘adjustment factor’ applicable to a fiscal year is the Consumer Price Index for all urban consumers (all items; United States city average) for October of the preceding fiscal year divided by—

“(A) for purposes of subsection (f)(1), such Index for October 2002; and

“(B) for purposes of subsection (g)(2)(A)(ii), such Index for October 2007.

“(3) COSTS OF RESOURCES ALLOCATED FOR THE PROCESS FOR THE REVIEW OF ABBREVIATED APPLICATIONS FOR GENERIC NEW ANIMAL DRUGS.—The term ‘costs of resources allocated for the process for the review of abbreviated applications for generic new animal drugs’ means the expenses in connection with the process for the review of abbreviated applications for generic new animal drugs for—

“(A) officers and employees of the Food and Drug Administration, contractors of the Food and Drug Administration, advisory committees consulted with respect to the review of specific abbreviated applications, supplemental abbreviated applications, or investigational submissions, and costs related to such officers, employees, commit-

tees, and contractors, including costs for travel, education, and recruitment and other personnel activities;

“(B) management of information, and the acquisition, maintenance, and repair of computer resources;

“(C) leasing, maintenance, renovation, and repair of facilities and acquisition, maintenance, and repair of fixtures, furniture, scientific equipment, and other necessary materials and supplies; and

“(D) collecting fees under this section and accounting for resources allocated for the review of abbreviated applications, supplemental abbreviated applications, and investigational submissions.

“(4) FINAL DOSAGE FORM.—The term ‘final dosage form’ means, with respect to a generic new animal drug product, a finished dosage form which is approved for administration to an animal without substantial further manufacturing. Such term includes generic new animal drug products intended for mixing in animal feeds.

“(5) GENERIC NEW ANIMAL DRUG.—The term ‘generic new animal drug’ means a new animal drug that is the subject of an abbreviated application.

“(6) GENERIC NEW ANIMAL DRUG PRODUCT.—The term ‘generic new animal drug product’ means each specific strength or potency of a particular active ingredient or ingredients in final dosage form marketed by a particular manufacturer or distributor, which is uniquely identified by the labeler code and product code portions of the national drug code, and for which an abbreviated application for a generic new animal drug or a supplemental abbreviated application has been approved.

“(7) GENERIC NEW ANIMAL DRUG SPONSOR.—The term ‘generic new animal drug sponsor’ means either an applicant named in an abbreviated application for a generic new animal drug that has not been withdrawn by the applicant and for which approval has not been withdrawn by the Secretary, or a person who has submitted an investigational submission for a generic new animal drug that has not been terminated or otherwise rendered inactive by the Secretary.

“(8) INVESTIGATIONAL SUBMISSION FOR A GENERIC NEW ANIMAL DRUG.—The terms ‘investigational submission for a generic new animal drug’ and ‘investigational submission’ mean—

“(A) the filing of a claim for an investigational exemption under section 512(j) for a generic new animal drug intended to be the subject of an abbreviated application or a supplemental abbreviated application; or

“(B) the submission of information for the purpose of enabling the Secretary to evaluate the safety or effectiveness of a generic new animal drug in the event of the filing of an abbreviated application or supplemental abbreviated application for such drug.

“(9) PERSON.—The term ‘person’ includes an affiliate thereof (as such term is defined in section 735(11)).

“(10) PROCESS FOR THE REVIEW OF ABBREVIATED APPLICATIONS FOR GENERIC NEW ANIMAL DRUGS.—The term ‘process for the review of abbreviated applications for generic new animal drugs’ means the following activities of the Secretary with respect to the review of abbreviated applications, supplemental abbreviated applications, and investigational submissions:

“(A) The activities necessary for the review of abbreviated applications, supplemental abbreviated applications, and investigational submissions.

“(B) The issuance of action letters which approve abbreviated applications or supplemental abbreviated applications or which set forth in detail the specific deficiencies in abbreviated applications, supplemental abbre-

viated applications, or investigational submissions and, where appropriate, the actions necessary to place such applications, supplemental applications, or submissions in condition for approval.

“(C) The inspection of generic new animal drug establishments and other facilities undertaken as part of the Secretary’s review of pending abbreviated applications, supplemental abbreviated applications, and investigational submissions.

“(D) Monitoring of research conducted in connection with the review of abbreviated applications, supplemental abbreviated applications, and investigational submissions.

“(E) The development of regulations and policy related to the review of abbreviated applications, supplemental abbreviated applications, and investigational submissions.

“(F) Development of standards for products subject to review.

“(G) Meetings between the agency and the generic new animal drug sponsor.

“(H) Review of advertising and labeling prior to approval of an abbreviated application or supplemental abbreviated application, but not after such application has been approved.

“(I) SUPPLEMENTAL ABBREVIATED APPLICATION FOR GENERIC NEW ANIMAL DRUG.—The terms ‘supplemental abbreviated application for a generic new animal drug’ and ‘supplemental abbreviated application’ mean a request to the Secretary to approve a change in an approved abbreviated application.”

SEC. 203. REAUTHORIZATION; REPORTING REQUIREMENTS.

Section 742 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 379j-22) is amended to read as follows:

“SEC. 742. REAUTHORIZATION; REPORTING REQUIREMENTS.

“(a) PERFORMANCE REPORTS.—Beginning with fiscal year 2014, not later than 120 days after the end of each fiscal year during which fees are collected under this part, the Secretary shall prepare and submit to the Committee on Health, Education, Labor, and Pensions of the Senate, and the Committee on Energy and Commerce of the House of Representatives a report concerning the progress of the Food and Drug Administration in achieving the goals identified in the letters described in section 201(b) of the Animal Generic Drug User Fee Amendments of 2013 toward expediting the generic new animal drug development process and the review of abbreviated applications for generic new animal drugs, supplemental abbreviated applications for generic new animal drugs, and investigational submissions for generic new animal drugs during such fiscal year.

“(b) FISCAL REPORT.—Beginning with fiscal year 2014, not later than 120 days after the end of each fiscal year during which fees are collected under this part, the Secretary shall prepare and submit to Committee on Health, Education, Labor, and Pensions of the Senate and the Committee on Energy and Commerce of the House of Representatives a report on the implementation of the authority for such fees during such fiscal year and the use, by the Food and Drug Administration, of the fees collected during such fiscal year for which the report is made.

“(c) PUBLIC AVAILABILITY.—The Secretary shall make the reports required under subsections (a) and (b) available to the public on the Internet Web site of the Food and Drug Administration.

“(d) REAUTHORIZATION.—

“(1) CONSULTATION.—In developing recommendations to present to Congress with respect to the goals, and plans for meeting the goals, for the process for the review of abbreviated applications for generic new animal drugs for the first 5 fiscal years after fiscal year 2018, and for the reauthorization of

this part for such fiscal years, the Secretary shall consult with—

“(A) the Committee on Energy and Commerce of the House of Representatives;

“(B) the Committee on Health, Education, Labor, and Pensions of the Senate;

“(C) scientific and academic experts;

“(D) veterinary professionals;

“(E) representatives of patient and consumer advocacy groups; and

“(F) the regulated industry.

“(2) PRIOR PUBLIC INPUT.—Prior to beginning negotiations with the regulated industry on the reauthorization of this part, the Secretary shall—

“(A) publish a notice in the Federal Register requesting public input on the reauthorization;

“(B) hold a public meeting at which the public may present its views on the reauthorization, including specific suggestions for changes to the goals referred to in subsection (a);

“(C) provide a period of 30 days after the public meeting to obtain written comments from the public suggesting changes to this part; and

“(D) publish the comments on the Food and Drug Administration’s Internet Web site.

“(3) PERIODIC CONSULTATION.—Not less frequently than once every 4 months during negotiations with the regulated industry, the Secretary shall hold discussions with representatives of veterinary, patient, and consumer advocacy groups to continue discussions of their views on the reauthorization and their suggestions for changes to this part as expressed under paragraph (2).

“(4) PUBLIC REVIEW OF RECOMMENDATIONS.—After negotiations with the regulated industry, the Secretary shall—

“(A) present the recommendations developed under paragraph (1) to the congressional committees specified in such paragraph;

“(B) publish such recommendations in the Federal Register;

“(C) provide for a period of 30 days for the public to provide written comments on such recommendations;

“(D) hold a meeting at which the public may present its views on such recommendations; and

“(E) after consideration of such public views and comments, revise such recommendations as necessary.

“(5) TRANSMITTAL OF RECOMMENDATIONS.—Not later than January 15, 2018, the Secretary shall transmit to Congress the revised recommendations under paragraph (4), a summary of the views and comments received under such paragraph, and any changes made to the recommendations in response to such views and comments.

“(6) MINUTES OF NEGOTIATION MEETINGS.—

“(A) PUBLIC AVAILABILITY.—Before presenting the recommendations developed under paragraphs (1) through (5) to Congress, the Secretary shall make publicly available, on the Internet Web site of the Food and Drug Administration, minutes of all negotiation meetings conducted under this subsection between the Food and Drug Administration and the regulated industry.

“(B) CONTENT.—The minutes described under subparagraph (A) shall summarize any substantive proposal made by any party to the negotiations as well as significant controversies or differences of opinion during the negotiations and their resolution.”

SEC. 204. SAVINGS CLAUSE.

Notwithstanding the amendments made by this title, part 5 of subchapter C of chapter VII of the Federal Food, Drug, and Cosmetic Act, as in effect on the day before the date of enactment of this title, shall continue to

be in effect with respect to abbreviated applications for a generic new animal drug and supplemental abbreviated applications for a generic new animal drug (as defined in such part as of such day) that on or after October 1, 2008, but before October 1, 2013, were accepted by the Food and Drug Administration for filing with respect to assessing and collecting any fee required by such part for a fiscal year prior to fiscal year 2014.

SEC. 205. EFFECTIVE DATE.

The amendments made by this title shall take effect on October 1, 2013, or the date of enactment of this Act, whichever is later, except that fees under part 5 of subchapter C of chapter VII of the Federal Food, Drug, and Cosmetic Act, as amended by this title, shall be assessed for all abbreviated applications for a generic new animal drug and supplemental abbreviated applications for a generic new animal drug received on or after October 1, 2013, regardless of the date of enactment of this Act.

SEC. 206. SUNSET DATES.

(a) AUTHORIZATION.—Section 741 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 379j-21) shall cease to be effective October 1, 2018.

(b) REPORTING REQUIREMENTS.—Section 742 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 379j-22) shall cease to be effective January 31, 2019.

(c) PREVIOUS SUNSET PROVISION.—

(1) IN GENERAL.—Section 204 of the Animal Generic Drug User Fee Act of 2008 (Public Law 110-316) is repealed.

(2) CONFORMING AMENDMENT.—The Animal Generic Drug User Fee Act of 2008 (Public Law 110-316) is amended in the table of contents in section 1, by striking the item relating to section 204.

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 material 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 S. 622, the Animal Drug and Animal Generic Drug User Fee Reauthorization Act of 2013. The Energy and Commerce Committee passed H.R. 1407, a nearly identical bill, through the committee last month with broad bipartisan support.

The agriculture industry, animal drug manufacturers, veterinarians, pet owners, and the Food and Drug Administration have all found both the Animal Drug User Fee and Animal Generic Drug User Fee to be very effective, and have asked Congress to reauthorize the programs as soon as possible. In addition, there is strong bipartisan support for the programs, which I think is a reflection of their success and effectiveness.

Passing S. 622 is extremely important for our Nation. First, having quality

and safe medications is essential for ensuring the safety of our Nation’s food supply chain. Second, these programs help livestock producers, poultry producers, and veterinarians keep their animals healthy. Third, these programs enable families to have safe and affordable drugs for their pets so they can live longer and healthier lives. It is essential that the House passes this bill swiftly so we can guarantee that these programs continue without interruption.

I would like to thank my colleagues, Mr. SHIMKUS and Mr. GARDNER, for their hard work on this very important piece of legislation. It is no small feat to move legislation to the President’s desk in such an efficient manner.

I would also like to thank our colleagues in the Senate, including Senator HARKIN and Senator ALEXANDER, for their leadership.

Mr. Speaker, I support this bill, encourage my colleagues to do the same, and I reserve the balance of my time.

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

I rise in support of H.R. 1407, the Animal Drug User Fee Amendments of 2013. FDA’s Animal Drug User Fee programs have been successful at speeding both brand and generic drugs for animals to the market, and that’s important.

However, I regret that we have not taken this opportunity to provide FDA with new tools to address a glaring public health crisis—the problem of antibiotic resistance.

Antibiotics are truly a lifesaving gift. Unfortunately, the more they are used, the less they work. Untold numbers of Americans die or are infected each year by antibiotic-resistant bugs.

We know that most antibiotic use occurs on the farm, and much of this issue is not to treat sick animals, but most of the use is for disease prevention or growth promotion. If it’s for treating sick animals, no one could quarrel with that. Unfortunately, if it’s used for growth promotion or disease prevention, that is a misuse of it and could lead to antibiotic-resistant bugs.

We don’t know exactly how much is for which of these two uses of the drug. That’s why we need to ask industry to give us more data on how these drugs are being used, and to take steps to curtail the inappropriate use in animals of important human antibiotics.

My bill, the Delivering Antibiotic Transparency in Animals, or DATA, Act, would enhance the information FDA gets about how these drugs are used. Representative SLAUGHTER has a bill, which I have cosponsored, the Preservation of Antibiotics for Medical Treatment Act, or PAMTA, that would curtail the inappropriate use in animals of important human antibiotics.

We need to ensure that FDA not only has the resources and procedures for speeding safe and effective animal drugs to market, but also the information and tools to ensure that they are being used judiciously.

□ 1640

I regret that we are not taking this opportunity to give FDA these tools, but I hope we will soon have an opportunity to move these bills forward.

Mr. Speaker, I ask unanimous consent that the control of the time on my side of the aisle be given to the gentleman from North Carolina (Mr. BUTTERFIELD), and I reserve the balance of my time.

The SPEAKER pro tempore. Without objection, the gentleman from North Carolina will control the time.

There was no objection.

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

Mr. UPTON. I rise today in strong support of S. 622, the Animal Drug and Animal Generic Drug User Fee Reauthorization Act of 2013.

This bipartisan bill is nearly identical to H.R. 1407, which we favorably reported out of the Energy and Commerce Committee last month. This bill, as well as the Animal Generic Drug User Fee Act, has proven to be very successful; and they are so important for the Nation's public health. Congress first created ADUFA back in 2003 and AGDUFA in 2008. Collectively, these programs have yielded many benefits for the American public.

These two bills have ensured that veterinarians, livestock, poultry producers, and pet owners have access to new and affordable animal drugs to keep their animals healthy. They have assisted animal drug producers by fostering a stable and predictable FDA review process, a rigorous process that helps expedite access to new therapies and fosters new drug development. The programs have also helped American consumers by keeping the food supply safe. Having medications that keep our animals healthy is essential to keeping our Nation's food supply safe. For companies like Zoetis, which employs some 700 people in southwest Michigan, these programs are vital in allowing them to keep producing innovative drugs for pets and livestock.

I was the lead sponsor of the original ADUFA legislation back in 2003, and it is terrific to see how successful it has been and how many Americans it has helped over the last decade.

I want to thank my colleagues, particularly Mr. SHIMKUS and Mr. GARDNER, for their real leadership on this important issue. They deserve tremendous credit as we work to get this bill to the President's desk, and I urge my colleagues to support it.

Mr. BUTTERFIELD. Mr. Speaker, at this time, I yield such time as she may consume to the gentlelady from New York (Ms. SLAUGHTER).

Ms. SLAUGHTER. I thank my friend for yielding.

Mr. Speaker, just today, The New York Times reported that we are simultaneously facing a shortage of effective antibiotics and the growing threat of antibiotic-resistant bacteria.

Already antibiotic-resistant disease claims 70,000 American lives each year.

According to today's story, Dr. Janet Woodcock, the director of the Center for Drug Evaluation and Research at the Food and Drug Administration, has warned "it is bad now, and the infectious disease docs are frantic, but what is worse is the thought of where we will be 5 to 10 years from now."

They are even desperate enough to ask GlaxoKleinSmith, which is working on some new antibiotics, to allow the use of them untested—the FDA is considering this—and to try, in perhaps what will turn out to be a vain attempt, to save people who are dying from infections that we can no longer cure. GlaxoKleinSmith has said the new antibiotics they are working on they will not license for livestock feed.

Eighty percent of the antibiotics produced in the United States of America is put every day in livestock feed. The major reason for the increase in the antibiotic-resistant bacteria is the routine overuse of antibiotics in the Nation's livestock. These are not sick livestock, Mr. Speaker. This is simply put in the feed because they grow faster and they are fatter and they can get to market a little quicker. This irresponsible practice has already been scientifically linked to the growth of superbugs.

It's clear—and it has been clear for quite a while—that the Federal Government must act to end this dangerous practice. Yet, incomprehensibly, for more than 35 years the United States Food and Drug Administration has refused to follow its own advice and ban the routine use of antibiotics in agriculture, not just use it for sick animals. Instead, they have proposed voluntary guidance that naively asks industry to put public welfare before private profits—something the industry has repeatedly shown in 35 years they will not do.

As if such dereliction of duty were not enough, the FDA is now panicked about the superbug threat that they helped to create; but instead of finally removing routine antibiotic use from livestock production, the FDA is thinking of waiving important drug-testing procedures, as I said, in order to rush new drugs to market. The testing procedures that are currently in place are in place for a reason. Waiving these requirements sets a dangerous precedent and is one that is only being considered because the FDA is panicked and has refused to challenge the special interests that have helped to create this superbug threat in the first place.

As the only legislator in Congress with a background in microbiology, I can assure you we will never win the arms race against nature. As long as we allow the irresponsible use of antibiotics in our society, nature will always evolve to create stronger bacteria. As I said, with 80 percent of all of the antibiotics going to agricultural use, our answer has to start on the

farm. We have to end the unnecessary use of antibiotics on healthy animals before it's too late. Indeed, it may almost be too late.

At the very least today, the ADUFA legislation should include language to collect important data on antibiotics. That provision would at least allow us to finally learn the full scope of the problem that we confront. Even more importantly, I urge my colleagues to support my legislation, H.R. 1150, the Preservation of Antibiotics for Medical Treatment Act, which would ban the routine use of eight important classes of antibiotics in livestock, but still allow a sick animal to be treated, and would help curb the growing threat of superbugs.

We are literally standing today on the brink of a public health crisis as the food industrial complex fritters away one of the most important advances in medical history—the beginning of the use of antibiotics to cure human beings. Already, some strains of tuberculosis have evolved that are incurable, and others are coming. Some experts have said that if we don't do something soon—and it may already be too late—that strep throat could become a fatal illness. That's what they're worried about, what could happen here in 5 years.

I urge my colleagues to oppose this legislation today and to please join me in the fight to protect the antibiotics for human health. It is so important. I cannot vote for this bill, although I recognize that some work has gone into it. I have spent years on this, and the years are running out, and the time is short.

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

Mr. PITTS. I rise today in support of the reauthorization of two successful programs—the Animal Drug User Fee Act, ADUFA, and the Animal Generic Drug User Fee Act, AGDUFA.

The bill we have before us today originated in the Senate and was approved by unanimous consent on May 8, 2013; and I urge my colleagues in the House to support this legislation as well.

In 2003, the first ADUFA was authorized to help the Food and Drug Administration's review of animal drugs. Similar to the Prescription Drug User Fee for human drugs, under ADUFA, FDA collected funds to help expedite the new animal drug approval process, to reduce application backlog, and to improve communications with drug sponsors. The program was authorized for 5 years, and Congress renewed the program for an additional 5 years in ADUFA II in 2008. In 2012, FDA completed 747 ADUFA reviews; and, according to FDA, the agency has exceeded all performance goals outlined in ADUFA I and ADUFA II. However, absent congressional action, FDA's ability to collect these user fees will expire on September 30, 2013.

□ 1650

AGDUFA I, ADUFA's generic cousin, was first authorized in 2008 for 5 years in order to improve the review of abbreviated new animal drug applications, eliminate application backlogs, and reduce review times.

To date, according to FDA, the agency has exceeded all performance goals but one from AGDUFA I. This program also expires September 30, 2013, unless it is reauthorized and FDA and industry have negotiated an agreement for AGDUFA II. These programs are extremely important not only for our animals and livestock on our farms and ranches, but for our pets' health and well-being as well.

I want to thank my colleagues, Representative JOHN SHIMKUS and Representative CORY GARDNER, for their outstanding work on this legislation, and I urge my colleagues to support this important legislation.

Mr. BUTTERFIELD. I inquire as to whether the gentleman from Ohio has any additional speakers.

Mr. LATTA. We have one, Mr. Speaker.

Mr. BUTTERFIELD. Then I will reserve the balance of my time.

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

Mr. GARDNER. Mr. Speaker, I thank the gentleman for yielding time.

I rise today in support of Senate Bill 622, the Animal Drug and Animal Generic Drug User Fee Reauthorization Act of 2013.

This legislation will reauthorize two very important programs at the Food and Drug Administration that will provide farmers, ranchers, pet owners, and veterinarians with speedy access to medications that they need for the treatment of herds and pets.

I would like to thank Senator HARKIN for leading its passage in the U.S. Senate, and I would also like to thank Congressman SHIMKUS for his leadership with the House version of H.R. 1407.

These programs have been a success story at the FDA, and this legislation will ensure that drug approvals are done efficiently and to the highest quality standards. ADUFA and AGDUFA expire at the start of September, and we will need to pass this reauthorization today to assure there is no delay for animal caretakers and livestock producers. This bill will also help companies that develop and manufacture animal drugs by providing predictable time lines. It will also help them to benefit from a more stable review process so they can make decisions about where to invest research dollars.

Colorado has a thriving livestock industry which supports rural communities and economic strength for the entire State. I said this during the committee markup of H.R. 1407: there is more livestock in my district than people, or at least that's what I'm told. Colorado is also home to one of the Na-

tion's premier schools of veterinary medicine at Colorado State University. Keeping livestock animals healthy, in particular, is crucial to ensuring our own health, not to mention the health of our family pets. The ADUFA and AGDUFA program keeps our food healthy and safe, while the application of animal drugs poses no risk to animal health.

I had the honor of introducing, with bipartisan support, H.R. 1408, the Animal Generic Drug User Fee Act, or AGDUFA. The bill was later incorporated into H.R. 1407. This program at FDA has achieved noteworthy success since first being authorized in 2008. The FDA has decreased a backlog of applications and reduced the review time for new generic drug applications. The reauthorization of this program will continue this success and allow our animal caretakers and livestock producers to utilize cost savings associated with generic medications.

Mr. BUTTERFIELD. Mr. Speaker, I ask if my friend has any further speakers on his side.

Mr. LATTA. I have none.

Mr. BUTTERFIELD. As we have no further speakers either, Mr. Speaker, I yield back the balance of my time.

Mr. LATTA. Mr. Speaker, I ask for passage of S. 622, and I yield back the balance of my time.

Mr. PALLONE. Mr. Speaker, I rise in strong support of S. 622, the Animal Drug and Animal Generic Drug User Fee Reauthorization Act.

Congress enacted the Animal Drug User Fee Act (ADUFA) in 2003 to help improve the FDA review of new animal drugs, and subsequently enacted the Animal Generic Drug User Fee Act (AGDUFA) to improve the review of abbreviated new animal drug applications, or generic versions of animal drugs. These programs have been extremely effective, and have helped expedite the approval process, reduce application backlogs, and improve communications with drug sponsors.

Without congressional action, the current agreements will expire at the end of this fiscal year, which would have a serious and harmful impact on the ability of the FDA's Center for Veterinary Medicine to review new and generic drug applications in a timely manner. S. 622 will extend FDA's authority to collect user fees from manufacturers for five years.

I urge my colleagues to vote in favor of S. 622, so that progress is not impeded and the Food and Drug Administration can continue to review new and generic animal drug applications in a timely manner. Industry, farmers, ranchers, and pet owners are counting on an uninterrupted supply of animal drugs.

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, S. 622.

The question was taken.

The SPEAKER pro tempore. In the opinion of the Chair, two-thirds being in the affirmative, the ayes have it.

Mr. BUTTERFIELD. Mr. Speaker, on that I demand the yeas and nays.

The yeas and nays were ordered.

The SPEAKER pro tempore. Pursuant to clause 8 of rule XX, further pro-

ceedings on this motion will be postponed.

COROLLA WILD HORSES PROTECTION ACT

Mr. WITTMAN. Mr. Speaker, I move to suspend the rules and pass the bill (H.R. 126) to direct the Secretary of the Interior to enter into an agreement to provide for management of the free-roaming wild horses in and around the Currituck National Wildlife Refuge.

The Clerk read the title of the bill.

The text of the bill is as follows:

H.R. 126

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 "Corolla Wild Horses Protection Act".

SEC. 2. WILD HORSES IN AND AROUND THE CURRITUCK NATIONAL WILDLIFE REFUGE.

(a) AGREEMENT REQUIRED.—

(1) IN GENERAL.—The Secretary of the Interior shall enter into an agreement with the Corolla Wild Horse Fund (a nonprofit corporation established under the laws of the State of North Carolina), the County of Currituck, North Carolina, and the State of North Carolina within 180 days after the date of enactment of this Act to provide for management of free-roaming wild horses in and around the Currituck National Wildlife Refuge.

(2) TERMS.—The agreement shall—

(A) allow a herd of not less than 110 and not more than 130 free-roaming wild horses in and around such refuge, with a target population of between 120 and 130 free-roaming wild horses;

(B) provide for cost-effective management of the horses while ensuring that natural resources within the refuge are not adversely impacted;

(C) provide for introduction of a small number of free-roaming wild horses from the herd at Cape Lookout National Seashore as is necessary to maintain the genetic viability of the herd in and around the Currituck National Wildlife Refuge; and

(D) specify that the Corolla Wild Horse Fund shall pay the costs associated with—

(i) coordinating a periodic census and inspecting the health of the horses;

(ii) maintaining records of the horses living in the wild and in confinement;

(iii) coordinating the removal and placement of horses and monitoring of any horses removed from the Currituck County Outer Banks; and

(iv) administering a viable population control plan for the horses including auctions, adoptions, contraceptive fertility methods, and other viable options.

(b) REQUIREMENTS FOR INTRODUCTION OF HORSES FROM CAPE LOOKOUT NATIONAL SEASHORE.—During the effective period of the memorandum of understanding between the National Park Service and the Foundation for Shackelford Horses, Inc. (a non-profit corporation organized under the laws of and doing business in the State of North Carolina) signed in 2007, no horse may be removed from Cape Lookout National Seashore for introduction at Currituck National Wildlife Refuge except—

(1) with the approval of the Foundation; and

(2) consistent with the terms of such memorandum (or any successor agreement) and the Management Plan for the

Shackleford Banks Horse Herd signed in January 2006 (or any successor management plan).

(c) NO LIABILITY CREATED.—Nothing in this section shall be construed as creating liability for the United States for any damages caused by the free-roaming wild horses to any person or property located inside or outside the boundaries of the refuge.

The SPEAKER pro tempore. Pursuant to the rule, the gentleman from Virginia (Mr. WITTMAN) and the gentleman from California (Mrs. NAPOLITANO) each will control 20 minutes.

The Chair recognizes the gentleman from Virginia.

GENERAL LEAVE

Mr. WITTMAN. Mr. Speaker, I ask unanimous consent that all Members may have 5 legislative days to revise and extend their remarks and include extraneous materials on the bill under consideration.

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

There was no objection.

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

In 2007, the State of North Carolina, the County of Currituck, the Corolla Wild Horse Fund, and the U.S. Fish and Wildlife Service signed a comprehensive wild horse management plan for the colonial Spanish mustangs that live on 7,500 acres of private and public lands in North Carolina. This plan expired last year, and the U.S. Fish and Wildlife Service indicated that it will not sign a new agreement.

H.R. 126, authored by Congressman WALTER B. JONES, requires the Secretary of the Interior to enter into a new agreement within 180 days of enactment. It will also cap the number of horses to no more than 130, allow the introduction of a small number of Shackleford Banks horses to improve genetic diversity, and will ensure that the Corolla Wild Horse Fund, which is a volunteer organization, will continue to pay for the cost of caring for and managing these horses in the future. These horses are living symbols of our colonial history. H.R. 126, which is a similar bill to one that passed the House by a voice vote last year, will ensure their survival at no cost to the taxpayers.

I urge adoption of the measure and compliment the author for his tireless leadership and his passion for this issue and reserve the balance of my time.

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

(Mrs. NAPOLITANO asked and was given permission to revise and extend her remarks.)

Mrs. NAPOLITANO. Mr. Speaker, H.R. 126 directs the Secretary of the Interior to enter into an agreement with the Corolla Wild Horse Fund, as well as local and State authorities, to provide for the management of the wild horses in and around the Currituck National Wildlife Refuge. The agreement will increase the cap on the herd size and specify that the privately funded Co-

rolla Wild Horse Fund will cover the cost of managing the herd.

This refuge was established in 1984 to preserve and protect the native coastal barrier ecosystem. The refuge provides habitat for the migrating wild fowl and for the endangered species, such as piping plover and sea turtles.

It is unusual to protect a nonnative species such as these horses in a wildlife refuge. Extra effort and resources are needed to ensure that the herd does not impair the ecosystem for the native animals and plants.

H.R. 126 is an imperfect solution, though a solution, to a very difficult problem. We must continue working with Fish and Wildlife Service and with the local community to achieve balance between the needs of the refuge and these wild horses.

With that, I reserve the balance of my time.

Mr. WITTMAN. Mr. Speaker, I yield as much time as he may consume to the gentleman from North Carolina (Mr. JONES).

Mr. JONES. Mr. Speaker, I want to thank the chairman and the ranking member for their words today, and I'll take just a few minutes.

Mr. Speaker, as has been said by both, this is a plan to maintain and protect a part of North Carolina's history. As Mr. WITTMAN said, these horses have been traced back by genetic experts to the Spanish mustangs that swam ashore in the 1600s. They are really part of our heritage.

These beautiful little horses roam, as has been said by both sides today, over 7,500 acres of public and private land. This is in Currituck County out at Corolla.

□ 1700

These little horses are so special that the citizens of our area decided that they should try to create a foundation where they could work together with the Federal Government, the State government, and the county government; and it's known as the Corolla Wild Horse Fund. It is a nonprofit. These people are absolutely convinced and committed to making sure that for years to come down the road that these little horses will still have the ability to reproduce. And that's been part of the problem, Mr. Speaker, is that if you allow this herd to get down to about 60 horses, you will not be able to maintain the diversity of the herd.

That is why an expert, Dr. Gus Cothran of Texas A&M, as has been said in the comments by both sides, has said that you have to have a minimum of 120 horses but no more than 130. We are of the firm belief that H.R. 126 will do what is necessary to continue to make sure that we have a viable herd of these horses that have been traced back to the Spanish galleons that came to the coast of North Carolina and wrecked and these horses swam ashore. They've been able to live for that many years.

This is very close to legislation, and I want to thank the House in a bipar-

tisan way, in 1998 we did the same thing that we are trying to do in Corolla down in Currituck County down at Shackleford Banks. And what was interesting, President Clinton was President at the time, and Erskine Bowles was Chief of Staff to President Clinton, and Erskine Bowles got behind the legislation, and that's exactly what we're trying to do. It was the Park Service down at Shackleford Banks; this is Fish and Wildlife, but thank you for your comments.

I want to thank the chairman for his comments because there's no reason that we cannot make both sides happy to do what needs to be done and to protect what, to me, when you look at this beautiful little horse, it is God's gift to the world. So thank you so much, Mr. Chairman and ranking member. Thank you for giving me this time to speak on behalf of these horses. I hope that we can pass this legislation.

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

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

The SPEAKER pro tempore. The question is on the motion offered by the gentleman from Virginia (Mr. WITTMAN) that the House suspend the rules and pass the bill, H.R. 126.

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

A motion to reconsider was laid on the table.

PERMANENT ELECTRONIC DUCK
STAMP ACT OF 2013

Mr. WITTMAN. Mr. Speaker, I move to suspend the rules and pass the bill (H.R. 1206) to grant the Secretary of the Interior permanent authority to authorize States to issue electronic duck stamps, and for other purposes.

The Clerk read the title of the bill.

The text of the bill is as follows:

H.R. 1206

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 "Permanent Electronic Duck Stamp Act of 2013".

SEC. 2. DEFINITIONS.

In this Act:

(1) **ACTUAL STAMP.**—The term "actual stamp" means a Federal migratory-bird hunting and conservation stamp required under the Act of March 16, 1934 (16 U.S.C. 718a et seq.) (popularly known as the "Duck Stamp Act"), that is printed on paper and sold through the means established by the authority of the Secretary immediately before the date of enactment of this Act.

(2) **AUTOMATED LICENSING SYSTEM.**—

(A) **IN GENERAL.**—The term "automated licensing system" means an electronic, computerized licensing system used by a State fish and wildlife agency to issue hunting, fishing, and other associated licenses and products.

(B) **INCLUSION.**—The term "automated licensing system" includes a point-of-sale, Internet, telephonic system, or other electronic applications used for a purpose described in subparagraph (A).

(3) **ELECTRONIC STAMP.**—The term “electronic stamp” means an electronic version of an actual stamp that—

(A) is a unique identifier for the individual to whom it is issued;

(B) can be printed on paper or produced through an electronic application with the same indicators as the State endorsement provides;

(C) is issued through a State automated licensing system that is authorized, under State law and by the Secretary under this Act, to issue electronic stamps;

(D) is compatible with the hunting licensing system of the State that issues the electronic stamp; and

(E) is described in the State application approved by the Secretary under section 4(b).

(4) **SECRETARY.**—The term “Secretary” means the Secretary of the Interior.

SEC. 3. AUTHORITY TO ISSUE ELECTRONIC DUCK STAMPS.

(a) **IN GENERAL.**—The Secretary may authorize any State to issue electronic stamps in accordance with this Act.

(b) **CONSULTATION.**—The Secretary shall implement this section in consultation with State management agencies.

SEC. 4. STATE APPLICATION.

(a) **APPROVAL OF APPLICATION REQUIRED.**—The Secretary may not authorize a State to issue electronic stamps under this Act unless the Secretary has received and approved an application submitted by the State in accordance with this section. The Secretary may determine the number of new States per year to participate in the electronic stamp program.

(b) **CONTENTS OF APPLICATION.**—The Secretary may not approve a State application unless the application contains—

(1) a description of the format of the electronic stamp that the State will issue under this Act, including identifying features of the licensee that will be specified on the stamp;

(2) a description of any fee the State will charge for issuance of an electronic stamp;

(3) a description of the process the State will use to account for and transfer to the Secretary the amounts collected by the State that are required to be transferred to the Secretary under the program;

(4) the manner by which the State will transmit electronic stamp customer data to the Secretary;

(5) the manner by which actual stamps will be delivered;

(6) the policies and procedures under which the State will issue duplicate electronic stamps; and

(7) such other policies, procedures, and information as may be reasonably required by the Secretary.

(c) **PUBLICATION OF DEADLINES, ELIGIBILITY REQUIREMENTS, AND SELECTION CRITERIA.**—Not later than 30 days before the date on which the Secretary begins accepting applications under this section, the Secretary shall publish—

(1) deadlines for submission of applications;

(2) eligibility requirements for submitting applications; and

(3) criteria for approving applications.

SEC. 5. STATE OBLIGATIONS AND AUTHORITIES.

(a) **DELIVERY OF ACTUAL STAMP.**—The Secretary shall require that each individual to whom a State sells an electronic stamp under this Act shall receive an actual stamp—

(1) by not later than the date on which the electronic stamp expires under section 6(c); and

(2) in a manner agreed upon by the State and Secretary.

(b) **COLLECTION AND TRANSFER OF ELECTRONIC STAMP REVENUE AND CUSTOMER INFORMATION.**—

(1) **REQUIREMENT TO TRANSMIT.**—The Secretary shall require each State authorized to issue electronic stamps to collect and submit to the Secretary in accordance with this section—

(A) the first name, last name, and complete mailing address of each individual that purchases an electronic stamp from the State;

(B) the face value amount of each electronic stamp sold by the State; and

(C) the amount of the Federal portion of any fee required by the agreement for each stamp sold.

(2) **TIME OF TRANSMITTAL.**—The Secretary shall require the submission under paragraph (1) to be made with respect to sales of electronic stamps by a State according to the written agreement between the Secretary and the State agency.

(3) **ADDITIONAL FEES NOT AFFECTED.**—This section shall not apply to the State portion of any fee collected by a State under subsection (c).

(c) **ELECTRONIC STAMP ISSUANCE FEE.**—A State authorized to issue electronic stamps may charge a reasonable fee to cover costs incurred by the State and the Department of the Interior in issuing electronic stamps under this Act, including costs of delivery of actual stamps.

(d) **DUPLICATE ELECTRONIC STAMPS.**—A State authorized to issue electronic stamps may issue a duplicate electronic stamp to replace an electronic stamp issued by the State that is lost or damaged.

(e) **LIMITATION ON AUTHORITY TO REQUIRE PURCHASE OF STATE LICENSE.**—A State may not require that an individual purchase a State hunting license as a condition of issuing an electronic stamp under this Act.

SEC. 6. ELECTRONIC STAMP REQUIREMENTS; RECOGNITION OF ELECTRONIC STAMP.

(a) **STAMP REQUIREMENTS.**—The Secretary shall require an electronic stamp issued by a State under this Act—

(1) to have the same format as any other license, validation, or privilege the State issues under the automated licensing system of the State; and

(2) to specify identifying features of the licensee that are adequate to enable Federal, State, and other law enforcement officers to identify the holder.

(b) **RECOGNITION OF ELECTRONIC STAMP.**—Any electronic stamp issued by a State under this Act shall, during the effective period of the electronic stamp—

(1) bestow upon the licensee the same privileges as are bestowed by an actual stamp;

(2) be recognized nationally as a valid Federal migratory bird hunting and conservation stamp; and

(3) authorize the licensee to hunt migratory waterfowl in any other State, in accordance with the laws of the other State governing that hunting.

(c) **DURATION.**—An electronic stamp issued by a State shall be valid for a period agreed to by the State and the Secretary, which shall not exceed 45 days.

SEC. 7. TERMINATION OF STATE PARTICIPATION.

The authority of a State to issue electronic stamps under this Act may be terminated—

(1) by the Secretary, if the Secretary—

(A) finds that the State has violated any of the terms of the application of the State approved by the Secretary under section 4; and

(B) provides to the State written notice of the termination by not later than the date that is 30 days before the date of termination; or

(2) by the State, by providing written notice to the Secretary by not later than the date that is 30 days before the termination date.

The **SPEAKER pro tempore**. Pursuant to the rule, the gentleman from Virginia (Mr. **WITTMAN**) and the gentlewoman from California (Mrs. **NAPOLITANO**) each will control 20 minutes.

The Chair recognizes the gentleman from Virginia.

GENERAL LEAVE

Mr. **WITTMAN**. Mr. Speaker, I ask unanimous consent that all Members may have 5 legislative days to revise and extend their remarks and include extraneous materials on the bill under consideration.

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

There was no objection.

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

Mr. Speaker, this legislation, which I sponsored, would make permanent the ability of a migratory waterfowl hunter to electronically purchase their annual Federal duck stamp.

For the past 6 years, eight States have participated in a pilot effort, and by all accounts this program has been a huge success. Many Americans have been able to enjoy the convenience of using their own personal computer to purchase a Federal duck stamp online and in some cases to obtain that required document the evening before a duck hunt. Mr. Speaker, I can tell you from experience and knowing that people want that opportunity, that that timeliness is a factor in people being able to enjoy waterfowl hunting.

In August 2011, the U.S. Fish and Wildlife Service submitted a report to Congress which stipulated that the E-Duck stamp program has proven to be a practical method that is readily accepted by the stamp-buying public. E-stamps now account for more than 20 percent of all duck stamp sales, which demonstrates widespread acceptance of this sales option.

As vice chair of the Congressional Sportsmen's Caucus, I can proudly say that this legislation is important to waterfowl hunters across the country. H.R. 1206 is supported by the Congressional Sportsmen's Foundation and Ducks Unlimited. I would also like to thank and acknowledge Representative **RON KIND** as an original cosponsor of this bill. The gentleman from Wisconsin is a dedicated conservationist, an avid outdoorsman, and a longtime supporter and friend to sportsmen.

There is no cost to the taxpayers, and there is broad bipartisan support for this innovative idea, and this convenient 21st-century delivery system will be utilized by thousands of American sportsmen in the future.

Allowing the purchase of duck stamps online is an important technological advancement, and it is time to make this a permanent feature of Federal law. During the last Congress, an identical bill passed the House by a

vote of 373–1. I urge adoption of this measure.

I reserve the balance of my time.

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

(Mrs. NAPOLITANO asked and was given permission to revise and extend her remarks.)

Mrs. NAPOLITANO. Mr. Speaker, H.R. 1206 would allow the Secretary of the Interior to continue the sale of electronic duck stamps and also expands the program to include all of our 50 States.

The Migratory Bird Hunting and Conservation Stamp, commonly known and called the “duck stamp,” must be purchased and carried by all waterfowl hunters 16 years and older when hunting migratory waterfowl on both public and private land.

Ninety-eight cents of every dollar generated by the sales of these stamps go to purchase or lease wetland habitat for the National Wildlife Refuge system, which benefits waterfowl. In some rural areas, purchasing the duck stamp can be very difficult. Often, hunters have to wait a significant amount of time to receive their official duck stamp, so utilizing the system of electronic duck stamp producing would eliminate the wait by issuing an electronic stamp with a unique identifying number to serve as a proof of purchase. Hunters can hunt and use the electronic stamp for 45 days until the actual duck stamp arrives via the postal service.

This is a worthwhile piece of legislation, and I reserve the balance of my time.

Mr. WITTMAN. Mr. Speaker, may I inquire if the minority has any more speakers.

Mrs. NAPOLITANO. No, sir, not on this bill.

Mr. WITTMAN. With that, Mr. Speaker, I yield back the balance of my time.

Mrs. NAPOLITANO. I yield back the balance of my time, sir.

Mr. KIND. Mr. Speaker, I rise today to show my strong support for the Permanent Electronic Duck Stamp Act of 2013, H.R. 1206. I want to thank my coauthor and friend, ROB WITTMAN, for his dedication to getting this important legislation passed. In the 109th Congress, I authored legislation that created a pilot program for selling duck stamps electronically. The legislation passed with wide bipartisan support and the Electronic Duck Stamp program went on to become one of the most successful conservation programs in our history.

Since the beginning of duck stamp sales in 1934, the stamps have generated more than \$750 million used to purchase more than 5.3 million acres of waterfowl habitat. In Wisconsin alone, 6.78 million duck stamps have been sold thereby conserving numerous acres for waterfowl, birds, reptiles, mammals, fish, and amphibians. In addition to the benefits of conservation for wildlife, the habitats preserved give hunters and nature enthusiasts places to enjoy hiking, hunting, and animals watching. Additionally, these wetlands naturally purify

water supplies, keep flood lands, and help decrease soil erosion.

The Electronic Duck Stamp is terribly important to the district I represent in Wisconsin, which is home to three wildlife refuges. Almost the entire west side of my district is a refuge—the Upper Mississippi River Wildlife & Fish Refuge which is visited by 4 million people every year, more than Yellowstone. I want to urge my colleagues to support this common-sense yet vital legislation. I look forward to working toward getting this bill through the Senate and signed into law this year.

The SPEAKER pro tempore. The question is on the motion offered by the gentleman from Virginia (Mr. WITTMAN) that the House suspend the rules and pass the bill, H.R. 1206.

The question was taken.

The SPEAKER pro tempore. In the opinion of the Chair, two-thirds being in the affirmative, the ayes have it.

Mr. WITTMAN. Mr. Speaker, on that I demand the yeas and nays.

The yeas and nays were ordered.

The SPEAKER pro tempore. Pursuant to clause 8 of rule XX, further proceedings on this motion will be postponed.

□ 1710

SAN ANTONIO MISSIONS NATIONAL HISTORICAL PARK BOUNDARY EXPANSION ACT OF 2013

Mr. WITTMAN. Mr. Speaker, I move to suspend the rules and pass the bill (H.R. 885) to expand the boundary of San Antonio Missions National Historical Park, to conduct a study of potential land acquisitions, and for other purposes, as amended.

The Clerk read the title of the bill.

The text of the bill is as follows:

H.R. 885

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 “San Antonio Missions National Historical Park Boundary Expansion Act of 2013”.

SEC. 2. BOUNDARY EXPANSION.

Section 201(a) of Public Law 95–629 (16 U.S.C. 410ee(a)) is amended—

(1) by striking “In order” and inserting “(1) In order”;

(2) by striking “The park shall also” and inserting the following:

“(2) The park shall also”;

(3) by striking “After advising the” and inserting the following:

“(5) After advising the”.

(4) by inserting after paragraph (2) (as so designated by paragraph (2)) the following:

“(3) The boundary of the park is further modified to include approximately 137 acres, as depicted on the map titled ‘San Antonio Missions National Historical Park Proposed Boundary Addition’, numbered 472/113,006A, and dated June 2012. The map shall be on file and available for inspection in the appropriate offices of the National Park Service, U.S. Department of the Interior.

“(4) The Secretary may not acquire by condemnation any land or interest in land within the boundaries of the park. The Secretary is authorized to acquire land and interests in land that are within the boundaries of the park pursuant to paragraph (3) by donation or exchange

only (and in the case of an exchange, no payment may be made by the Secretary to any landowner). No private property or non-Federal public property shall be included within the boundaries of the park without the written consent of the owner of such property. Nothing in this Act, the establishment of the park, or the management plan of the park shall be construed to create buffer zones outside of the park. That an activity or use can be seen or heard from within the park shall not preclude the conduct of that activity or use outside the park.”.

The SPEAKER pro tempore. Pursuant to the rule, the gentleman from Virginia (Mr. WITTMAN) and the gentleman from California (Mrs. NAPOLITANO) each will control 20 minutes.

The Chair recognizes the gentleman from Virginia.

GENERAL LEAVE

Mr. WITTMAN. Mr. Speaker, I ask unanimous consent that all Members may have 5 legislative days to revise and extend their remarks and include extraneous materials on the bill under consideration.

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

There was no objection.

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

Mr. Speaker, H.R. 885 will expand the San Antonio Missions National Historical Park to include an additional 137 acres. Each of these 137 acres is currently owned and being managed by the National Park Service, so additional operating costs will be minimal, if there are any at all.

The Natural Resources Committee amended H.R. 885 to further control costs by requiring that any property acquired through this legislation be only by donation or exchange, and condemnation is explicitly prohibited. Additional property rights provisions require written consent of property owners before their land can be included in the boundaries of the park, and the creation of buffer zones around the park is forbidden.

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

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

I rise in strong support of H.R. 885, the San Antonio Missions National Historical Park Boundary Expansion Act 2013. Being a born-and-raised Texan, this is a very dear to my heart issue.

I do want to thank Congressman LLOYD DOGGETT and the entire bipartisan San Antonio delegation for pushing this very important piece of legislation forward. This is the third time the House has considered legislation to expand the San Antonio Missions. Hopefully, the third time will be the charm.

Currently, there are 137 acres of land managed by the National Park Service that are not part of the existing San Antonio Missions National Historical Park. Expanding the boundaries of the park will ensure that these cultural and archaeological resources are protected.

Mr. DOGGETT has been involved with this legislation since the proposal first came before us several years ago—I'm not sure when. Though I know that he would have preferred a broader bill that included a study of the additional potential park areas, I thoroughly appreciate his efforts to work with our Republican colleagues to obtain a bill that they can support.

It's a very unique place, and I can appreciate Mr. DOGGETT's commitment to getting this legislation approved, and I look forward to working with him on this.

Again, this is a very important bill for Texans, and I urge your support.

I reserve the balance of my time.

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

Mrs. NAPOLITANO. Mr. Speaker, I yield as much time as he may consume to the sponsor of this piece of legislation, the gentleman from Texas (Mr. LLOYD DOGGETT).

Mr. DOGGETT. Thank you to my colleague from California, who has ties directly to San Antonio and appreciates the importance of this legislation.

I do rise in support of the San Antonio Missions National Historic Park Boundary Expansion Act, a measure that has enjoyed the support of all of the members of the Texas delegation who represent a part of Bexar County. The bill does expand the park by 137 acres.

The Spanish Missions in San Antonio are truly a unique treasure—for us as Texans, and for all Americans. The Missions National Historic Park preserves the largest collection of Spanish colonial resources anywhere in the United States. It's an educational, historical, and cultural resource that each year is bringing over a million people to enjoy and learn from it.

The park is important to the understanding of Texas and the development of the United States and, of course, it has a significant impact on San Antonio and Bexar County economically.

In his famous "San Antonio Rose," Bob Wills sung of the Alamo and "old San Antonio." And most people do associate San Antonio with the Alamo, a landmark of Texas independence. But in addition to the Alamo, there are five remaining Spanish Missions in San Antonio.

The Alamo lies just north of these four missions that compose the Missions National Historical Park. All of them date back to the 1600s, 1700s, the oldest one to 1690, and they were built when the first of six flags flew over Texas, as Spanish colonialists settled San Antonio, then on the frontier with the Comanches and Apaches.

The missions reached out to a number of local Native American tribes, teaching them trades and crafts. The missions do reflect the original "old San Antonio."

Thanks to the leadership of Bexar County Judge Nelson Wolff, there's now a great new Mission Reach Trail that connects from near the Alamo to

all four missions within the park. It's possible to walk or cycle that trail along the San Antonio River, from the excitement of downtown, first to Mission Concepcion.

Next up is the larger Mission San Jose, site of so many gatherings. Recently, I joined Father Tony Posadas, Andrew Anguiano, Neighborhood Association President Armando Cortez and thousands of people who gathered there for the annual Mission Fest.

Nearby is Mission San Juan Capistrano, a very narrow white stucco building, beautiful with its simplicity. Archbishop Gustavo Garcia-Siller, Father David Garcia and Father Jim Galvin recently reopened that mission after an impressive and complex restoration effort. Each of these missions is a working parish church, relying on their parishioners, and fully restored thanks to the leadership of Father Garcia.

Working closely with him is a group called Los Compadres, a group of committed citizens who've raised over \$1 million for the continued restoration and preservation of the missions, led by Pamela Bain and Executive Director Susan Chandoha. Their annual Music Under the Stars concert at Mission San Jose is a great way to experience the park.

And thanks to the leadership of State Representative Joe Farias, park visitors also benefit now from a newly dedicated Veterans Memorial Bridge in the historic Bergs Mill area.

The last of the missions, or the first when it comes to our colleague, Congressman GALLEGRO, is Mission Espada, and he'll have more to say about it, a very important part of the park.

Among the many community partners who've joined with us in the delegation for park expansion are Susan Snow, the World Heritage coordinator of the National Park Service; Suzanne Dixon, with the National Parks Conservation Association; Bexar County Commissioners Tommy Adkisson and Chico Rodriguez; Shannon Miller, with the city's Historic Preservation Office; Suzanne Scott, with the River Authority; and Marco Barros, with the San Antonio Tourism Council. They're making the missions even more accessible and enjoyable for both neighbors and tourists.

One economic study has recently concluded that the park is already supporting almost \$100 million in annual economic activity and over 1,100 jobs. With the completion of initiatives associated with this park expansion, the missions can more than double their economic impact in San Antonio.

In addition to the bill that we have here today, it is very important that we achieve our Quest for World Heritage Status for the missions. About a year ago this week, then-Secretary of the Interior Ken Salazar announced that the Department of the Interior had officially authorized the Spanish Missions for nomination to the UNESCO World Heritage List.

Another economic study has found that that World Heritage status for this expanded park could yield over \$500 million for the San Antonio area within a decade of the World Heritage status.

Unfortunately, because the United States is not paying its dues to UNESCO, which funds the World Heritage Committee, our application could be hampered. I hope that obstacle can be overcome by the time next year that there's a formal submission of this application.

I'm hopeful that by passing this bill relatively early in this Congress that the Senate will finally be able to move it and have ample time to consider it.

Frankly, as my colleague Mrs. NAPOLITANO pointed out, I would have liked to have achieved more today. There are other lands in Bexar and Wilson County with historic ties to the mission that should really be a part of this park. I know the Wilson County part is of particular importance to Congressman CUELLAR. But after so many years of failed attempts to secure this legislation, it's better to move forward together and achieve what is possible today.

So together, I believe we are taking constructive steps forward to enhance a national treasure. Our action is not only about preserving culture but about promoting jobs. This park expansion provides another good reason for family vacations and national conventions to take the "road to San Antonio."

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

Mrs. NAPOLITANO. Mr. Speaker, how much time is left?

The SPEAKER pro tempore. The gentleman from California has 12½ minutes remaining.

Mrs. NAPOLITANO. I yield 3 minutes to the gentleman from Texas (Mr. GALLEGRO).

□ 1720

Mr. GALLEGRO. I'd like to thank Chairman HASTINGS and the ranking member for their work on this vital piece of legislation.

I'm proud to be an original cosponsor of the San Antonio Missions National Historical Park Boundary Expansion Act of 2013. This bill would expand the boundaries of the San Antonio Missions National Historical Park, including the Espada Mission in the 23rd District.

Originally, the Espada Mission was the front door. It was the mission in San Antonio that grew the food that raised the cattle that fed the rest of the missions. It's the only mission that still retains its original property. This is a great opportunity for the redevelopment on the south side of San Antonio.

Texas' missions are inextricably part of our culture, our heritage, and our history. Like the families of their founders, the missions can trace their history back to decades before the

United States ever claimed its independence. All four of the missions, as Congressman DOGGETT has said, are within several miles of each other. Individually, they're marvels of architecture and history. Together, they're an incomparable treasure, allowing each of us the opportunity to come face-to-face with our Nation's proud past. Enacting this legislation is critical to the completion of the world-famous San Antonio Mission Trail, which is a national example of public and private cooperation. The community needs the resources and the expertise of the National Park Service. Yet the National Park Service could not operate without the investment of time and money by the local community.

As the Congressman who represents the Espada Mission—and as a personal fan of the missions and their history—I believe the National Park Service, the city of San Antonio, and the county of Bexar, will benefit historically and economically with the passage of this act. It's very rare that we can protect key areas, preserve history, and create jobs all at the same time. Expanding the mission boundaries will do all of that—and much more.

I encourage my colleagues to support and pass this bill.

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

Mrs. NAPOLITANO. I yield 3 minutes to the gentleman from Texas (Mr. CUELLAR).

Mr. CUELLAR. I want to thank the gentlewoman from California and also the chairman.

Mr. Speaker, I also rise to encourage my colleagues to support the San Antonio Missions National Historical Park Boundary Expansion Act. I want to thank in particular my colleague, Representative LLOYD DOGGETT, who's taken the leadership on this particular bill, along with the entire San Antonio delegation of Congressman GALLEGU, Congressman CASTRO, and Congressman LAMAR SMITH, all working in a bipartisan way to make sure that this legislation passes.

The San Antonio Missions are a crucial piece of history to the State of Texas, and we have to make sure that the National Park Service has the ability to make needed improvements to the park and the ability to expand the areas under its protection. The lands operated by the National Park Service reflect our Nation's historical treasures and tell the story of our country, and it's important that Texas' history is preserved and included among them.

The San Antonio Missions National Historical Park is the home to four Spanish frontier missions first established in the 1600s. The Park was established by the National Park Service in 1975. However, over the past 37 years, the needs and the scope of the park require this legislation.

This bill would authorize the transfer of 137 acres by the San Antonio River Authority, Bexar County, and the city of San Antonio, to the National Park

Service. This land transfer will allow for the expansion of Missions Park, which I used to represent some time ago. Again, it's needed to ensure that these parks are accessible and serving the public to the fullest extent possible.

I'm proud to have this legislation considered today, as we must preserve our Nation's treasures for many years. I know the park missing is in Wilson County. We're hoping that we can continue to work to make sure that we include that sometime in the future, but we must continue working together now.

I urge all my colleagues to vote "yes" on this bill.

Mr. WITTMAN. Mr. Speaker, I'd like to advise the gentlelady from California that I have no other speakers and am prepared to yield back the balance of my time if she is prepared to close.

Mrs. NAPOLITANO. I do urge my colleagues to support this legislation. It is critical to help Texas preserve such a national treasure that all of us have seen in the movies and heard about and read about.

I yield back the balance of my time.

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

Mr. SESSIONS. Mr. Speaker, I rise to congratulate the bi-partisan effort that took place here today to resurrect a piece of legislation that is very important to San Antonio, Texas and to our national heritage.

Last Congress my good friend and our former colleague, Mr. Canseco of San Antonio, worked diligently for over a year to craft this legislation only to see its success thwarted at the last minute by our colleagues in the United States Senate.

I want to thank Mr. DOGGETT for not letting this issue go away and helping to fulfill Mr. Canseco's vision for San Antonio and for the protection of such a historical landmark in Texas.

I am proud to stand today and support this bill, which most of us voted for last year, so that we may see through the vision Mr. Canseco had for the San Antonio Missions National Park.

The SPEAKER pro tempore. The question is on the motion offered by the gentleman from Virginia (Mr. WITTMAN) that the House suspend the rules and pass the bill, H.R. 885, as amended.

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

The title was amended so as to read: "A bill to expand the boundary of the San Antonio Missions National Historical Park, and for other purposes."

A motion to reconsider was laid on the table.

AUTHORIZING THE IMPLEMENTATION OF CERTAIN SANCTIONS SET FORTH IN THE IRAN FREEDOM AND COUNTER-PROLIFERATION ACT OF 2012 AND ADDITIONAL SANCTIONS WITH RESPECT TO IRAN—MESSAGE FROM THE PRESIDENT OF THE UNITED STATES (H. DOC. NO. 113-32)

The SPEAKER pro tempore laid before the House the following message from the President of the United States; which was read and referred to the Committee on Foreign Affairs and ordered to be printed:

To the Congress of the United States:

Pursuant to the International Emergency Economic Powers Act (50 U.S.C. 1701 *et seq.*) (IEEPA), I hereby report that I have issued an Executive Order (the "order") that takes additional steps with respect to the national emergency declared in Executive Order 12957 of March 15, 1995, and implements certain statutory requirements of the Iran Freedom and Counter-Proliferation Act of 2012 (subtitle D of title XII of Public Law 112-239) (22 U.S.C. 8801 *et seq.*) (IFCA), which amends the Comprehensive Iran Sanctions, Accountability, and Divestment Act of 2010 (Public Law 111-195) (22 U.S.C. 8501 *et seq.*) (CISADA).

In Executive Order 12957, the President found that the actions and policies of the Government of Iran threaten the national security, foreign policy, and economy of the United States. To deal with that threat, the President declared a national emergency and imposed prohibitions on certain transactions with respect to the development of Iranian petroleum resources. To further respond to that threat, Executive Order 12959 of May 6, 1995, imposed comprehensive trade and financial sanctions on Iran. Executive Order 13059 of August 19, 1997, consolidated and clarified the previous orders. To take additional steps with respect to the national emergency declared in Executive Order 12957 and to implement section 105(a) of CISADA, I issued Executive Order 13553 on September 28, 2010, to impose sanctions on officials of the Government of Iran and other persons acting on behalf of the Government of Iran determined to be responsible for or complicit in certain serious human rights abuses.

To take additional steps with respect to the threat posed by Iran and to provide implementing authority for a number of the sanctions set forth in the Iran Sanctions Act of 1996 (Public Law 104-172) (50 U.S.C. 1701 note) (ISA), as amended by CISADA, I issued Executive Order 13574 on May 23, 2011, to authorize the Secretary of the Treasury to implement certain sanctions imposed by the Secretary of State pursuant to ISA, as amended by CISADA. I also issued Executive Order 13590 on November 20, 2011, to take additional steps with respect to this emergency by authorizing the Secretary of State

to impose sanctions on persons providing certain goods, services, technology, or support that contribute either to Iran's development of petroleum resources or to Iran's production of petrochemicals, and to authorize the Secretary of the Treasury to implement some of those sanctions. On February 5, 2012, in order to take further steps pursuant to this emergency, and to implement section 1245(c) of the National Defense Authorization Act for Fiscal Year 2012 (Public Law 112-81) (22 U.S.C. 8513a), I issued Executive Order 13599 blocking the property of the Government of Iran, all Iranian financial institutions, and persons determined to be owned or controlled by, or acting for or on behalf of, such parties. On April 22, 2012, and May 1, 2012, I issued Executive Orders 13606 and 13608, respectively. Executive Orders 13606 and 13608 each take additional steps with respect to various emergencies, including the emergency declared in Executive Order 12957 concerning Iran, to address the use of computer and information technology to commit serious human rights abuses and efforts by foreign persons to evade sanctions.

To take additional steps with respect to the national emergency declared in Executive Order 12957, I issued Executive Order 13622 of July 30, 2012, imposing further sanctions in light of the Government of Iran's use of revenues from petroleum, petroleum products, and petrochemicals for illicit purposes; Iran's continued attempts to evade international sanctions through deceptive practices; and the unacceptable risk posed to the international financial system by Iran's activities.

Most recently, I issued Executive Order 13628 of October 9, 2012, to take additional steps with respect to the national emergency declared in Executive Order 12957 and to implement certain statutory requirements of the Iran Threat Reduction and Syria Human Rights Act of 2012 (Public Law 112-158) (22 U.S.C. 8701 *et seq.*) (TRA), including its amendments to the statutory requirements of ISA and CISADA.

With respect to the order that I have just issued, section 1 of the order authorizes the Secretary of the Treasury, in consultation with the Secretary of State, to impose financial sanctions on or to block all property and interests in property that are in the United States, that come within the United States, or that are or come within the possession or control of any United States person (including any foreign branch) of a foreign financial institution determined to have, on or after the effective date of the order:

knowingly conducted or facilitated any significant transaction related to the purchase or sale of Iranian rials or a derivative, swap, future, forward, or other similar contract whose value is based on the exchange rate of the Iranian rial; or

maintained significant funds or accounts outside the territory of Iran denominated in the Iranian rial.

Section 2 of the order authorizes the Secretary of the Treasury, in consulta-

tion with the Secretary of State, to block all property and interests in property that are in the United States, that come within the United States, or that are or come within the possession or control of any United States person (including any foreign branch) of any person upon determining:

that the person has materially assisted, sponsored, or provided financial, material, or technological support for, or goods or services to or in support of, any Iranian person included on the list of Specially Designated Nationals and Blocked Persons maintained by the Office of Foreign Assets Control (SDN List) (other than an Iranian depository institution whose property and interests in property are blocked solely pursuant to Executive Order 13599) or any other person included on the SDN List whose property and interests in property are blocked pursuant to this paragraph or Executive Order 13599 (other than an Iranian depository institution whose property and interests in property are blocked solely pursuant to Executive Order 13599); or

pursuant to authority delegated by the President and in accordance with the terms of such delegation, that sanctions shall be imposed on such person pursuant to section 1244(c)(1)(A) of IFCA.

Section 3 of the order authorizes the Secretary of the Treasury, in consultation with the Secretary of State, to impose financial sanctions on a foreign financial institution determined to have knowingly conducted or facilitated any significant financial transaction:

on behalf of any Iranian person included on the SDN List (other than an Iranian depository institution whose property and interests in property are blocked solely pursuant to Executive Order 13599) or any other person included on the SDN List whose property and interests in property are blocked pursuant to subsection 2(a)(i) of the order or Executive Order 13599 (other than an Iranian depository institution whose property and interests in property are blocked solely pursuant to Executive Order 13599); or

on or after the effective date of the order, for the sale, supply, or transfer to Iran of significant goods or services used in connection with the automotive sector of Iran.

Section 5 of the order authorizes the Secretary of State, in consultation with the Secretary of the Treasury, the Secretary of Commerce, the Secretary of Homeland Security, and the United States Trade Representative, and with the President of the Export-Import Bank, the Chairman of the Board of Governors of the Federal Reserve System, and other agencies and officials as appropriate, to impose sanctions on a person upon determining that the person:

on or after the effective date of the order, knowingly engaged in a significant transaction for the sale, supply, or transfer to Iran of significant goods or services used in connection with the automotive sector of Iran;

is a successor entity to a person determined to meet that criterion;

owns or controls a person determined to meet that criterion, and had knowledge that the person engaged in the activities referred to therein; or

is owned or controlled by, or under common ownership or control with, a person determined to meet that criterion, and knowingly participated in the activities therein.

Sections 6 and 7 of the order provide that, for persons determined to meet any of these criteria, the heads of the relevant agencies, in consultation with the Secretary of State, shall implement the sanctions imposed by the Secretary of State. Those sanctions may include the following actions:

the Board of Directors of the Export-Import Bank shall deny approval of the issuance of any guarantee, insurance, extension of credit, or participation in an extension of credit in connection with the export of any goods or services to the sanctioned person;

agencies shall not issue any specific license or grant any other specific permission or authority under any statute that requires the prior review and approval of the United States Government as a condition for the export or reexport of goods or technology to the sanctioned person;

for a sanctioned person that is a financial institution: the Chairman of the Board of Governors of the Federal Reserve System and the President of the Federal Reserve Bank of New York shall take such actions as they deem appropriate, including denying designation, or terminating the continuation of any prior designation of, the sanctioned person as a primary dealer in United States Government debt instruments; or agencies shall prevent the sanctioned person from serving as an agent of the United States Government or serving as a repository for United States Government funds;

agencies shall not procure, or enter into a contract for the procurement of, any goods or services from the sanctioned person;

the Secretary of State shall deny a visa to, and the Secretary of Homeland Security shall exclude from the United States, any alien that the Secretary of State determines is a corporate officer or principal of, or a shareholder with a controlling interest in, a sanctioned person;

the heads of the relevant agencies, as appropriate, shall impose on the principal executive officer or officers, or persons performing similar functions and with similar authorities, of a sanctioned person any of the sanctions described above, as selected by the Secretary of State;

the Secretary of the Treasury shall take actions where necessary to:

prohibit any United States financial institution from making loans or providing credits to the sanctioned person totaling more than \$10,000,000 in any 12-month period, unless such person is engaged in activities to relieve human suffering and the loans or credits are provided for such activities;

prohibit any transactions in foreign exchange that are subject to the jurisdiction of the United States and in which the sanctioned person has any interest;

prohibit any transfers of credit or payments between financial institutions or by, through, or to any financial institution, to the extent that such transfers or payments are subject to the jurisdiction of the United States and involve any interest of the sanctioned person;

block all property and interests in property that are in the United States, that come within the United States, or that are or come within the possession or control of any United States person, (including any foreign branch) of the sanctioned person, and provide that such property and interests in property may not be transferred, paid, exported, withdrawn, or otherwise dealt in;

prohibit any United States person from investing in or purchasing significant amounts of equity or debt instruments of a sanctioned person;

restrict or prohibit imports of goods, technology, or services, directly or indirectly, into the United States from the sanctioned person; or

impose on the principal executive officer or officers, or persons performing similar functions and with similar authorities, of a sanctioned person any of the sanctions described above, as appropriate.

Section 7 of the order also provides that, when the Secretary of State or the Secretary of the Treasury pursuant to authority delegated by the President and in accordance with the terms of such delegation, has determined that sanctions shall be imposed on a person pursuant to sections 1244(d)(1)(A), 1245(a)(1), or 1246(a)(1) of IFCA (including in each case as informed by section 1253(c)(2) of IFCA), such Secretary may select one or more of the sanctions described above for which the Secretary of the Treasury shall take such action, and the Secretary of the Treasury shall take actions where necessary to implement those sanctions.

Sections 8 and 11 of the order implement the statutory requirements of CISADA, as amended by section 1249 of IFCA. They authorize the Secretary of the Treasury to block all property and interests in property that are in the United States, that come within the United States, or that are or come within the possession or control of any United States person (including any foreign branch), and the Secretary of State to suspend entry into the United States, of persons determined by the Secretary of the Treasury, in consultation with or at the recommendation of the Secretary of State:

to have engaged, on or after January 2, 2013, in corruption or other activities relating to the diversion of goods, including agricultural commodities, food, medicine, and medical devices, intended for the people of Iran;

to have engaged, on or after January 2, 2013, in corruption or other activities relating to the misappropriation of proceeds from the sale or resale of goods described above;

to have materially assisted, sponsored, or provided financial, material, or technological support for, or goods or services to or in support of, the activities described above or any person whose property and interests in property are blocked pursuant to these provisions; or

to be owned or controlled by, or to have acted or purported to act for or on behalf of, directly or indirectly, any person whose property and interests in property are blocked pursuant to these provisions.

I have delegated to the Secretary of the Treasury the authority, in consultation with the Secretary of State, to take such actions, including the promulgation of rules and regulations, and to employ all powers granted to the President by IEEPA, as may be necessary to carry out the purposes of the order, other than the purposes described in sections 5, 6, and 11 of the order. All agencies of the United States Government are directed to take all appropriate measures within their authority to carry out the provisions of the order.

The order, a copy of which is enclosed, becomes effective at 12:01 a.m. eastern daylight time on July 1, 2013.

BARACK OBAMA.

THE WHITE HOUSE, June 3, 2013.

RECESS

The SPEAKER pro tempore. Pursuant to clause 12(a) of rule I, the Chair declares the House in recess until approximately 6:30 p.m. today.

Accordingly (at 5 o'clock and 29 minutes p.m.), the House stood in recess.

□ 1830

AFTER RECESS

The recess having expired, the House was called to order by the Speaker pro tempore (Mr. MILLER of Florida) at 6 o'clock and 30 minutes p.m.

ANNOUNCEMENT BY THE SPEAKER PRO TEMPORE

The SPEAKER pro tempore. Pursuant to clause 8 of rule XX, proceedings will resume on motions to suspend the rules previously postponed.

Votes will be taken in the following order: H.R. 1206, by the yeas and nays; and S. 622, by the yeas and nays.

The first electronic vote will be conducted as a 15-minute vote. The remaining electronic vote will be conducted as a 5-minute vote.

PERMANENT ELECTRONIC DUCK STAMP ACT OF 2013

The SPEAKER pro tempore. The unfinished business is the vote on the motion to suspend the rules and pass the bill (H.R. 1206) to grant the Secretary of the Interior permanent authority to authorize States to issue electronic duck stamps, and for other purposes, on which the yeas and nays were ordered.

The Clerk read the title of the bill.

The SPEAKER pro tempore. The question is on the motion offered by the gentleman from Virginia (Mr. WITTMAN) that the House suspend the rules and pass the bill.

The vote was taken by electronic device, and there were—yeas 401, nays 0, not voting 32, as follows:

[Roll No. 184]

YEAS—401

Aderholt	Bishop (NY)	Bustos	Herrera Beutler	Moran
Amash	Bishop (UT)	Butterfield	Higgins	Mullin
Amodei	Black	Calvert	Himes	Mulvaney
Andrews	Blackburn	Camp	Hinojosa	Murphy (FL)
Bachmann	Blumenauer	Cantor	Holding	Murphy (PA)
Bachus	Bonamici	Capito	Holt	Nadler
Barber	Boustany	Capps	Horsford	Napolitano
Barletta	Brady (PA)	Capuano	Hoyer	Negrete McLeod
Barr	Brady (TX)	Carney	Hudson	Neugebauer
Barrow (GA)	Braleley (IA)	Carson (IN)	Huelskamp	Noem
Barton	Bridenstine	Carter	Huffman	Nolan
Bass	Brooks (AL)	Cartwright	Huizenga (MI)	Nugent
Beatty	Brooks (IN)	Castor (FL)	Hultgren	Nunes
Becerra	Brown (GA)	Castro (TX)	Hunter	Nunnelee
Benishek	Brownley (CA)	Chabot	Hurt	O'Rourke
Bentivolio	Buchanan	Chaffetz	Issa	Olson
Bera (CA)	Bucshon	Chu	Jackson Lee	Owens
Bishop (GA)	Burgess	Cicilline	Jeffries	Palazzo
			Jenkins	Pascrell
			Johnson (GA)	Pastor (AZ)
			Johnson (OH)	Paulsen
			Johnson, E. B.	Payne
			Johnson, Sam	Pearce
			Jones	Pelosi
			Jordan	Perlmutter
			Joyce	Perry
			Kaptur	Peters (CA)
			Kelly (IL)	Peters (MI)
			Kelly (PA)	Peterson
			Kennedy	Petri
			Kildee	Pingree (ME)
			Kilmer	Pittenger
			Kind	Pitts
			King (IA)	Pocan
			King (NY)	Poe (TX)
			Kingston	Polis
			Kinzinger (IL)	Pompeo
			Kirkpatrick	Posey
			Kline	Price (GA)
			Kuster	Price (NC)
			Labrador	Quigley
			LaMalfa	Radel
			Lamborn	Rahall
			Lance	Rangel
			Langevin	Reed
			Lankford	Reichert
			Larsen (WA)	Renacci
			Larson (CT)	Ribble
			Latham	Rice (SC)
			Latta	Rigell
			Lee (CA)	Roby
			Levin	Roe (TN)
			Lewis	Rogers (AL)
			Lipinski	Rogers (KY)
			LoBiondo	Rogers (MI)
			Lofgren	Rohrabacher
			Long	Rokita
			Lowenthal	Rooney
			Lowe	Ros-Lehtinen
			Lucas	Roskam
			Luetkemeyer	Ross
			Lujan Grisham (NM)	Rothfus
			Lujan, Ben Ray (NM)	Roybal-Allard
			Lummis	Royce
			Lynch	Ruiz
			Maffei	Runyan
			Maloney, Sean	Ruppersberger
			Marchant	Ryan (OH)
			Marino	Ryan (WI)
			Massie	Salmon
			Matheson	Sánchez, Linda T.
			Matsui	Sanford
			McCarthy (CA)	Sarbanes
			McCaul	Scalise
			McClintock	Schiff
			McCollum	Schneider
			McGovern	Schock
			McHenry	Schwartz
			McIntyre	Schweikert
			McKeon	Scott (VA)
			McKinley	Scott, Austin
			McMorris	Scott, David
			Rodgers	Sensenbrenner
			McNerney	Serrano
			Meadows	Sessions
			Hall	Sewell (AL)
			Meehan	Shea-Porter
			Meeke	Sherman
			Hanabusa	Shuster
			Hanna	Simpson
			Harper	Sinema
			Harris	Sires
			Hartzler	Miller (FL)
			Hastings (FL)	Miller (MI)
			Hastings (WA)	Miller, Gary
			Heck (NV)	Miller, George
			Heck (WA)	Moore
			Heck (WA)	
			Hensarling	

Southerland	Turner	Webster (FL)	Coble	Holt	Nolan	Tierney	Wagner	Williams
Speier	Upton	Welch	Coffman	Horsford	Nugent	Tipton	Walberg	Wilson (FL)
Stewart	Valadao	Wenstrup	Cohen	Hoyer	Nunes	Titus	Walden	Wilson (SC)
Stivers	Van Hollen	Westmoreland	Cole	Hudson	Nunnelee	Tonko	Walorski	Wittman
Stockman	Vargas	Williams	Collins (GA)	Huelskamp	O'Rourke	Tsongas	Walz	Wolf
Stutzman	Veasey	Wilson (FL)	Collins (NY)	Huffman	Olson	Turner	Wasserman	Womack
Swalwell (CA)	Vela	Wilson (SC)	Conaway	Huizenga (MI)	Owens	Upton	Schultz	Woodall
Takano	Velázquez	Wittman	Connolly	Hultgren	Palazzo	Valadao	Waters	Yarmuth
Terry	Visclosky	Wolf	Conyers	Hunter	Pallone	Van Hollen	Waxman	Yoder
Thompson (CA)	Wagner	Womack	Cook	Hurt	Pascarell	Vargas	Weber (TX)	Yoho
Thompson (MS)	Walberg	Woodall	Cooper	Israel	Pastor (AZ)	Veasey	Webster (FL)	Young (AK)
Thompson (PA)	Walden	Yarmuth	Costa	Issa	Paulsen	Vela	Welch	Young (FL)
Thornberry	Walorski	Yoder	Cotton	Jackson Lee	Payne	Velázquez	Wenstrup	Young (IN)
Tiberi	Walz	Yoho	Courtney	Jeffries	Pearce	Visclosky	Westmoreland	
Tierney	Wasserman	Young (AK)	Cramer	Jenkins	Pelosi			
Tipton	Schultz	Young (FL)	Crawford	Johnson (GA)	Perlmutter			
Titus	Waters	Young (IN)	Crenshaw	Johnson (OH)	Perry	Edwards	McCollum	Pingree (ME)
Tonko	Waxman		Crowley	Johnson, E. B.	Peters (CA)	Ellison	McGovern	Pocan
Tsongas	Weber (TX)		Cuellar	Johnson, Sam	Peters (MI)	Lewis	Miller, George	Slaughter
			Culberson	Jones	Peterson	Lofgren	Moore	Speier
			Cummings	Jordan	Petri			
			Daines	Joyce	Pittenger			
			Davis (CA)	Kaptur	Pitts	Alexander	Fattah	McDermott
			Davis, Danny	Keating	Poe (TX)	Bilirakis	Fleischmann	Neal
			DeFazio	Kelly (IL)	Polis	Bonner	Granger	Richmond
			DeGette	Kelly (PA)	Pompeo	Brown (FL)	Grijalva	Rush
			Delaney	Kennedy	Possey	Campbell	Gutierrez	Sanchez, Loretta
			DeLauro	Kildee	Price (GA)	Cárdenas	Honda	Schakowsky
			DelBene	Kilmer	Price (NC)	Cassidy	Loeb sack	Schrader
			Denham	Kind	Quigley	Clarke	Maloney,	Shimkus
			Dent	King (IA)	Radel	Davis, Rodney	Carolyn	Watt
			DeSantis	King (NY)	Rahall	Dingell	Markley	Whitfield
			DesJarlais	Kingston	Rangel	Doyle	McCarthy (NY)	
			Deutch	Kinzinger (IL)	Reed			
			Diaz-Balart	Kirkpatrick	Reichert			
			Doggett	Kline	Renacci			
			Duckworth	Kuster	Ribble			
			Duffy	Labrador	Rice (SC)			
			Duncan (SC)	LaMalfa	Rigell			
			Duncan (TN)	Lamborn	Roby			
			Ellmers	Lance	Roe (TN)			
			Engel	Langevin	Rogers (AL)			
			Enyart	Lankford	Rogers (KY)			
			Eshoo	Larsen (WA)	Rogers (MI)			
			Esty	Larson (CT)	Rohrabacher			
			Farenthold	Latham	Rokita			
			Farr	Latta	Rooney			
			Fincher	Lee (CA)	Ros-Lehtinen			
			Fitzpatrick	Levin	Roskam			
			Fleming	Lipinski	Ross			
			Flores	LoBiondo	Rothfus			
			Forbes	Long	Roybal-Allard			
			Fortenberry	Lowenthal	Royce			
			Foster	Lucas	Ruiz			
			Fox	Luetkemeyer	Runyan			
			Frankel (FL)	Lujan Grisham	Ruppersberger			
			Franks (AZ)	(NM)	Ryan (OH)			
			Frelinghuysen	Luján, Ben Ray	Ryan (WI)			
			Fudge	(NM)	Salmon			
			Gabbard	Lummis	Sánchez, Linda			
			Gallego	Lynch	T.			
			Garamendi	Maffei	Sanford			
			Garcia	Maloney, Sean	Sarbanes			
			Gardner	Marchant	Scalise			
			Garrett	Marino	Schiff			
			Gerlach	Massie	Schneider			
			Gibbs	Matheson	Schock			
			Gibson	Matsui	Schwartz			
			Gingrey (GA)	McCarthy (CA)	Schweikert			
			Gohmert	McCaull	Scott (VA)			
			Goodlatte	McClintock	Scott, Austin			
			Gosar	McHenry	Scott, David			
			Gowdy	McIntyre	Sensenbrenner			
			Graves (GA)	McKeon	Serrano			
			Graves (MO)	McKinley	Sessions			
			Grayson	McMorris	Sewell (AL)			
			Green, Al	Rodgers	Shea-Porter			
			Green, Gene	McNerney	Sherman			
			Griffin (AR)	Meadows	Shuster			
			Griffith (VA)	Meehan	Simpson			
			Grimm	Meeke	Sinema			
			Guthrie	Meng	Sires			
			Hahn	Messer	Smith (NE)			
			Hall	Mica	Smith (NJ)			
			Hanabusa	Michaud	Smith (TX)			
			Hanna	Miller (FL)	Smith (WA)			
			Harper	Miller (MI)	Southerland			
			Harris	Miller, Gary	Stewart			
			Hartzler	Moran	Stivers			
			Hastings (FL)	Mullin	Stockman			
			Hastings (WA)	Mulvaney	Stutzman			
			Heck (NV)	Murphy (FL)	Swalwell (CA)			
			Heck (WA)	Murphy (PA)	Takano			
			Hensarling	Nadler	Terry			
			Herrera Beutler	Napitano	Thompson (CA)			
			Higgins	Negrete McLeod	Thompson (MS)			
			Himes	Neugebauer	Thompson (PA)			
			Hinojosa	Noem	Thornberry			
			Holding		Tiberi			

NOT VOTING—32

Alexander	Fattah	McCarthy (NY)
Bilirakis	Fleischmann	McDermott
Bonner	Granger	Neal
Brown (FL)	Grijalva	Richmond
Campbell	Gutierrez	Rush
Cárdenas	Honda	Sanchez, Loretta
Cassidy	Keating	Schakowsky
Clarke	Loeb sack	Schrader
Davis, Rodney	Maloney,	Shimkus
Dingell	Carolyn	Watt
Doyle	Markley	Whitfield

□ 1854

Mr. BRADY of Pennsylvania changed his vote from “nay” to “yea.”

So (two-thirds being in the affirmative) the rules were suspended and the bill was passed.

The result of the vote was announced as above recorded.

A motion to reconsider was laid on the table.

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

The SPEAKER pro tempore. The unfinished business is the vote on the motion 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, on which the yeas and nays were ordered.

The Clerk read the title of the bill.

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.

This will be a 5-minute vote.

The vote was taken by electronic device, and there were—yeas 390, nays 12, not voting 31, as follows:

[Roll No. 185]

YEAS—390

Aderholt	Bishop (UT)	Calvert
Amash	Black	Camp
Amodel	Blackburn	Cantor
Andrews	Blumenauer	Capito
Bachmann	Bonamici	Capps
Bachus	Boustany	Capuano
Barber	Brady (PA)	Carney
Barletta	Brady (TX)	Carson (IN)
Barr	Braley (IA)	Carter
Barrow (GA)	Bridenstine	Cartwright
Barton	Brooks (AL)	Castor (FL)
Bass	Brooks (IN)	Castro (TX)
Beatty	Broun (GA)	Chabot
Becerra	Brownley (CA)	Chaffetz
Benishek	Buchanan	Chu
Bentivolio	Bucshon	Cicilline
Bera (CA)	Burgess	Clay
Bishop (GA)	Bustos	Cleaver
Bishop (NY)	Butterfield	Clyburn

Davis (CA)	Davis, Danny	DeFazio	DeGette	Delaney	DeLauro	DelBene	Denham	Dent	DeSantis	DesJarlais	Deutch	Diaz-Balart	Doggett	Duckworth	Duffy	Duncan (SC)	Duncan (TN)	Ellmers	Engel	Enyart	Eshoo	Esty	Farenthold	Farr	Fincher	Fitzpatrick	Fleming	Flores	Forbes	Fortenberry	Foster	Fox	Frankel (FL)	Franks (AZ)	Frelinghuysen	Fudge	Gabbard	Gallego	Garamendi	Garcia	Gardner	Garrett	Gerlach	Gibbs	Gibson	Gingrey (GA)	Gohmert	Goodlatte	Gosar	Gowdy	Graves (GA)	Graves (MO)	Grayson	Green, Al	Green, Gene	Griffin (AR)	Griffith (VA)	Grimm	Guthrie	Hahn	Hall	Hanabusa	Hanna	Harper	Harris	Hartzler	Hastings (FL)	Hastings (WA)	Heck (NV)	Heck (WA)	Hensarling	Herrera Beutler	Higgins	Himes	Hinojosa	Holding
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Edwards	McCollum	Pingree (ME)
Ellison	McGovern	Pocan
Lewis	Miller, George	Slaughter
Lofgren	Moore	Speier

NOT VOTING—31

Alexander	Fattah	McDermott
Bilirakis	Fleischmann	Neal
Bonner	Granger	Richmond
Brown (FL)	Grijalva	Rush
Campbell	Gutierrez	Sanchez, Loretta
Cárdenas	Honda	Schakowsky
Cassidy	Loeb sack	Schrader
Clarke	Maloney,	Shimkus
Davis, Rodney	Carolyn	Watt
Dingell	Markley	Whitfield
Doyle	McCarthy (NY)	

□ 1902

Ms. McCOLLUM changed her vote from “yea” to “nay.”

So (two-thirds being in the affirmative) the rules were suspended and the bill was passed.

The result of the vote was announced as above recorded.

A motion to reconsider was laid on the table.

EXPRESSING SORROW OF THE HOUSE AT THE DEATH OF THE HONORABLE FRANK R. LAUTENBERG, A SENATOR FROM THE STATE OF NEW JERSEY

Mr. SMITH of New Jersey. Mr. Speaker, I offer a privileged resolution, and ask for its immediate consideration.

The Clerk read the resolution, as follows:

H. RES. 242

Resolved, That the House has heard with profound sorrow of the death of the Honorable Frank R. Lautenberg, a Senator from the State of New Jersey.

Resolved, That a committee of such Members of the House as the Speaker may designate, together with such Members of the Senate as may be joined, be appointed to attend the funeral.

Resolved, That the Clerk communicate these resolutions to the Senate and transmit a copy thereof to the family of the deceased.

Resolved, That when the House adjourns today, it adjourn as a further mark of respect to the memory of the deceased Senator.

The SPEAKER pro tempore. The gentleman from New Jersey is recognized for 1 hour.

Mr. SMITH of New Jersey. Mr. Speaker and Members of the House, it is my sad duty to inform you that Senator FRANK LAUTENBERG has passed away. He died from complications from viral pneumonia this morning at New York-Presbyterian Hospital. FRANK LAUTENBERG was 89 years old.

I join with my friends and colleagues from our delegation—and, I know, with

the entire House—in expressing our profound sorrow to his family—his wife, Bonnie, his six children, and his 13 grandchildren. Senator LAUTENBERG will be deeply missed.

We will have a Special Order to honor this wonderful man, but just one point: that with his passing he is the last of World War II—of the Greatest Generation—to serve in the United States Senate, and I want everyone to know he will be deeply missed. I, personally, worked very closely with him on a number of issues, in particular on combating anti-Semitism, so I just want to say that we are all in sorrow for his passing. We pray for him and for his family.

I would like to yield to my good friend and colleague from New Jersey (Mr. PALLONE) for any comments he might have.

Mr. PALLONE. I want to thank my colleague.

It's really with a great deal of sadness that we come to the well this evening to announce—or to comment, if you will—on Senator LAUTENBERG's passing.

I really can't imagine the Congress without him. I worked on his campaign from the very first day in 1982, and he was the longest-serving Member of the U.S. Senate from the State of New Jersey in our entire history.

The fact of the matter is that Senator LAUTENBERG was always there for the little guy. Many of you know that he was a wealthy individual, but he never forgot his roots, and they were very humble roots. He always believed that the Congress should be there for people in need and that the American Dream required that everyone had an equal opportunity and that Congress could do things. FRANK LAUTENBERG understood that there were a lot of problems out there, but he felt that Congress needed to work together on a bipartisan basis to solve those problems.

There are so many that I can mention, but I won't. Whether it was the Nation's infrastructure, mass transit, all of the environmental concerns, whether he wanted to clean up the ocean or clean the air or clean the water for the next generation, he really believed that things could get done here, and he worked hard to get things done. We know, more than anybody else, he was able to accomplish a lot because of the hard work that he put into it.

So I just want to thank him for all of that and for his legacy, and I want to express sympathy, obviously, to Bonnie and his family. He will be missed for what he accomplished and also for what he told us about what our job is when we're here—to get things done and to worry about the little guy and to make sure that we are always out there, working every day to make this a better country.

Mr. SMITH of New Jersey. I yield to my colleague from New Jersey (Mr. LANCE).

Mr. LANCE. Thank you, Congressman PALLONE, and thank you, Congressman SMITH, the dean of the delegation.

Senator LAUTENBERG was a tenacious fighter for the 9 million residents of the State of New Jersey, and tenacity was at the heart of his public service. New Jersey is a State that is complex and that is comprised of many different ethnicities, and Senator LAUTENBERG represented all of us extremely well. The only person in history of the State to serve five terms in the United States Senate, Senator LAUTENBERG died with his boots on in the saddle as he would have wished.

He was extremely proud of his roots in Paterson, a great industrial city in this Nation, where he was born and raised; and at age 18 he went off to war, World War II, as one of the Greatest Generation. Senator LAUTENBERG was the beneficiary of the GI Bill of Rights, and he was able to attend Columbia University from which he graduated after the Second World War, and his brilliant career in the private sector at ADP is a hallmark to the entrepreneurial spirit of the American people; but he recognized that he could do more for the people of our State and of the Nation when he was elected to the United States Senate in 1982, reelected in 1988 and reelected again in 1994, a hiatus of 2 years, then elected for a fourth term in 2002, and again for a fifth term in 2008. He was a person of perseverance.

To Mrs. Lautenberg and the Lautenberg children and family, we extend our profound sympathy. The people of New Jersey and, might I suggest, the Nation are saddened by his death.

Mr. SMITH of New Jersey. I yield to the gentleman from New Jersey (Mr. ANDREWS).

Mr. ANDREWS. I thank my friends and colleagues for joining in this moment of solemn remembrance.

There is not a corner of our State that does not bear the manifestation of the greatness of Senator LAUTENBERG's career. Some of the manifestations are functional and somewhat ordinary—bridges and exit ramps—but so many of the things are things of beauty and splendor. This is a person who risked his life for his country in the Second World War and who gave his life to building a successful business and building a great State and a great country.

We are profoundly saddened by his loss, but we are heartened by his example, and I thank all of us on both sides of the aisle for remembering him. Our prayers go to his family, and our thanks go to him for a great life well led.

Mr. SMITH of New Jersey. I yield to the gentleman from New Jersey (Mr. PASCRELL).

Mr. PASCRELL. FRANK LAUTENBERG was my friend for 45 years. We drank the same water in Paterson, New Jersey. He was a person of very small means when you looked at his mom

and dad. They worked in the factories in Paterson, New Jersey, as so many other people did. His father died when he was 43 years of age. He got sick from the jobs that he had when there was no protection for workers, not like it is now.

Now, can you picture this in a garage in Paterson, New Jersey, off of Carroll Street, four guys together, putting a company together, that if you didn't invest in it you kicked yourself after that, ADP?

He had a business acumen, a business sense, that went beyond votes on the floor of the Senate. He was a good guy, and I know that the talking heads would say he was a liberal's liberal. FRANK LAUTENBERG was a very basic, conservative guy when it came to our values in this country. He was not a spectator by any stretch. He was in there. He was in the battle. He came back to School No. 6 on Mercer Street in Paterson to take care of those kids, to give them computers and to say make sure you take care of those computers because this is going to get you, perhaps, on a path to something better in life for you and your family. He didn't forget it. A lot of people say he didn't forget his roots. That's a wave. That's a passing by. He was not that kind of a person.

So, to Bonnie and to his beautiful family, our best, best, deepest feelings of condolences and sorrow.

We don't know what we've lost—we never do—but we pray that everyone begins to understand, at least now, that each of us is significant, that each of us is important and, as FRANK would say, that no one is better than anyone else.

God bless FRANK LAUTENBERG.

Mr. SMITH of New Jersey. I yield to the gentleman from New Jersey (Mr. HOLT).

Mr. HOLT. We mark with sorrow and with admiration the loss of FRANK LAUTENBERG—a loss to Bonnie and his family, a loss to this Congress, a loss to New Jersey, a loss to America.

He served in the Army as a youngster. His father died while he was serving in the Second World War—and “serve” is the right word. He saw service as his duty, as his life—serving other people, never forgetting the common person and the common good. Whether he was working for public health or individual health care or education or was helping prevent bullying in schools or was teaching foreign languages or was providing for safety in chemical plants, he was thinking about the ordinary person. He never forgot that, he never stopped fighting, and the people of New Jersey knew that. They knew they had somebody in the Senate who was looking out for them.

What I think of most is his work that he did on the Transportation Subcommittee about the blood alcohol level and drunk driving. He did more than any other single person in this country to prevent drunk driving. You could fill many football stadiums with

people who are alive today because of FRANK LAUTENBERG. The interesting thing is that not one of them would know who they are.

We have a lot to be grateful for to FRANK LAUTENBERG, and his legacy is something that we should work hard to continue.

Mr. SMITH of New Jersey. I yield to the gentleman from New Jersey (Mr. GARRETT).

Mr. GARRETT. To the dean of the delegation and to the rest of my colleagues from New Jersey, Washington, D.C., the Senate, the Chambers will not be the same without FRANK LAUTENBERG walking about.

He is and he was a man who lived truly an extraordinary life. You've heard of his humble beginnings that BILL, I guess, knows pretty well, of his growing up in that neighborhood and going on to fight through World War II, as LEONARD points out; and of that extraordinary entrepreneurial spirit. In all of those ways, he lived an extraordinary life that left an extraordinary impact upon the people of his community and the State and on all of those people who benefited from his business acumen—to be able to use that service—to the jobs that he provided and then to take that and bring it here to Washington and the benefits that he provided even far beyond his own humble beginnings back in Paterson, New Jersey, but across the country as well.

So we come here today, joined in the thought that our prayers are with him, his family, his children, and grandchildren. We just hope that through this difficult time that they must be going that they can find some solace in the fact that so many people who have come here today and who are back in New Jersey respect him and appreciate him and thank him for what he did for the State.

Mr. SMITH of New Jersey. I yield to the gentleman from New Jersey (Mr. SIRES).

Mr. SIRES. I want to thank my colleagues for being here today and for expressing the sentiment towards a friend.

I knew FRANK LAUTENBERG for a long time. I was a mayor when I first met him. He never changed. He was a fighter. He was a real product of New Jersey in his coming from Paterson, serving in the service, starting a business. He became one of the best Senators we ever had in New Jersey. He was a man who had a vision, because he was one of the first ones who saw that riding on a plane and having somebody smoking next to you was not healthy. FRANK fought that fight, and President Reagan signed it into law.

So, today, New Jersey is sad. It's sad because one of its own is not going to be with us any more. Right down to the end, FRANK fought. I will remember him fighting Governor Christie. I remember him fighting for the tunnel. So we are all sad in New Jersey today.

To the whole family, we extend our condolences.

Mr. SMITH of New Jersey. I yield to the gentleman from New Jersey (Mr. RUNYAN).

Mr. RUNYAN. I, too, want to reflect on all of the kind and gracious words that my colleagues have expressed up here.

I, only being in my second term, can't say that I knew FRANK that well, but I want to point out one thing: that it's unfortunate that sometimes it takes someone's passing to realize all of the great things he did in his life. I've learned in coming here to Washington sometimes that people forget they are people who come here to represent the people back home, and you forget about the good deeds, the hard work. When you look at what FRANK did, working every single day until today, that is something that, I think, we as Americans do—take that work ethic into everything we do every single day. That's what makes us the greatest country in the world.

With FRANK's obviously being that type of role model, I think we are all saddened by his passing. We will miss him. Again, our condolences go out to his family, and I thank you all for taking time out to recognize him as an individual because, I think, sometimes that is lost.

Mr. SMITH of New Jersey. I yield to the gentleman from New Jersey (Mr. PAYNE).

Mr. PAYNE. Thank you to my colleagues from New Jersey and in the House of Representatives.

Once again, I stand here in almost over a year with sorrow in my heart. The New Jersey delegation has lost another great member.

Senator LAUTENBERG had been an example to me over the course of his career. I'd seen him in many instances in Newark and in other settings, and he always had a common message to young people. It was that there was nothing special about me that you could not do this yourself. If you applied yourself in school, worked hard, honored your country, and did the things that were right, one day you could be in this position as well.

FRANK LAUTENBERG embodies what a New Jerseyan is. So look at his career. Look at his life. He is a true New Jerseyan. He will sorely be missed in this delegation, in this House, in this Congress, and in this country. My condolences to his family on this sad occasion.

Mr. SMITH of New Jersey. Mr. Speaker, FRANK LAUTENBERG will be missed. As you could hear from my colleagues on both sides of the aisle, it is a great loss for the State of New Jersey. We will have a Special Order next Tuesday to speak even more to his legacy.

With that, I yield back the balance of my time.

Ms. PELOSI. Mr. Speaker, today, our country mourns the loss of Senator FRANK LAUTENBERG—a man whose life embodied the American Dream and who dedicated his career to putting that dream in reach for all Americans.

The longest-serving senator in New Jersey's history and the last remaining World War II veteran in the Senate, he served us all with the strength, perseverance, and compassion that exemplifies the greatest generation.

A proud son of hard-working immigrants, Senator LAUTENBERG rose from humble beginnings to meet great success in business and public service. He was an entrepreneur who turned a small business into one of the largest computing services companies in the world. He was a soldier who put his life on the line to protect our country. He was a Senator who helped ban smoking in airplanes and around children, who worked to ensure parents could take time off to care for sick family members, who helped modernize the G.I. bill to ensure today's veterans could benefit from the same opportunity that he received.

Senator LAUTENBERG spent each day fighting to protect and improve the health, security, and well-being of every American. His lifetime of service leaves a legacy we must follow, and an expectation we must meet. We only hope it is a comfort to his wife Bonnie, his children and grandchildren that so many mourn their loss at this sad time.

The previous question was ordered.

The resolution was agreed to.

A motion to reconsider was laid on the table.

HONORING THE MEMORY AND SACRIFICE OF FIREFIGHTERS MATTHEW RENAUD, ROBERT BEBEE, ROBERT GARNER, AND ANNE SULLIVAN

(Ms. JACKSON LEE asked and was given permission to address the House for 1 minute and to revise and extend her remarks.)

Ms. JACKSON LEE. Mr. Speaker, I, along with fellow Members of the Texas and Harris County delegation, stand together to honor and recognize the sacrifice of four fallen firefighters who died last Friday, May 31, 2013, in the city of Houston serving in the line of duty.

We offer our heartfelt sympathy to the families and fellow firefighters of those who died and those who were injured.

We are united with the city of Houston in grief over the deaths of Captain EMT Matthew Renaud, Engineer Operator EMT Robert Bebee, Firefighter EMT Robert Garner, and Probationary Firefighter Anne Sullivan, who died last Friday while searching a blazing hotel and restaurant for possible trapped victims.

In the 118-year history of the Houston City Fire Department, this was the greatest loss of life of their members while on duty. Their heroism will not be soon forgotten nor their sacrifice dimmed by time.

In the Firemen's Creed, these words are heard loudly:

But, above all, our proudest endeavor is to save lives of men, the work of God, Himself.

We ask that our colleagues join us now in a moment of silence in their memory.

Mr. Speaker, we wish all firefighters injured last Friday a speedy recovery.

Mr. Speaker, I along with fellow members of the Harris County Delegation stand together to honor and recognize the sacrifice of four fallen Firefighters who died last Friday, May 31, 2013 in the City of Houston, Texas serving in the line of duty.

We offer our heartfelt sympathy to the families and fellow firefighters of those who died.

We are united with the City of Houston in grief over the deaths of Captain EMT Matthew Renaud, Engineer Operator EMT Robert Bebee, Firefighter EMT Robert Garner and Probationary Firefighter Anne Sullivan who died on Friday, while searching a blazing hotel and restaurant for possible trapped victims.

In the 118 year history of the Houston City Fire Department this was the greatest loss of life of their members while on duty. Their heroism will not be soon forgotten nor their sacrifice dimmed by time.

EXCERPTS FROM THE FIREMEN'S CREED

I have no ambition in this world but one and that is to be a fireman . . . We strive to preserve from destruction the wealth of the world . . . We are the defenders from fire . . . But, above all, our proudest endeavor is to save lives of men, the work of GOD himself.

We ask that our colleagues join us in a moment of silence in their memory.

We wish a speedy recovery for all those firefighters injured during Friday's tragedy.

MENTAL HEALTH TREATMENT

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

Mr. THOMPSON of Pennsylvania. Mr. Speaker, today the White House held a conference on mental health and the importance of removing the stigma associated with seeking mental health treatment. The conference dovetailed with an announcement by the Department of Veterans Affairs that it had met its goal to hire 1,600 new mental health professionals.

Despite the positive news from the VA, the President appropriately stated:

It's not enough to help more Americans seek treatment. We also have to make sure the treatment is there when they are ready to seek it.

I could not agree more, for a major barrier for individuals seeking care is not just access, but the stigma that is oftentimes associated with seeking professional help—especially for our veteran population.

Thankfully, there is more we can do.

I encourage my colleagues to learn more about H.R. 2001, the Veterans E-Health & Telemedicine Support Act. This bipartisan, no-cost bill expands the number of qualified providers servicing our veteran population and also helps remove the stigma associated with seeking treatment through the expansion of telemedicine at the VA.

CONGRATULATING MARK CROGHAN

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

Mr. SWALWELL of California. I rise today to recognize Mark Croghan, the longest serving school administrator from Castro Valley Unified School District, which is in my district, who will be retiring this year after 27 years of service in the East Bay.

Mark was raised and educated in Hayward, California. After a swimming career at Hayward High School, he earned a swimming scholarship to attend the University of California at Berkeley, where he received his college degree.

Mark began a long teaching career after college. He taught kids both in and out of the classroom, coaching a variety of sports, including swimming, basketball, softball, and he even served as the advisor for the ski team.

After receiving his master's degree in 1993, Mark began his administrative career as an assistant principal of Canyon Middle School in Castro Valley. Since then, Mark has served as a principal at both Marshall Elementary and Canyon Middle School.

Over his career as an administrator, Mark has created a positive learning environment and has prioritized the needs of students and their families. His leadership surely will be missed.

But if Mark's past service is any evidence of what to expect of him in the future, surely we have a lot in store for what his public service will bring to our community.

I wish Mark the best in his retirement. It is well earned.

□ 1930

LINE DANCING AT THE IRS

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

Mr. POE of Texas. Mr. Speaker, the taxman has gone wild. The IRS spent \$50 million on boondoggle conferences. At one conference, the agency declined the cheaper government group rate and instead opted for perks including stays at swanky presidential suites, free drinks, and high-dollar tickets to the L.A. Angels baseball game. Now, isn't that lovely?

The IRS spent thousands on touchy-feely speakers, including a \$17,000 lecture about "leadership through art." More like the art of wasting money.

The taxacrats-turned film-makers spent \$50,000 for videos, including spoofs of "Star Trek," "Gilligan's Island," and line dancing to "Cupid Shuffle." Cupid Shuffle? Are you kidding me?

Mr. Speaker, this is corrupt, contemptible behavior. Ironically, instead of tracking our tax dollars, the Internal Revenue Squanderers waste tax dollars.

The head of the IRS says the expenses were inappropriate. Well, no kidding.

When the revenueers find inappropriate behavior by taxpayers, the taxpayers pay more taxes with interest.

The IRS should return the \$50 million with interest to the Treasury, and it's time it audited the taxman.

And that's just the way it is.

SAFE CLIMATE CAUCUS

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

Mr. WAXMAN. Mr. Speaker, I rise today as a member of the Safe Climate Caucus to urge the House to act on climate change.

Last month, scientists recorded atmospheric concentrations of carbon dioxide at more than 400 parts per million. The long-term consequences of this development are going to get worse in the future, but we're already seeing the immediate impacts today.

The Philadelphia Inquirer has recently reported on the sea level rising along the Delaware Bay and the spring season coming earlier to the Philadelphia region. I will insert these two articles into the CONGRESSIONAL RECORD.

And just last month, the Natural Resources Defense Council released a report on the cost of climate change, showing that the Federal Government spent \$100 billion on disaster relief last year. That's more than we spent on education, transportation, or even non-discretionary spending on health.

And, yet, not only does the Republican majority in the House refuse to address climate change; they're actively pursuing legislation that is sure to make things worse. We must address this problem now.

ALONG N.J. BAY, RISING SEA DRAWS EVER CLOSER

[The Inquirer, Apr. 29, 2013]

[By Sandy Bauers]

The night Meghan Wren got stranded by floodwaters and had to sleep in her car, she knew it was time for a reckoning.

She had been driving to her waterfront home along the Delaware Bay in South Jersey. As she crossed the wide marsh in the dark, the water rose quickly. It became too deep—ahead and behind. She had to stop and wait.

To her, no longer were climate-change predictions an abstract idea. Sea level has been rising, taking her waterfront with it.

"This isn't something that's coming," she later told a group of bay shore residents and officials. "It's here. We just happen to live in a place that will affect us sooner."

Wren lives on tiny Money Island—more a peninsula of bayfront land with about 40 small homes and trailers in Cumberland County.

Just visible across the grassy marsh is Gandys Beach with 80 homes. Farther south, Fortescue with 250 homes. All three are steadily disappearing.

On the Atlantic coast, beach replenishment masks the effects of sea-level rise. But along the low-lying bay shore, veined with creeks, the problems are striking.

With each nor'easter, more of the beachfronts erode. More of the streets and driveways flood. Septic systems, inundated with salt water, are failing.

"We're seeing beyond the normal damage," said Steve Eisenhauer, a regional director with the Natural Lands Trust, which has a

7,000-acre preserve in the area “We see the problems getting worse.”

In the last century, sea level in the bay has risen a foot, gauges show, partly because the warming ocean is expanding and polar ice is melting. Also, New Jersey is sinking.

All the while, humans have been pumping more and more greenhouse gases into the atmosphere. The planet’s average temperature has increased.

“All those links are very strong,” said Pennsylvania State University’s Raymond Najjar Jr., an expert on climate change in Mid-Atlantic estuaries.

“The reason the sea is rising as fast as it is in the Delaware Bay is human-induced climate change,” he said, echoing many experts.

Sea level is rising faster now than in the early 20th century, and scientists expect it to rise even faster in the future.

The three towns’ beachfronts and marshes have always been nibbled away by ship wakes, storms, and more typical erosion—but sea-level rise, combined with more frequent and intense storms, makes them all worse.

Can these three communities, all within Downe Township, adapt to climate change?

Or is there a point beyond which no amount of money can stop the sea? Should everyone relocate?

It’s been done. After a \$1.8 million seawall in nearby Sea Breeze failed a year after being built, the state bought out the 23 remaining households three years ago for \$3.3 million. Tiny Thompson’s Beach and Moore’s Beach are gone, too.

These are special places, where people look out their windows and see eagles soaring. The bay turns red at sunset. Salt marshes thick with aquatic life stretch for miles.

With marinas in Fortescue and Money Island, they are among the last places in South Jersey where people can access Delaware Bay—vital for generating support to preserve the rich habitat.

But, like Wren, residents sometimes see white caps in their driveways.

Downe officials have come up with a \$50 million plan to not only shore up the shore, but also add amenities across the township to draw tourists who could revive the economy.

The plan, which would cost the equivalent of \$31,500 per resident, calls for bulkheads and truckloads of sand, restrooms, picnic benches, nature-viewing areas, and a township visitor center.

Officials identified nearly 30 “potential” funders—from agencies to nonprofits. But many feel the project is a long shot. Meanwhile, bumper stickers are plastered on homes: “No retreat. Save the Bayshore communities.”

“I refuse to give up one house, one lot, one piece of land,” said Robert Campbell, Downe’s mayor. “These towns are 200 years old . . . Its a special place. We’ve got to preserve it.”

Their survival is also fiscally crucial: they represent half of Downe’s tax base

He and others blame flooding not on sea-level rise but on the decline of dikes once used for salt hay farming. (Scientists say the dikes blocked the tides from naturally bolstering marshes with sediment.)

Campbell also blames the state for being too tough in issuing permits for bulkheads and jetties.

After Hurricane Irene struck in 2011, the town put up temporary bulkheads. The state issued violation notices. Now, those structures need restoration, too.

“WE CAN SURVIVE”

Before modern travel made all the Atlantic beaches so easily accessible, Delaware Bay

was the shore that many Philadelphians went to.

In the late 1800s, Fortescue was the Cape May of the bay shore, with hotels and a boardwalk.

“We are so rich in our history,” said Dennis Cook of Money Island, who specified in his will that his ashes be thrown off his pier “We can survive.”

Or at least they feel compelled to try. Many residents are retirees who have sunk their savings into their homes. Now that prices have fallen, they can’t get out unless the state buys them out.

Nine Money Island property owners have already requested that.

One is Tony Novak, owner of the local marina. He wants to stay, and thinks he can for the near future, but “there is no doubt that the only reasonable, logical, long-term approach is strategic retreat.”

“I have neighbors,” he said, “and all they have left in the world is being washed away.”

In October, Wren held a forum on what many consider the hot issue for the bay shore: “Rising Tides.”

About 100 people went to the nearby hamlet of Bivalve on the Maurice River, and filled a chilly room in a historic shipyard shed owned by the nonprofit Bayshore Discovery Project, which Wren founded.

It owns New Jersey’s tall ship, a historic oyster schooner called the A.J. Meerwald, and the walls of the room were lined with vintage oyster cans.

Outside, docks built in the early 1900s still exist, and old-timers notice that the tide comes up higher than it used to. On the serpentine Maurice River, erosion—a natural process worsened by sea-level rise—has almost cut through the bend at Bivalve. If it occurs, the docks might end up high and dry, and land to the east will flood.

Toward the bay are “ghost forests”—skeletons of trees killed by saltwater intrusion.

Upstream, a quarter century of bird counts shows that black vultures, a Southern species, are becoming more numerous.

In decline are American black ducks, which depend on a freshwater wild rice that is being depleted as saltier water moves up the Maurice River.

“The coast is changing,” Jennifer Adkins told the group in Bivalve that night.

The executive director of the Partnership for the Delaware Estuary, she cited research showing the dramatic loss of the bay’s wetlands. Nearly 5,000 football fields’ worth vanished from 1996 to 2006 alone, mostly from sea-level rise and erosion.

Wetlands protect coastal areas by absorbing water from storm surges, so losing these natural buffers makes the bay shore communities more vulnerable.

And then Matt Blake, then with the American Littoral Society, raised the topic few wanted to hear.

“Strategic retreat,” he said “The questions of whether to pull back or reinforce are going to come up again and again.”

He didn’t claim to have an answer. But he said solutions should be based on research, not emotion “We’ll never have enough resources to defend every community. Before we start spending on new roads and bridges and pipes, we have to run a cost-benefit analysis.”

But Campbell wouldn’t hear of it. “There seems to be a double standard between the Atlantic coast communities and the Delaware Bay,” the mayor said when he got to the lectern. A murmur of assent rose from the audience.

“I don’t hear anybody talking about retreat in Atlantic City,” he said. Or “moving the casinos back to Absecon.”

Still, he handed out a summary of township problems: collapsed pavement, eroded road shoulders, failing seawalls.

“Downe Township is just one hurricane away from becoming a bayfront statistic” like the three other abandoned towns.

Eleven days later, Hurricane Sandy hit. Bayfront houses were undermined, the sand washing out from under them. Front steps hung in the air. Decks and front rooms were gone.

Campbell said damage along the bay front totaled \$20 million; about 30 homes were destroyed.

“Sandy focused everybody’s attention,” Wren said. You can’t just quietly ignore [the rising ocean] anymore.”

REMOTE AND LITTLE CLOUT

The bay shore, unlike the Atlantic coast, is ill equipped to respond.

Cumberland County is remote, rural, and economically depressed, the poorest county in the state.

“They don’t have the population. They don’t have the tax base. They don’t have the votes,” said the trust’s Eisenhauer. “They don’t have the clout to get the funding they get on the Atlantic coast.”

Yet the area is hugely vulnerable. About 12 percent of the county’s population lives in a floodplain, according to a federal analysis. Ditto 6 percent of the schools, police stations, and other “critical facilities.” Plus 10 percent of the road miles.

Local leaders feel they aren’t getting much help.

Across the bay, Delaware has a climate-change action plan and a sea-level rise advisory group. It has listed strategies for its bay shore and analyzed the costs and benefits.

“The first step is to have rock-solid science and good economics,” said the state’s environmental head, Collin O’Mara.

In New Jersey, Gov. Christie closed the Office of Climate Change, although a spokesman said several agencies deal with the issue, and many efforts have been launched since Sandy.

Department of Environmental Protection spokesman Larry Hajna said officials visited Downe “to see what we can do”

“Sea-level rise is clearly one of the biggest concerns along the bay,” he said. “But at this point there aren’t any long-term answers.” Federal, state, and local entities would have to get involved, he said.

Ultimately, the question may not be how to keep the waterfront intact but how to get to the towns in the first place.

A new sea-level rise mapping tool from Rutgers University shows that with one more foot of rise—easily possible before century’s end—the roads through the marshes would be underwater at high tide.

RUDE AWAKENING

Wren thought she would have more time.

She imagined that the changes “would be far enough in the future that I could figure out how to manage it”—maybe by working from home during floods. Not anymore.

She and her husband, Jesse Briggs, subscribe to an alert system for when higher-than-usual tides are predicted.

But in December, an alert went out at 3 a.m. When Wren woke up, it was already too late. Her Prius was swamped. Now, she drives a hybrid SUV that is six inches higher.

She thinks it was hubris for humans to build on the shore. And “it seems like folly to be trying to control nature” now.

But she’s lived on the water her whole life. Briggs is captain of the A.J. Meerwald. They named their son Delbay—for Delaware Bay.

“I can kind of see it from all sides,” Wren said of the debate over Money Island and its neighbors. So far, it comes down to this: “If the township decides to keep the infrastructure, I’m committed to keeping my house.”

[From the Inquirer, May 22, 2013]
SPRING COMES SOONER TO PHILA.—AND THAT’S NOT GOOD

(By Sandy Sabers, Inquirer Staff Writer)

One in an occasional series about the regional effects of climate change and how we're coping.

On May 2, 1908, as he strolled along the Perkiomen Creek in Montgomery County, Bayard Long collected a flowering sprig of redbud.

He mounted it, labeled it, and added it to the herbarium at the Academy of Natural Sciences, where he was the curator.

A century later, but just miles away in Chester County, botany graduate student Zoe Panchen also found a redbud in flower. But this time, the short-lived blooms had appeared much earlier. It was April 13, 2010.

Those two data points—and 2,537 others that Panchen analyzed—show a dramatic change in this region's flowering plants.

On average, about 20 species of common spring plants are flowering a day earlier every decade, Panchen concluded.

That scenario is happening across the biological spectrum in ways that could put nature out of sync, worsening pest problems and helping invasive species to flourish.

Migrating birds are arriving earlier, frogs are calling earlier, and insects are emerging earlier than they were decades ago, according to an analysis of the Northeastern United States by a national group focused on phenology—the study of all the things that animals and plants do that are related to the seasons.

Researchers link the numerous shifts they're seeing to climate change—mostly, the warmer springs associated with it.

Individual years are highly variable, of course. Last year was the earliest spring in the North American record, based on "indicators" such as plant leaf-out and flowering. This year in the Philadelphia region, temperatures were slightly cooler than normal. But many creatures shift their cycles to go with the overall trend.

"Climate change is here, it's now, it's in your backyard: that's the way we put it," said ecologist Jake Weltzin, who directs the National Phenology Network, a federal program that is enlisting citizen scientists to gather data on the plants and animals in their own backyards.

Weltzin and others acknowledge that many factors affect living things—habitat loss, pollution, urban heat islands.

But as they try to understand the changes in timing and shifts in abundance, again and again, climate change appears dominant.

"If you have multiple species that aren't even related, and they're all doing something similar, it's likely that there's a shared cause," said Keith Russell, science coordinator with Audubon Pennsylvania. "Climate change is the one thing that makes the most sense."

An international coalition of scientists that produced the seminal analyses of climate change noted in their latest report, in 2007, that phenology "is perhaps that simplest process in which to track . . . responses to climate change."

Even then, they were seeing it. Numerous studies had documented a progressively earlier spring—by two to five days a decade, the group said.

The evidence continues to mount.

A longtime study of lilacs and honeysuckles across North America shows the plants are leafing out several days earlier than in the early 1900s.

Ten bee species have accelerated their emergence date by roughly 10 days over the last 130 years, a Rutgers University entomologist and others reported in a 2011 paper.

Several studies have pointed to earlier bird migrations. One analysis found that 17 forest species were arriving in Pennsylvania earlier over the last 40 or so years—three days for the cerulean warbler to 25 days for the purple finch.

In addition, a National Audubon Society study looking at 305 species found that birds' wintering grounds had shifted northward an average of 35 miles in four decades.

In Pennsylvania and New Jersey, black vultures moving up from the south are becoming more numerous.

"We're seeing this in real time," said Eric Stiles, president of New Jersey Audubon, whose data collectors are part of a national breeding bird survey that is seeing species show up two and three weeks early. "It's all happening in our lifetime."

Some of these changes in patterns may not be bad. They're just changes.

But some changes have been linked to pest outbreaks. A longer growing season for some plants means a lengthening of the allergy season.

Scientists don't know how the changes will reverberate, "If you tug at anything in nature, it's a web," said Gary Stolz, manager of the John Heinz National Wildlife Refuge at Tinicum. "You pull one little string, and it's tied to everything else on Earth."

Researchers have found some cases where early bird arrivals put them out of sync with the sweet spot of insect emergence—their dinner.

Plants that shift their bloom times earlier could be damaged by even a normally timed frost—a potential disaster if the flower happens to be a crop species. Last year in Michigan, frost damage to fruit trees totaled half a billion dollars.

Organizers may need to rethink the timing of a few festivals to boot.

Last year, the parade for cherry blossoms in Washington happened just as the flowers were beginning to fade. The town's cherry tree cultivars now bloom an average of seven days earlier than in the 1970s.

Scientists say much more research is needed.

Some important data are coming from citizen scientists—people who go out in their backyards and simply notice what's going on. Even with inevitable mistakes, the bigger picture emerges.

Observers are reporting leaf-outs and flowering times to Project BudBurst, nighttime trills and croaks to FrogWatch USA, and backyard bird sightings to Cornell University's FeederWatch project.

Diane House, a physician who lives in Newtown Square, tracks beeches and red maples for the Phenology Network's "Nature's Notebook."

The granddaddy of citizen-science efforts, it has nearly 2,000 data gatherers. Its more than 1.8 million records on plants, trees, animals, and birds are already informing research, including a paper showing how ruby-throated hummingbirds are arriving in North America 12 to 18 days earlier than in the 1960s.

In 2010, with a grant from Toyota, Moravian College biologist Diane Husic began a local version, the Eastern Pennsylvania Phenology Project.

She now has 50 regular contributors—master gardeners, nature center staffers, even grade-school teachers who take students on a recess walks past the same trees every day.

Scientists also have a mother lode of data from more than a century ago—before the Industrial Revolution, when temperatures and CO2 levels began to rise.

In the mid-1800s in Concord, Mass., Henry David Thoreau noted enough about the flowering plants of the region that a modern Boston University professor was able to determine that, on average, spring flowers in Concord are blooming 20 days earlier. The work is being featured in a special exhibit at the Concord Museum through Sept. 15.

Philadelphia's Academy of Natural Sciences of Drexel University is known for its wealth of early data.

Its herbarium—with 400,000 specimens from Pennsylvania, New Jersey, Delaware, and Maryland—was crucial to Panchen, who at the time was in the Longwood graduate program at the University of Delaware.

In recent years, volunteers at the North American Bird Phenology Program have begun to transcribe more than 1.2 million bird-migration records—most of them handwritten on old cards—that were collected between 1881 and 1970.

The idea is to digitize the records and make them more researcher-friendly.

None too soon. Within the last month, the level of heat-trapping carbon dioxide in the atmosphere, as measured at a key station in Hawaii, has breached levels that haven't been seen in millions of years.

"All the models say changes are going to accelerate," Husic said. The more data, the better.

AMERICAN FAMILIES CANNOT AFFORD OBAMACARE

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

Mr. FLEMING. Mr. Speaker, two-thirds of the uninsured say they may not purchase insurance under ObamaCare. A new survey of the uninsured says only 19 percent will opt for coverage by January 1, meaning that only the sickest will buy insurance, driving up the cost of health care for all of us.

In fact, 61 percent expect their health care costs to go up as a result of ObamaCare. You may recall that earlier this year a Federal analysis estimated that the cheapest health insurance plan available for a family in 2016 will cost no less than \$20,000 a year per family.

And it's not just the uninsured who are filled with uncertainty about ObamaCare. More than two-thirds of small business owners surveyed by the U.S. Chamber say ObamaCare will make it harder for them to hire more employees. Many are busily converting employees to part-time as we speak.

American families cannot afford ObamaCare. It must be repealed, just as I and my Federal Republicans, and even some Democrats, have voted to do.

CONGRESSIONAL BLACK CAUCUS

The SPEAKER pro tempore (Mr. WEBER of Texas). Under the Speaker's announced policy of January 3, 2013, the gentleman from Nevada (Mr. HORSFORD) is recognized for 60 minutes as the designee of the minority leader.

Mr. HORSFORD. Mr. Speaker, tonight the Congressional Black Caucus comes before this body and the American people for the next hour to talk about important issues facing our country.

Tonight, we will discuss the problem of poverty in America and what we can do to bring more Americans into the middle class. From SNAP to the earned income tax credit, from Head Start to TRIO and GEAR UP, we have effective programs that reduce poverty and open

up opportunities for people in the low income. Unfortunately, these programs are often the first targeted for cuts.

When you are worrying where your next meal is going to come from, you probably don't have a lot of time to lobby Congress. Well, tonight, we're here to speak to these important issues, and we're also here to listen. So, hopefully, we will be able to answer some questions from our constituents from across America.

If you're watching and you have something that you'd like to let us know about, get on Twitter and tweet #CBCtalks, and we'll do our best to answer your questions.

At this time, I'd like to turn to the chair of the Congressional Black Caucus, the gentlelady from Ohio, the woman providing tremendous leadership to the members of the Congressional Black Caucus to bring forward the issues that are facing so many American families, and those families particularly in poverty today, they have a voice, and for the next hour we're going to bring their voice to this body here in Congress.

Ms. FUDGE. Thank you so very, very much for yielding. And I, as always, want to thank Congressmen HORSFORD and JEFFRIES for leading the Congressional Black Caucus hour.

Today's topic is critically important. The rapid rise of poverty and, particularly, the rapid growth of poverty in minority communities, is troubling. The latest Census Bureau numbers report that 15 percent of Americans live in poverty.

The poverty rate among African Americans is nearly double the national rate, 27 percent. And almost 1 in 4 African American children lives in poverty. I'm not sure how many children you come in contact with each day, but this statistic means that every fourth African American child you see lives a life of struggle. Food is scarce in their home. Their neighborhoods are riddled with crime. There is no guarantee that the lights and heat will be on when they come home from school each day.

As our economy sputters and more Americans slip below the poverty line, Federal anti-poverty programs are essential. Yet, over the last year, conservatives on and off the Hill have begun to spin a story of how anti-poverty programs have done nothing but foster a culture of dependency.

On Capitol Hill, lawmakers have used this narrative over and over again, giving them license to place social safety net programs on the chopping block. While the Republican budget retains tax breaks for the wealthiest Americans, it places Social Security and Medicare on the chopping block.

House leadership will send a farm bill to the floor that reduces total spending by almost \$40 billion over 10 years. And what's most troubling, more than half of the cuts come from the Supplemental Nutrition Assistance Program, otherwise known as SNAP, otherwise

known as food stamps. This bill alone would cut off nearly 2 million people from SNAP.

Making matters worse, anti-poverty programs around the country are reducing services because of sequester. Our communities cannot continue to face cut after cut, while Washington does little to create economic opportunity.

This week we will consider the Military Construction and Veterans' Affairs appropriations bill. I want to make sure we bring attention to the vast poverty plaguing veterans. As our troops come home from Iraq and Afghanistan, the United States must prepare for their return. Many of our vets will need help from local safety net programs; but due to budget cuts, help is not guaranteed. As the statistics show, homelessness will be the reality of thousands of returning veterans.

This Congress cannot continue to ignore poverty in our communities. This Congress cannot ignore the fact that nearly 1½ million veterans live in poverty. America cannot be complicit in allowing families, children, and our Nation's veterans to struggle without assistance, not now, not ever.

□ 1940

The CBC will continue to advocate for policies that eliminate persistent poverty. We will rightfully defend critically important antipoverty programs. Our goal is to create opportunities for all Americans—opportunities that help improve lives and move people closer to achieving their version of the American Dream.

Mr. HORSFORD. Thank you for your leadership and for fighting the fight on this very important issue of poverty in America.

Over the last week, we had our work period. And I had the opportunity to be in my district, Mr. Speaker. One of the things we did was an outreach event where we had a "Commuting with your Congressman." I boarded a bus—public transportation in my district—and I met and listened to my constituents for 4 hours as we traveled throughout the various corners of my district—from Centennial Hills to downtown to the new veterans' hospital, where our veterans literally board a bus in a wheelchair—to listen to the struggle that so many Americans are facing; the fact that they are even struggling to make ends meet. There was a mom who boarded the bus who said it takes 2 hours each way to get to work. They can't always make it to a town hall meeting. They can't always come to our district offices. But they deserve to have a voice here in Washington on these important issues.

So much of what this Congress is talking about is the budget and the priorities of the budget. Well, that mom is a priority of mine. That veteran who takes public transportation to get to their veterans' appointment is a priority of mine. That young man who is 17 years old and going to his first job

interview so that he can work his way through college is a priority of mine. And it's a priority of my colleagues who are here tonight, along with the cochair for the CBC hour, Mr. JEFFRIES from New York. We're going to bring a voice to these issues tonight—and everyday—as the CBC does.

At this time I would like to turn to my colleague who cochairs Poverty and the Economy for the CBC, as well as chairing the whip's task force on eliminating poverty, the gentlelady from California, Representative LEE.

Ms. LEE of California. First, let me thank my colleague for your tremendous leadership and yourself and Congressman JEFFRIES for leading the charge on another timely and important topic: the ongoing crisis of poverty. You both are continuing in the tradition of the Congressional Black Caucus being the conscience of the Congress. And so thank you very much for your leadership and for your commitment to the least of these. I think in your remarks, Congressman HORSFORD, you laid it out as clear as anyone could lay it out.

As the cochair of the Congressional Black Caucus' Poverty and Economy Task Force, as well as, as Congressman HORSFORD said, the chair of the new Whip Task Force on Poverty and Opportunity, let me just highlight how truly important it is to continue to, first, fund programs that lift Americans out of poverty. Income inequality continues to grow. Unfortunately, too many people who are working are poor, and they're living on the edge. It's truly unacceptable that 46 million people in our country live in poverty in the richest and most powerful country in the world. And 16 million of those are children. In communities of color, poverty rates are even worse. A staggering 27 percent of African Americans are living in poverty. And so the Congressional Black Caucus, through the tremendous leadership of our chairwoman, Congresswoman MARCIA FUDGE, has made the eradication of poverty a key priority.

Our policies and programs addressing poverty have not kept pace with the growing needs of millions of Americans. It is time that we make a commitment to confront poverty head on, create pathways out of poverty and provide opportunities for all. Yes, we want to make sure the middle class is strong and survives and the middle class does not fall back into poverty. But we have many, many people who are not even part of the middle class and who are striving and working hard just to maintain and take care of their families and who would one day like to be part of the middle class. And so the Congressional Black Caucus and our whip task force and many in this body continue to speak on their behalf and represent them.

That's why many of our CBC colleagues and I came together to introduce H.R. 2182, which is the Half-in-Ten Act of 2013. The Half-in-Ten Act would

establish the Federal agency working group on reducing poverty. The working group will develop and implement a national strategy to reduce poverty in half in 10 years, as well as provide regular reports of its progress to Congress and the American people. Our Nation needs a coordinated and comprehensive plan to bring an end to poverty in America. It is morally right, economically sound, and fiscally prudent.

So I urge all of our colleagues to join us and support the Half-in-Ten Act. It's beyond time that we put the ongoing crises of poverty on the front burner for this country. Yet the draconian sequester and harmful budget cuts to vital human-needs programs are only making things worse for struggling families.

I serve on the Budget Committee and the Appropriations Committee. It was mind-boggling to hear the other side talk about a commitment to reducing poverty. Yet they gut the vital programs, the ladders of opportunity, the pathways out of poverty such as the Supplemental Nutrition Assistance Program, better known as food stamps; the Women, Infants, and Children program, or WIC; Meals on Wheels; the Earned Income Tax Credit, and all of these programs that lift people out of poverty.

Our chair mentioned the House farm bill. Let me emphasize this again. The reauthorization includes more than \$20 billion in harmful and fiscally irresponsible cuts to the food stamp program, our Nation's first line of defense against hunger. Not only is cutting SNAP morally wrong, it's economically bankrupt. Cuts to nutrition programs will cost the government more money in the long run, but also it is just probably the worst thing that I have ever seen proposed.

As a former food stamp recipient myself, I know firsthand how important these safety net programs are. I would not be here today if it were not for the lifeline that the American people extended to me when I was a single mother struggling to care for my kids. No one wants to be on food stamps. No one. Everyone wants a job. They want to take care of their kids. But there are bumps in the road and the economy has not turned around for many. And so that bridge over troubled waters needs to be there.

So a \$20 billion cut, people cannot afford that. Our economy cannot support that. Hungry children do not deserve these cuts. And cuts to any hunger program will have further cascading impacts that will create a bleaker future for our children. Communities of color, again, especially African American communities, will feel these impacts even more. African American communities have higher infant mortality rates, diabetes, HIV and AIDS and are more likely to be uninsured. If we continue to balance our budget on the backs of the most vulnerable, we will surely push these families over the edge. That is why members of the Con-

gressional Black Caucus will do everything in our power to ensure that our Nation's most vulnerable are protected.

Starting next week, in an effort to highlight the impact of any further cuts to our Nation's food and nutrition programs, myself, as well as Congressman JIM MCGOVERN; our Congressional Black Caucus chair, MARCIA FUDGE; Congresswoman JAN SCHAKOWSKY; our Democratic vice chair, JOE CROWLEY; and others are, leading and taking part in the food stamp challenge.

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We need to raise the level of awareness of what is taking place here in Washington, D.C. So we are going to commit ourselves to limiting our food budget to the average SNAP benefit for a week; that's \$1.50 per person per meal. We will show how vital it is to strengthen and fully fund SNAP, and we're asking all of those who can do so to join with us. We will just be on this for a day or a week. Millions of people will live daily on \$4.50 with no end in sight.

Finally, let me just say we must protect the most vulnerable and grow the economy and our antipoverty programs like SNAP, which is one of the best programs to do that.

So I urge my colleagues to reject these cuts, stop sequestration, and let's work together to create jobs—because that's what everyone needs and wants—and lift the economy for all.

Thank you again for your leadership, Mr. HORSFORD. Thank you, Congresswoman. Let me just engage you for a moment because you hit on a number of points.

I want, again, to make sure that we are providing a voice to these very important issues. And to follow the conversation, if you're tuning in, go to our hashtag at #CBCTalks.

But you focused on the fact that nearly 46 million people in our country live in poverty; 16 million of them are children. You talked about the poverty line. In 2013, the poverty line for an individual is \$11,490. For a family of four, it's \$23,550.

So can you elaborate further on the SNAP program, how that program provides for a safety net for individuals and how is it that a family of four in America can survive on \$23,550 a year?

Ms. LEE of California. Thank you very much, Congressman HORSFORD, for that question and for laying the facts out.

There's no way a family can survive on \$23,000 a year in America, I don't care what region that they live in. Secondly—and Congressman ELLISON is going to speak in a moment—the Progressive Caucus held a hearing, and we talked with low-wage workers, workers who are actually working for Federal Government contractors in our Nation's capital making \$6, \$7, \$8 an hour. You know what? These are working men and women who need food stamps. They're working each and every day, 10, 12 hours a day.

So when you look at what a cut like this would do, first, you have people who are making \$6 or \$7 an hour, living on \$23,000 a year, family of four, and then you're going to cut their food supply. I mean, people are going to go hungry. We are going to see an increase in hunger both in rural communities and in urban communities in our country. In the long run, it's going to just cost us. If people just care about the fiscal impact—which I hope everyone in this body cares about, first, the human and the moral impact, but also the economy and the economic impact—you know, we're going to pay in the long run.

So it's just wrong and it doesn't make any economic sense. There's no way people in this country, in America, the wealthiest and most powerful country in the world, can survive off of \$23,000 a year. We need to, first of all, raise the minimum wage. We need a living wage. In my region, it would be about \$25 an hour. People deserve to live the American Dream, and they're not.

Mr. HORSFORD. Well, I know the challenge is something that you have called upon for people to accept. This is a reality for 16 million children, 46 million Americans who are living at this level now. The average meal is \$1.48 per meal.

Ms. LEE of California. \$4.50 a day, Congressman HORSFORD. And let me tell you, these people are living in our districts, in Democratic Members of Congress' districts and Republicans' districts and Independents' districts. They're in rural communities and in urban communities. So, unfortunately, it's an equal opportunity.

Mr. HORSFORD. Poverty is not partisan.

Ms. LEE of California. No way. So we need bipartisan support to begin to eliminate poverty.

Mr. HORSFORD. Thank you very much, Congresswoman LEE. Thank you for your leadership and for those solutions that you're offering to help move people out of poverty and into the middle class and recognizing that many of these programs that those on the other side propose to cut are actually safety nets.

The sequester alone would cut \$85 billion but would directly affect 50 million Americans living below the poverty income line. So they're hurting the very people that we should be sustaining during these difficult economic times.

Ms. LEE of California. Adding insult to injury. That's what's happening here.

Mr. HORSFORD. At this time, Mr. Speaker, I'd like to turn to my colleague, the gentlelady of Wisconsin (Ms. MOORE), the alum of TRIO. She is a dynamic leader who talks so much about the need to help young people get the quality education, particularly first generation college students. I know we're having a college student debate right now on whether or not

we're going to allow student loan rates to double on July 1. The Republican plan puts students in debt, provides no certainty. We're hoping that between now and July 1 we will come up with a bipartisan solution that will keep our college loan rates and will address the more comprehensive need to make college more affordable.

I defer to the gentlelady from Wisconsin, Congresswoman MOORE.

Ms. MOORE. I want to thank you so much, Representative HORSFORD from Nevada—and Representative HAKEEM JEFFRIES as well, who is here with us—for focusing on this effort and to conduct, this evening, this Special Order on lifting Americans out of poverty.

You know, it was very, very difficult to listen to Representative BARBARA LEE provide those data and those statistics of the numbers of Americans who are living in poverty. Reflecting on my own personal experience, reflecting on what I see every single day among my constituents, the stark poverty, especially of children, it is very, very difficult to talk about this because this is just not abstract; this is very real.

For the purposes of this discussion though, with your permission, Representative HORSFORD, I would like to just modify your motto or your theme for one moment. Instead of talking about lifting Americans out of poverty, I'd like to talk about lifting America out of poverty.

You see, America is heading down the road to not just having 46 million Americans living in poverty, not just having half of Americans during the recession relying on food stamps and having that as their only means of support, not just having African Americans or Hispanics or those living in stark rural poverty being the victims of poverty, but having poverty pervade our entire community. Because we, by not investing in educational opportunity of young people, are eating our seed corn.

Rice farmers have taught us not to eat our seed corn. They say that when we do that, when you plant something, you eat a certain portion of it and you preserve some of it so that you can plant and have a harvest for the future. Those people who eat their seed corn are committing an act of desperation. And that is what we're doing by cutting off educational opportunity to programs.

I'm specifically talking about TRIO. TRIO is a set of federally funded college and university-based educational opportunity outreach programs that modify and support students from low-income backgrounds from first generations. It's not a race-based program, but it includes military veterans, students with disabilities. Currently, they serve about 790,000 students from middle schools through postgraduate studies.

These programs are very, very important because we have found that there aren't enough trust fund kids, Rep-

resentative HORSFORD, to really put this country on a sustainable course of graduating enough high-skilled workers and innovators for our country to enjoy the kind of economic hegemony in a global economy. There aren't enough.

If we graduated every high school senior this June, if every single high school senior went to college, it still would not be enough in order for us to reach those goals of maintaining global hegemony. Yet we have allowed, since 2005, the TRIO programs to lose \$66 million in funding, which translates into 88,000 fewer low-income and potential first-generation students—including adult learners, military veterans, and students with disabilities—to study.

Of course, under sequestration, which went into effect March 1, TRIO has received another \$42 million cut, which means that in the beginning of the 2013-2014 program year, individual grant awards will be reduced by 5 percent. That translates into 40,000 fewer students to be served by TRIO.

□ 2000

Now, as I indicated in the beginning of my discussion here, this program is a set of programs that seek to identify brilliant students, but for their income, or but for their having not been born into a family where college was a tradition, who can contribute to the growth of our economy in our society.

Talent Search is a very low-cost early invention program which identifies students with college potential in grades 6 through 12. They really work toward giving students information about going to college. Seventy-nine percent of Talent Search participants were admitted to postsecondary institutions.

Upper Bound is an intensive intervention program that prepares students for higher education. Seventy-seven percent of these students who participated in Upper Bound enrolled in college.

The Upper Bound Math/Science program—which we know we need more of them—is a model similar to Upper Bound; 86.5 percent of these students go on to college.

We have Veterans Upper Bound and Student Support Services. Again, the numbers are very, very high for students who matriculate and complete in these programs.

The Educational Opportunity Centers is a program where we have reached back for displaced workers, people who have not been in college, and bring them back into the fold. We have seen a 57 percent increase in the number of participants who have been college dropouts that have re-enrolled or displaced workers.

We also have the Ronald E. McNair Postbaccalaureate Achievement Program—named after the famous astronaut who lost his life—which prepares low-income minority students for doctoral programs.

I will yield to you for questions, Mr. HORSFORD, but just let me finish this segment by reiterating this point. If we fail to invest in young people, I mean starting out with starving them—you know I'm still reeling from the comments of my colleague BARBARA LEE because the food stamp bill that is before us will have nearly a quarter of a million students lose their free lunch program. And the majority of folks who are served by the food stamp program are not these welfare queens or slick hustlers; they're elderly children and disabled people—so if we as a country have decided that we don't need to feed babies, we're eating our seed corn, and that is an act of desperation that will take us down a perilous road.

Mr. HORSFORD. Thank you, Congresswoman MOORE. I couldn't agree with you more when you talk about, first and foremost, your last point, which is if we fail to invest in our children, in our elderly, and in the disabled, then we have done a disservice to them and to society as a whole.

Ms. MOORE. That's exactly right, because we can't lift America out of poverty without lifting Americans out of poverty. We are a family.

Mr. HORSFORD. And so a lot of times when these programs get talked about, the various acronyms, billions of dollars here and billions of dollars there—waste, fraud, and abuse I know gets brought up oftentimes as kind of the red herring in the room in a lot of our committee hearings—but really the reality is there's a face behind each one of these programs. There's real people depending on them—as you indicate, the 250,000 children who would lose free and reduced-cost lunches.

How is a child supposed to learn if they're hungry? How are they supposed to focus if they haven't been able to see a doctor or see a dentist? These are real issues that are facing this Congress. And I know a lot of times, again, those on the other side somehow want to make this out to be more than what it is on people, and how it affects people.

Ms. MOORE. Well, I can tell you, we can have a society by design or by default. We can just let it all go as it will.

I was very moved earlier by the tribute that our colleagues on a bipartisan basis made to Senator LAUTENBERG upon his passing. And once again, here's an example of an American who ultimately became very wealthy, but it was because America embraced him with their values.

He went to school on the GI bill. He was able to go to school. He did not have any wealth. And because he was an American and an American soldier, he was able to benefit from our community of interests to build not only a great senator, but great economic enterprises and a lot of jobs that he created. That's the way America is supposed to work. And we need to realize that educational opportunity is one of our basic strategies for staying on top in a global economy.

Mr. HORSFORD. “Opportunity” I think is the key word there, Mr. Speaker. This isn’t about a handout, this isn’t about providing social services; it’s about opportunity. Education is one of those most fundamental opportunities. And you, again, as an alum of TRIO programs and an advocate for funding up TRIO/GEARUP, these programs which provide tremendous opportunity to particularly first generation college students, those who may not have even had the knowledge of how to go about applying to enroll, let alone financial aid and scholarships—but yet it’s that opportunity, that door to opportunity that then leads to careers and their ability to contribute, to sustain for themselves and their family.

That’s what we’re talking about, Mr. Speaker, is providing that opportunity. And right now we’re having this big debate of whether that opportunity should come with a huge burden of debt.

Ms. MOORE. Exactly.

Mr. HORSFORD. Because if they finish school, when they finish school, should they be so far in debt they can’t afford to buy a home, to buy a car, to start saving for their future, or should they be focused on paying \$1,000, \$1,500, \$2,000 a month in debt for college loans?

Ms. MOORE. And that is an extremely important point, because these young people who are going to college are doing us a favor to become educated. The jobs, you know, making the widgets, are dying out from not only technology but from outsourcing.

We are going to only win this game by having the highest skilled worker, whether it be in farming or manufacturing or research and development. And to see this Congress gutting research and development, anything that looks academic or associated with intelligence or studying at all, it’s just across the board decimating it. Again, it’s eating our seed corn. Hopefully we can reverse this curse before they get too far down the line.

Thank you so much for letting me participate in this Special Order.

Mr. HORSFORD. Of course. And with your voice and your continued participation I’m sure we will do just that, which is to continue to advocate for these as priorities.

And I do want to go, as I turn to my colleague from North Carolina, the vice chairman of the CBC, to a quick question that came in from the Twitter line. It’s from Dr. Davis 920, who asks: How can we increase money in underserved areas for students from high school to college instead of doing more with less funding?

I’m going to ask our vice chairman if he would tackle that question as he provides his response.

I yield now to the gentleman from North Carolina, Congressman BUTTERFIELD.

Mr. BUTTERFIELD. Well, let me thank you, Mr. HORSFORD. I have a few points that I want to make.

Do you have an idea of how much time we have remaining so I can allocate my time?

The SPEAKER pro tempore. The gentleman from Nevada has 26 minutes remaining.

□ 2010

Mr. BUTTERFIELD. Mr. HORSFORD, I think the question that has been raised by the gentleman is a very pertinent point.

We have seen over the last 18 to 24 months some very deep cuts in our Federal budget. There are some who believe that discretionary spending is too much and that we need to engage in what I call “draconian cuts” to discretionary spending. Because of that, we’ve seen discretionary accounts reduced significantly, and it’s going to affect what the gentleman has in mind. It’s going to affect not only higher education but public education as well.

Mr. HORSFORD. I want to thank you for allowing me to say a few words here this evening. This is a very appropriate conversation for the Congressional Black Caucus to have. I want to thank you and Mr. JEFFRIES for coming to the floor each week and for lifting up the issues that the Congressional Black Caucus feels are so vitally important for us to debate here in this Congress.

Ms. FUDGE has left the floor, but I certainly want to thank MARCIA FUDGE of Ohio, the chair of our caucus, for all that she does. She somehow just stays in perpetual motion, and her staff works so very closely with her. I just want to thank her publicly for all that she does, not only for the people of Ohio, but for us here in the Congress.

And what can I say about BARBARA LEE? BARBARA LEE has been talking about issues of poverty ever since I came to this place 9 years ago, and I just want to associate myself with everything that she has said and with everything that Congresswoman GWEN MOORE said just a moment ago.

Mr. HORSFORD, I don’t know much about your State of Nevada, but I can tell you a lot about my State of North Carolina. I can tell you that these are some tough times. These are tough times for poor people. These are tough times for rural communities all across America. I represent one of the poorest districts in the whole country in which one in four people in my district, Mr. Speaker, including 36 percent of children, live at or below the poverty level. That’s a statistic that is worth bearing. I want to repeat it: 36 percent of the children who live in my congressional district live below the poverty level. That is unacceptable.

The poverty problem in America is actually getting worse. At a time when it should be getting better, it is actually getting worse. There is a huge difference, there is a huge gap, between the haves and the have-nots. The poverty rate now is the highest that it has been in the last 20 years; and in rural North Carolina, median household incomes have dropped since the year 2000.

My district has vivid and unfortunate illustrations of poverty. For example, nearly one in 20 homes in some counties does not have a telephone or a kitchen. A lot of my friends in urban communities cannot relate to that, but nearly one in 20 homes in some counties does not have a telephone or a kitchen. Many of my constituents are still living without indoor plumbing in the year 2013. The time to invest in our children and in our Nation’s future is now.

We must first undo the cuts from sequestration. The gentleman who sent us the message a few moments ago may have been referring to sequestration. We must undo the cuts that we are seeing involving sequestration. They are devastating to our communities all across the country. Sequestration has slashed Head Start funding, impacting thousands and thousands of children. It has cut job search assistance for thousands of people. It eliminated millions of dollars from the meals for low-income seniors program. Sequestration cut nutrition funding for 600,000 women and children all across the country, housing and emergency shelter funding for nearly 100,000 homeless people and emergency unemployment compensation benefits by nearly 11 percent.

Instead of indiscriminately cutting funding for critical economic development programs, we must invest in programs. I think, Mr. HORSFORD, that’s what you’ve been saying each week that we have this conversation. We must invest in programs which give people a hand up toward making it on their own, important programs such as emergency unemployment insurance, the Workforce Investment Act, the Supplemental Nutrition Assistance Program, and the special supplemental nutrition program for Women, Infants, and Children—we call it the WIC program—which gives people the ability to provide for their families.

The House version of the farm bill, which has been alluded to by the two previous speakers, cuts \$20 billion from the SNAP program. That is unthinkable. The House version of the farm bill has cut \$20 billion from the SNAP program. SNAP is not a government throwaway or a handout. SNAP monies go directly to needy families that are in need the most. We are talking about seniors and children and families who need it the most. Republican proposals to slash funding for a program that feeds poor people is simply unacceptable.

There is hope on the horizon for some of our country’s poor and uninsured. We can be encouraged that the Affordable Care Act will be fully implemented in just a few months, helping some of the one and a quarter million uninsured people in my State qualify for affordable health coverage through the marketplace.

I will say in closing that the Congressional Black Caucus is very concerned about poverty. We have constructed a plan to address persistent poverty. We

are alarmed that so many communities all across the country have experienced a poverty level that exceeds 20 percent and that has persisted now for more than 30 years. So our plan in the Congressional Black Caucus is to target Federal resources and Census tracts that have high levels of unemployment and high levels of poverty. We call it the 10-20-30 plan. We must do it. We have to do it for the sake of America.

Mr. HORSFORD. Thank you again to our vice chairman for the Congressional Black Caucus, the gentleman from North Carolina.

I really want to commend you for being very plain with how desperate the situation is for so many people. You talked about 36 percent of the people in North Carolina, in parts of your district, who are living in poverty and about the fact that they are going without basic fundamentals, things that many of us probably just take for granted in America. There are people in America who are going without the basics, and that is not something often that's talked about here in Washington, definitely not in this House. When so much attention is placed on corporate special interests and subsidies for big corporations, it's time that we start changing the debate and focusing on the people who most need government support, and those are the people you just talked about, so I commend you for that.

Mr. BUTTERFIELD. Poverty is all around us, Mr. HORSFORD, whether it's in my district or in your district or in any of my colleagues' districts. Poverty is persistent, and it's all across America. It's within the shadows of this Capitol. When I drive home in just a few minutes here in Washington, I will go right through some very poor, low-income communities within blocks of this Capitol. We must do better. We have got to address as a Congress the whole issue of poverty.

Mr. HORSFORD. You were very clear, and I know Mr. CLYBURN would expect nothing less than for us to lay out what our position is.

I know some people ask: What is the Congressional Black Caucus' position on how to address poverty?

You touched on it. It's the 10-20-30 policy. This means that 10 percent of funds from certain accounts would be directed to areas that have had a poverty rate of 20 percent for the last 30 years in America.

So, rather than spending money everywhere, let's spend it where there is the most need, the most critical need, and where there has been a generational need now for 30 years so that we can see the type of outcomes, the return on investment and the change that people so desperately need.

Mr. BUTTERFIELD. Absolutely.

Mr. HORSFORD. Thank you to the gentleman from North Carolina.

Now I would like to turn to the co-chairman of the Progressive Caucus, the gentleman from Minnesota. I want to commend the gentleman and the

Progressive Caucus because I know you had a hearing before the recess in which you brought low-income wage earners and had a special hearing to listen to their concerns and on how working people, really the working poor, are struggling. I would like to yield to the gentleman from Minnesota at this time.

□ 2020

Mr. ELLISON. Mr. Speaker, I just want to say that the Congressman from Nevada, my friend STEVE HORSFORD, and HAKEEM JEFFRIES are doing such an awesome job. I'm so proud to see you gentlemen holding forth about the issues that affect this whole country and things that the Congressional Black Caucus, of which we are all members, are doing.

I also just want to let people know who may be tuned in, Mr. Speaker, there are people in this Congress who believe that hard work should be rewarded, who believe that when people get up in the morning, pound it out all day to put food on the table for their families, that it is nothing less than an insult for somebody else who is living in plenty to look back on them and say, You're not working hard enough; you're not doing quite enough.

The fact is that sometimes hard-working people need the help of their government. There's no shame in that. There is nothing wrong with that. Lord knows, Apple Computer agrees that sometimes hardworking people need the help of their government.

The fact of the matter is that we did have a hearing and that hearing did involve low-wage workers, people making \$7, \$8, \$8.25 an hour, some of whom were working for contractors who had contracts with the Federal Government, people who were literally working in buildings like Union Station, like the Reagan building, Federal buildings across Washington but also across this country, who were not working for the Federal Government but were working for contractors who had contracts with the Federal Government, paying them \$8 an hour, a wage that is not livable, is not sustainable.

Folks often speak derisively, Mr. Speaker, about low-income folks. They'll say, Why don't they make more money? What's wrong with them? They're working 8 hours a day. They're working 40 hours a week. They're working three jobs, but they can still barely put food on the table, and they're raising their children. They need food stamps. And if we cut the food stamp budget by \$20 billion, we're going to be cutting families who work hard at two or three jobs every day.

I've heard my Republican friends talk about this cultural dependency. Somehow that moral judgment—you know, the Good Book says, Judge not, lest ye be judged.

Mr. HORSFORD. What's ironic about the culture of dependency is they never talk about it when we bring up corporate welfare and corporate entitlements.

If we really want to talk about entitlements and who is depending upon government, then let's put it all on the table: the billions of dollars that go to special interests, but yet we want to take away services for poor, needy children, families, the elderly, and the disabled. That's really the comparison.

Mr. ELLISON. The gentleman is absolutely right.

I mean, it is utter hypocrisy to sit up here and talk about the cultural dependency and not talk about corporate welfare.

Senator BERNIE SANDERS and I—an awesome gentleman, by the way—have a bill called the End Corporate Welfare Act in which we identify \$110 billion worth of corporate giveaways to Big Oil, Big Coal, and Big Natural Gas.

Look, these are industries that are making record profits. ExxonMobil is not having any trouble. Why do they need the American people's money? Why do they need a subsidy? Well, they're getting one, and yet people in this very body are willing to stand back and say that poor folks working three or four jobs need to have their money cut. I mean, it is astounding. It is shocking how hypocritical some of things that we see go on now.

I just want to say this, Mr. Speaker. This is a country of, by, and for the people. It's a country designed to let the voice of the people be heard, and yet sometimes the people's voice is muted because it's so difficult for the average person to take off time to come down here to talk about what they want to talk about, to be able to access their government.

So these are times when you and Mr. JEFFRIES can come down here and talk about the importance of food stamps, of TRIO, and talk about the absolute concentration of wealth at the very tip-top of the economic stream in this committee.

I'm going to wrap up here, Mr. HORSFORD, but I just want to wrap up by saying this: working people around this country need to know that when poverty increases, the money just doesn't disappear; it goes to the very top of the economy. That is why, since about 2008, if you look at the newly created wealth in this economy, about 93 percent of it went to the top 1 percent.

My friends in the Republican caucus believe that rich people don't have enough money and poor people have too much, which is why they want to cut food stamps and cut taxes for the richest people. One of them even said to me one time, KEITH, a poor person has never given me a job.

Like, wow. That's the attitude we're dealing with.

The bottom line, Mr. HORSFORD, is that low-income workers are taking matters in their own hands. Low-income workers in Detroit and Chicago and New York and St. Louis, even here in Washington, D.C., have come together and had strikes—even McDonald's workers—in order to get better

pay. They are brave and they are courageous. They're taking their families' needs in their own hands. We wish them the best. We had a hearing so they could let their voices be heard.

But if we had a functioning National Labor Relations Board, would they need to go on strike and risk their jobs? If we had a social safety net, would they be in such dire straits? If we made sure that American workers had an increase in the minimum wage and we were paying a livable wage, would they be in this situation?

The American people are standing up for a better life, but the truth is public policies are failing them and we've got to do better. We can start by getting rid of sequester and getting rid of this very bad idea of cutting \$20 billion out of supplemental nutrition.

Thank you for your excellent work.

Mr. HORSFORD. Thank you to the gentleman from Minnesota, and, again, thank you for your leadership. On behalf of the Progressive Caucus, we work together here to try to bring these issues forward and we appreciate your hard work.

I'm so pleased to be joined by the co-anchor for this hour, my good friend, the gentleman from New York, who represents, I think, a community that has constituents who are struggling, like many constituents in my district, the Fourth District in Nevada.

So I just want to pose the question to you, Mr. JEFFRIES, around this whole issue of income inequality that we just spent nearly the hour talking about. The fact that it's increased by more over the last 3 years than in the previous 12 years, that under the Republican policies, the budget that they proposed, middle class families with children pay, on average, \$3,000 more in taxes, but yet higher tax cuts, upwards of \$245,000, were given to some of the wealthiest in America, and here we've heard about so many programs such as SNAP to GEAR UP to TRIO, funding for K-12 education, for Head Start, \$20 billion cuts to SNAP that are on the cutting board, and yet we are giving tax cuts to wealthy Americans and corporate subsidies, what do you say about that, my friend from New York? I yield to you at this time.

Mr. JEFFRIES. I want to thank my good friend, the distinguished gentleman from the Silver State, for once again anchoring this the CBC Special Order, this hour of power where, for the 60 minutes that we've been allotted, we in the Congressional Black Caucus have an opportunity to speak directly to the American people on an issue of great significance, income inequality, which, as you have pointed out Representative HORSFORD, has increased, has gotten worse, not better, in recent years and, in fact, in recent decades. It's a very troubling trend.

The fact is, in America, we celebrate success, celebrate entrepreneurship and the ability of people to prosper. But we in the CBC think that America is at its greatest when we promote progress for

everybody, when we work as hard as we can in this Congress and this country to lift the entire civic participation rates and economic participation rates of everybody in this country.

For the last several decades, objectively and empirically, the rich have gotten richer. They've seen their incomes increase since 1979 in excess of 275 percent. In isolation, that wouldn't be problematic. But when you consider what has happened to the least of those amongst us, to middle-income Americans as well, the situation is extremely troubling. The poor in many instances have gotten poorer, and working families and middle class folks and those who aspire to be part of the middle class are still struggling. In many instances, they've been left behind.

□ 2030

Now it has often been said that when Wall Street catches a cold, many low-income Americans get a fever. Well, we know in 2008, Wall Street, in fact, Representative HORSFORD, got the flu. And ever since, many low-income communities across this great country have been dealing with economic pneumonia. That's bad for the country, that's bad for our democracy, and we here in the country ought to do something about it.

Now, since the collapse of the economy in 2008, one of the things that has exacerbated the income and inequality dynamic is the fact that some Americans have recovered, but others have been left behind. We are in the midst of a very schizophrenic economic situation right now. Corporate profits are way up. The stock market is way up. The productivity of the American worker is way up. Yet unemployment remains stubbornly high and wages for working families and for low-income Americans has remained stagnant.

That's why we're arguing in the CBC that what we should be doing in America right now is investing in our economy, lifting up low-income workers and working families and those who aspire to be part of the middle class; invest in education; invest in job training; invest in research and development; invest in transportation and infrastructure and technology and innovation. Invest in America in these ways. Put people back to work so we can increase consumer demand; and if you increase consumer demand, the economy is going to grow. And if the economy grows, then the deficit as a percentage of GDP will reduce itself, and everybody benefits.

So if you can't find the compassion simply to do the right thing for those low-income Americans who are struggling here in this great country, basic economic theory suggests that the right thing to do would be to provide support to those Americans who will spend that additional income that they have, put it into the economy in order to help create a more robust recovery.

So I thank the gentleman from Nevada for his leadership on this issue of great importance.

Mr. HORSFORD. I thank, again, my good friend from New York, Mr. JEFFRIES. I just want to ask you, the proposal by the CBC which supports a 10-20-30 policy for Federal spending, how do you feel this would improve outcomes, address prioritizing of resources, and create the type of positive impact that would ultimately lead to reduced poverty in America?

Mr. JEFFRIES. Well, we don't need slash-and-burn budgets that reduce our investment in social safety net programs that are an important part of who we are in America. What we should be doing, consistent with the 10-20-30 proposal, is targeting our investment in a way that is nonpartisan in nature, that will direct resources to rural America and to urban America, to blue States and to red States, that will focus on the poverty problem in a way that will benefit Americans no matter where they might be. That's what we should be doing as a Congress. That's what 10-20-30 is all about, and I'm hopeful that we can find our way to a bipartisan meeting of the minds, find common ground, and engage in investing in programs that will lift people out of poverty in this great country.

Mr. HORSFORD. I thank my friend and co-anchor and those who have listened for the last hour. Thank you for joining the conversation at #CBCTalks, and we are going to continue this conversation because 46 million people in our country live in poverty; 16 million of them are children. The U.S. poverty rate has risen and approaches a 50-year high. There's no way in America a family of four can live on \$23,550 and not expect some type of support.

So these are the issues that we're confronting, Mr. Speaker. We want to work with our colleagues on the other side, but we want to do it in a way that addresses the root causes of the issue.

GENERAL LEAVE

Mr. HORSFORD. Mr. Speaker, I ask unanimous consent that all Members have 5 legislative days to revise and extend their remarks and insert additional materials on this topic and also House Resolution 242.

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

There was no objection.

Ms. EDDIE BERNICE JOHNSON of Texas. Mr. Speaker, I rise today to discuss the ongoing crisis of poverty in some of the most vulnerable communities in our country. In the United States, one out of every three African American children lives in poverty, which is three times higher than the rate of white American children living in poverty. Over 30 percent of African American children suffer from food insecurity—more than twice the rate of food insecurity among white children. At the same time, residents of predominantly black or Hispanic neighborhoods have access to about half as many social services as residents of predominantly white neighborhoods.

These disparities are unacceptable. Every American deserves enough food to eat and an equal opportunity to get a quality education, a good job, and safe housing.

Our Nation's basic social safety net improves access to affordable housing, childhood education, and adequate nutrition, and serves as a lifeline for millions of Americans. Providing a helping hand to the nearly 50 million Americans who are living in poverty should be at the forefront of Congress' priorities. Instead, we are still living with the sequester, which has delivered devastating cuts to many of our essential safety net programs. I call on my colleagues to prioritize our most vulnerable communities and replace the sequester with an agreement that protects vital safety net programs.

In particular, the Supplemental Nutrition Assistance Program, or SNAP, helps low-income families across the country put food on the table. Of the 47 million Americans who rely on SNAP for access to nutritious food, nearly half are children. Even more strikingly, nearly half of all American children will receive SNAP benefits at some point in their lives. SNAP is one of our Nation's most effective anti-poverty programs, helping families get back on their feet while providing an economic stimulus to the local economy.

We must not balance our budget on the backs of children and families struggling to make ends meet. With our economy still recovering, it is time to invest in Americans and in our Nation's future, by supporting important programs like SNAP.

Mrs. BEATTY. Mr. Speaker, first I want to thank Mr. HORSFORD and Mr. JEFFRIES for leading this important effort for the CBC this evening—so that we can discuss a particularly important issue for me, my district, and this nation, and that is: "Lifting Americans out of Poverty."

As many of my constituents and colleagues already know, the great recession cost this country roughly 13 trillion dollars in household wealth, and pushed millions of Americans into poverty.

The poverty rate is at levels not seen in twenty years, and the most recent numbers show that more than 46 million Americans are currently living below the poverty line.

The most distressing fact is that the youngest Americans represent a disproportionate share of the poor in the U.S.

Though children make up less than a quarter of the population, they constitute more than one-third of Americans in poverty.

And, studies by the American Psychological Association have found correlations between poverty in children and higher rates of illness, abuse, neglect, developmental and educational delays, participation in risky behaviors such as smoking or sexual activities, and problems with self-esteem and depression.

And worse, growing up in poverty has a lasting negative impact on lifetime earning potential.

As a joint Princeton University—Brookings Institute study reported, the U.S. has decreasing income mobility, and increasing income inequality.

This means that more than ever, youths that grow up in poverty are more likely to remain in poverty for the duration of their lives.

But we have programs designed to buffer our youth from some of the harshest effects of situations for which they deserve no blame, and over which they have no control.

Programs like the Supplemental Nutrition Assistance Program which provides nutritional support for the most vulnerable families, and

which will face cuts in just a few months without intervening Congressional action.

Or programs like Section 8 Housing Choice Vouchers. The Housing Choice Vouchers provide subsidies to landlords directly by public housing agencies, to create housing options for very low-income families.

Though it varies from state to state, on average, a family earning \$26,000 per year would be making too much to be eligible.

This program for the least fortunate among us will likely have to cut aid to 125,000 families immediately, due to cuts from sequestration.

Or programs like the Earned Income Tax Credit. This tax credit for low-to moderate-income couples, primarily those with qualifying children, not only provides a tax refund to the most deserving, but it dually functions to incent work even if the pay isn't great.

This is the type of progressive tax system that encourages self-sufficiency and in the long-run can reduce the need for government dependence.

Yet even this simple, long-standing beneficial tax credit is being offered up by some as ripe for elimination.

I can talk about the children and families who need these programs, in the abstract, as if they are some sort of different Americans—people who didn't work hard, or didn't spend wisely.

But the reality is: this type of poverty can happen to anyone.

Anyone in this Chamber, or watching at home on Wall Street or Main Street—this can happen to you.

One unexpected illness, one lost job due to "just a bad economy," or one elderly family member whose medical and caretaking bills continue to pile up, and anyone can find themselves unable to make it without a little help.

That's what these vital programs do. That's why these programs are so important.

We as legislators have the opportunity and obligation to make sure that we put safeguards in place to ensure that no one is left out from the chance to pursue the American dream.

It's not just about helping the poorest Americans. It's about doing the right thing to help our neighbors, knowing that at any time, the shoe could be on the other foot.

I thank you for the opportunity to speak on this most important issue.

REPORT ON RESOLUTION PROVIDING FOR CONSIDERATION OF H.R. 2216, MILITARY CONSTRUCTION AND VETERANS AFFAIRS AND RELATED AGENCIES APPROPRIATIONS ACT, 2014; AND PROVIDING FOR CONSIDERATION OF H.R. 2217, DEPARTMENT OF HOMELAND SECURITY APPROPRIATIONS ACT, 2014

Mr. WEBSTER of Florida, from the Committee on Rules, submitted a privileged report (Rept. No. 113-95) on the resolution (H. Res. 243) providing for consideration of the bill (H.R. 2216) making appropriations for military construction, the Department of Veterans Affairs, and related agencies for the fiscal year ending September 30, 2014, and for other purposes; and providing for consideration of the bill

(H.R. 2217) making appropriations for the Department of Homeland Security for the fiscal year ending September 30, 2014, and for other purposes, which was referred to the House Calendar and ordered to be printed.

LEAVE OF ABSENCE

By unanimous consent, leave of absence was granted to:

Mr. RODNEY DAVIS of Illinois (at the request of Mr. CANTOR) for today on account of personal reasons.

ENROLLED BILL SIGNED

Karen L. Haas, Clerk of the House, reported and found truly enrolled a bill of the House of the following title, which was thereupon signed by the Speaker:

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

ADJOURNMENT

Mr. WEBSTER of Florida. Mr. Speaker, I move that the House do now adjourn.

The motion was agreed to; accordingly (at 8 o'clock and 36 minutes p.m.), under its previous order and pursuant to House Resolution 242, the House adjourned until tomorrow, Tuesday, June 4, 2013, at 10 a.m., for morning-hour debate, as a further mark of respect to the memory of the late Honorable FRANK R. LAUTENBERG.

EXECUTIVE COMMUNICATIONS, ETC.

Under clause 2 of rule XIV, executive communications were taken from the Speaker's table and referred as follows:

1689. A letter from the Secretary, Department of the Interior, transmitting the Department's semiannual report from the office of the Inspector General for the period October 1, 2012 through March 31, 2013, pursuant to 5 U.S.C. app. (Insp. Gen. Act), section 5(b); to the Committee on Oversight and Government Reform.

1690. A letter from the Chairman, Federal Maritime Commission, transmitting the Commission's semiannual report from the office of the Inspector General for the period October 1, 2012 through March 31, 2013; to the Committee on Oversight and Government Reform.

[Pursuant to the provisions of H. Res. 232, the following report was filed on May 28, 2013:]

Mr. CULBERSON: Committee on Appropriations. H.R. 2216. A bill making appropriations for military construction, the Department of Veterans Affairs, and related agencies for the fiscal year ending September 30, 2014, and for other purposes (Rept. 113-90). Referred to the Committee of the Whole House on the state of the Union.

REPORTS OF COMMITTEES ON PUBLIC BILLS AND RESOLUTIONS

Under clause 2 of rule XIII, reports of committees were delivered to the Clerk

for printing and reference to the proper calendar, as follows:

[Pursuant to the provisions of H. Res. 232, the following report was filed on May 29, 2013:]

Mr. CARTER: Committee on Appropriations. H.R. 2217. A bill making appropriations for the Department of Homeland Security for the fiscal year ending September 30, 2014, and for other purposes (Rept. 113-91). Referred to the Committee of the Whole House on the state of the Union.

[Submitted June 3, 2013]

Mr. UPTON: Committee on Energy and Commerce. H.R. 1919. A bill to amend the Federal Food, Drug, and Cosmetic Act with respect to the pharmaceutical distribution supply chain, and for other purposes; with an amendment (Rept. 113-93). Referred to the Committee of the Whole House on the state of the Union.

Mr. MILLER of Florida: Committee on Veterans' Affairs. H.R. 357. A bill to amend title 38, United States Code, to require courses of education provided by public institutions of higher education that are approved for purposes of the educational assistance programs administered by the Secretary of Veterans Affairs to charge veterans tuition and fees at the in-State tuition rate; with amendments (Rept. 113-94). Referred to the Committee of the Whole House on the state of the Union.

Mr. WEBSTER of Florida: Committee on Rules. H. Res. 243. A resolution providing for consideration of the bill (H.R. 2216) making appropriations for military construction, the Department of Veterans Affairs, and related agencies for the fiscal year ending September 30, 2014, and for other purposes; and providing for consideration of the bill (H.R. 2217) making appropriations for the Department of Homeland Security for the fiscal year ending September 30, 2014, and for other purposes (Rept. 113-95). Referred to the House Calendar.

REPORTED BILL SEQUENTIALLY REFERRED

Under clause 2 of rule XII, bills and reports were delivered to the Clerk for printing, and bills referred as follows:

[Pursuant to the provisions of H. Res. 232 the following report was filed on May 29, 2013:]

Mr. LUCAS: Committee on Agriculture. H.R. 1947. A bill to provide for the reform and continuation of agricultural and other programs of the Department of Agriculture through fiscal year 2018, and for other purposes; with an amendment; referred to the Committee on Foreign Affairs for a period ending not later than June 7, 2013 for consideration of such provisions of the bill and amendment as fall within the jurisdiction of those committees pursuant to clause 1(i) of rule x; referred to the Committee on the Judiciary for a period ending not later than June 7, 2013 for consideration of such provisions of the bill and amendment as fall within the jurisdiction of those committees pursuant to clause 1(l) of rule x. (Rept. 113-92, Part I). Ordered to be printed.

PUBLIC BILLS AND RESOLUTIONS

Under clause 2 of rule XII, public bills and resolutions of the following titles were introduced and severally referred, as follows:

By Mr. MCKINLEY (for himself, Mr. PETERSON, Mr. WHITFIELD, Mr. ENYART, Mr. ROGERS of Kentucky, Mr. BARROW of Georgia, Mr. RAHALL,

Mr. KIND, Mr. JOHNSON of Ohio, Mr. CUELLAR, Mr. STUTZMAN, Mr. WALZ, Mrs. CAPITO, Mr. WOMACK, Mr. HARPER, Ms. JENKINS, Mr. GIBBS, Mrs. BLACKBURN, Mr. NUNNELEE, Mr. GOSAR, Mr. BARLETTA, Mr. MATHESSON, Mr. STIVERS, Mr. LONG, Mr. GUTHRIE, Mr. BARR, Mr. ROKITA, Mrs. ELLMERS, Mr. YOUNG of Indiana, Mr. BUCSHON, Mrs. LUMMIS, Mr. RENACCI, Mr. BISHOP of Georgia, Mr. THOMPSON of Mississippi, Mr. SHIMKUS, and Mr. KELLY of Pennsylvania):

H.R. 2218. A bill to amend subtitle D of the Solid Waste Disposal Act to encourage recovery and beneficial use of coal combustion residuals and establish requirements for the proper management and disposal of coal combustion residuals that are protective of human health and the environment; to the Committee on Energy and Commerce.

By Mr. YOUNG of Alaska:

H.R. 2219. A bill to reauthorize the Integrated Coastal and Ocean Observation System Act of 2009; to the Committee on Natural Resources, and in addition to the Committee on Science, Space, and Technology, for a period to be subsequently determined by the Speaker, in each case for consideration of such provisions as fall within the jurisdiction of the committee concerned.

By Mr. POE of Texas (for himself, Mr. FLORES, Mr. SMITH of Texas, Mrs. BLACK, and Mr. GINGREY of Georgia):

H.R. 2220. A bill to provide for operational control of the international border of the United States, and for other purposes; to the Committee on Homeland Security, and in addition to the Committees on Armed Services, Rules, Energy and Commerce, and Agriculture, for a period to be subsequently determined by the Speaker, in each case for consideration of such provisions as fall within the jurisdiction of the committee concerned.

By Mr. CRAWFORD (for himself, Mr. COTTON, Mr. GRIFFIN of Arkansas, and Mr. WOMACK):

H.R. 2221. A bill to create a centralized website on reports issued by the Inspectors General, and for other purposes; to the Committee on Oversight and Government Reform.

By Mr. FITZPATRICK (for himself and Mr. MEADOWS):

H.R. 2222. A bill to prohibit performance awards in the Senior Executive Service during sequestration periods; to the Committee on Oversight and Government Reform.

By Mr. BENISHEK (for himself, Mr. CONYERS, Mrs. MILLER of Michigan, Mr. CAMP, Mr. LEVIN, Mr. DINGELL, Mr. HUIZENGA of Michigan, Mr. AMASH, Mr. WALBERG, and Mr. KILDEE):

H.R. 2223. A bill to designate the facility of the United States Postal Service located at 220 Elm Avenue in Munising, Michigan, as the "Elizabeth L. Kinnunen Post Office Building"; to the Committee on Oversight and Government Reform.

By Mr. DOYLE:

H.R. 2224. A bill to amend the Animal Welfare Act to ensure that all dogs and cats used by research facilities are obtained legally; to the Committee on Agriculture.

By Ms. HANABUSA:

H.R. 2225. A bill to restore the traditional day of observance of Memorial Day, and for other purposes; to the Committee on Oversight and Government Reform, and in addition to the Committee on the Judiciary, for a period to be subsequently determined by the Speaker, in each case for consideration of such provisions as fall within the jurisdiction of the committee concerned.

By Mr. JOHNSON of Ohio:

H.R. 2226. A bill to amend the Comprehensive Environmental Response, Compensa-

tion, and Liability Act of 1980 relating to State consultation on removal and remedial actions, State concurrence with listing on the National Priorities List, and State credit for contributions to the removal or remedial action, and for other purposes; to the Committee on Energy and Commerce, and in addition to the Committee on Transportation and Infrastructure, for a period to be subsequently determined by the Speaker, in each case for consideration of such provisions as fall within the jurisdiction of the committee concerned.

By Mrs. NOEM:

H.R. 2227. A bill to improve the response to and prevention of sexual assaults involving members of the Armed Forces; to the Committee on Armed Services.

By Mr. PETRI (for himself and Mr. BUTTERFIELD):

H.R. 2228. A bill to increase assessment accuracy to better measure student achievement and provide States with greater flexibility on assessment design; to the Committee on Education and the Workforce.

By Mr. ROSS (for himself and Ms. CASTOR of Florida):

H.R. 2229. A bill to require the Commissioner of Social Security to issue uniform standards for the method for truncation of Social Security account numbers in order to protect such numbers from being used in the perpetration of fraud or identity theft and to provide for a prohibition on the display to the general public on the Internet of Social Security account numbers by State and local governments and private entities, and for other purposes; to the Committee on Ways and Means.

By Ms. LORETTA SANCHEZ of California:

H.R. 2230. A bill to address the prevalence of sexual harassment and sexual assault in the Armed Forces; to the Committee on Armed Services.

By Mr. SMITH of New Jersey:

H. Res. 242. A resolution relating to the death of the Honorable Frank R. Lautenberg, a Senator from the State of New Jersey; considered and agreed to. considered and agreed to.

By Ms. NORTON:

H. Res. 244. A resolution expressing support for Lunchtime Music on the Mall in Washington, DC, to benefit the District of Columbia, regional residents, and visitors and recognizing the public service of the performers and sponsors; to the Committee on Natural Resources.

CONSTITUTIONAL AUTHORITY STATEMENT

Pursuant to clause 7 of rule XII of the Rules of the House of Representatives, the following statements are submitted regarding the specific powers granted to Congress in the Constitution to enact the accompanying bill or joint resolution.

By Mr. CULBERSON:

H.R. 2216.

Congress has the power to enact this legislation pursuant to the following:

The principal constitutional authority for this legislation is clause 7 of section 9 of article I of the Constitution of the United States (the appropriation power), which states: "No Money shall be drawn from the Treasury, but in Consequence of Appropriations made by Law . . ." In addition, clause 1 of section 8 of article I of the Constitution (the spending power) provides: "The Congress shall have the Power . . . to pay the Debts and provide for the common Defence and general Welfare of the United States.

... Together, these specific constitutional provisions establish the congressional power of the purse, granting Congress the authority to appropriate funds, to determine their purpose, amount, and period of availability, and to set forth terms and conditions governing their use.

By Mr. CARTER:

H.R. 2217

Congress has the power to enact this legislation pursuant to the following:

The principal constitutional authority for this legislation is clause 7 of section 9 of article I of the Constitution of the United States (the appropriation power), which states: "No Money shall be drawn from the Treasury, but in Consequence of Appropriations made by Law . . ." In addition, clause 1 of section 8 of article I of the Constitution (the spending power) provides: "The Congress shall have the Power . . . to pay the Debts and provide for the common Defence and general Welfare of the United States. . ." Together, these specific constitutional provisions establish the congressional power of the purse, granting Congress the authority to appropriate funds, to determine their purpose, amount, and period of availability, and to set forth terms and conditions governing their use.

By Mr. MCKINLEY:

H.R. 2218.

Congress has the power to enact this legislation pursuant to the following:

According to Article I, Section 8, Clause 3 of the Constitution: The Congress shall have power to enact this legislation to regulate commerce with foreign nations, and among the several states, and with the Indian tribes.

By Mr. YOUNG of Alaska:

H.R. 2219.

Congress has the power to enact this legislation pursuant to the following:

Article 1, Section 8, Clause 3.

By Mr. POE of Texas:

H.R. 2220.

Congress has the power to enact this legislation pursuant to the following:

Clause 1 of Section 8, of Article 1, in the United States Constitution.

By Mr. CRAWFORD:

H.R. 2221.

Congress has the power to enact this legislation pursuant to the following:

Clauses 1 and 3 of Section 8 of Article I of the Constitution of the United States.

By Mr. FITZPATRICK:

H.R. 2222.

Congress has the power to enact this legislation pursuant to the following:

Article I, Section 8, Clause 1: The Congress shall have the power to lay and collect taxes, duties, imposts, and excises, to pay the Debts and provide for the common Defense and general welfare of the United States;

By Mr. BENISHEK:

H.R. 2223.

Congress has the power to enact this legislation pursuant to the following:

Article I, Section 8, Clause 7

The Congress shall have Power . . . To establish Post Offices and post roads.

By Mr. DOYLE:

H.R. 2224.

Congress has the power to enact this legislation pursuant to the following:

This law is enacted pursuant to Article 1, Section 8, Clauses 1 and 3 to the U.S. Constitution.

By Ms. HANABUSA:

H.R. 2225.

Congress has the power to enact this legislation pursuant to the following:

The power granted to Congress under Article I, Section 8, Clause 18 of the United States Constitution, to make all laws which shall be necessary and proper for carrying

into execution the foregoing Powers, and all other powers vested by the Constitution in the Government of the United States, or in any Department or officer thereof.

By Mr. JOHNSON of Ohio:

H.R. 2226.

Congress has the power to enact this legislation pursuant to the following:

According to Article I, Section 8, Clause 3 of the Constitution: The Congress shall have power to enact this legislation to regulate commerce with foreign nations, and among the several states, and with the Indian tribes.

By Mrs. NOEM:

H.R. 2227.

Congress has the power to enact this legislation pursuant to the following:

Article I, Section 8, Clause 14: To make Rules for the Government and Regulation of the land and naval Forces.

By Mr. PETRI:

H.R. 2228.

Congress has the power to enact this legislation pursuant to the following:

Article 1, Section 8, Clause 1 of the Constitution

By Mr. ROSS:

H.R. 2229.

Congress has the power to enact this legislation pursuant to the following:

Article I, Section 8, Clause 18; Article I, Section 8, Clause 3—This legislative action is necessary and proper for the protection of American citizen's identity, where possession and subsequent inter/intrastate transmission of individuals unique Social Security Number is concerned.

By Ms. LORETTA SANCHEZ of California:

H.R. 2230.

Congress has the power to enact this legislation pursuant to the following:

"The constitutional authority of Congress to enact this legislation is provided by Article I, section 8 of the United States Constitution (clauses 12, 13, 14, 16, and 18), which grants Congress the power to raise and support an Army; to provide and maintain a Navy; to make rules for the government and regulation of the land and naval forces; to provide for organizing, arming, and disciplining the militia; and to make all laws necessary and proper for carrying out the foregoing powers."

ADDITIONAL SPONSORS

Under clause 7 of rule XII, sponsors were added to public bills and resolutions as follows:

H.R. 7: Mr. STIVERS, Mr. MURPHY of Pennsylvania, and Mr. SENSENBRENNER.

H.R. 32: Ms. DELBENE, Mr. KEATING, and Mr. VELA.

H.R. 50: Mr. DEUTCH.

H.R. 104: Mr. GENE GREEN of Texas.

H.R. 148: Mr. DEUTCH.

H.R. 183: Ms. SINEMA.

H.R. 241: Mr. GARY G. MILLER of California and Ms. SINEMA.

H.R. 288: Mr. CONNOLLY and Ms. SINEMA.

H.R. 301: Mr. DUFFY.

H.R. 303: Mr. VELA, Mr. VEASEY, and Ms. SINEMA.

H.R. 322: Mr. HOLDING and Mr. COTTON.

H.R. 335: Ms. BONAMICI.

H.R. 343: Mr. DUNCAN of South Carolina.

H.R. 419: Mrs. HARTZLER.

H.R. 455: Mrs. NAPOLITANO and Mrs. DAVIS of California.

H.R. 460: Mr. DAVID SCOTT of Georgia.

H.R. 508: Mr. HECK of Nevada and Mr. MEEHAN.

H.R. 515: Mrs. KIRKPATRICK.

H.R. 521: Ms. ESHOO.

H.R. 556: Mr. WOMACK and Mr. PAULSEN.

H.R. 594: Mr. TONKO and Mr. COHEN.

H.R. 595: Mrs. DAVIS of California.

H.R. 621: Mr. COTTON.

H.R. 640: Mr. BARLETTA.

H.R. 655: Mr. VISCLOSKEY and Mr. CARSON of Indiana.

H.R. 664: Mr. CONNOLLY.

H.R. 676: Mr. TONKO.

H.R. 685: Mr. KENNEDY and Ms. NORTON.

H.R. 698: Mr. RADEL, Mr. COSTA, and Mr. MICHAUD.

H.R. 708: Mr. TERRY.

H.R. 719: Mr. RANGEL.

H.R. 721: Mr. FLEISCHMANN, Mr. SIMPSON, and Mr. NEAL.

H.R. 736: Mr. LOWENTHAL.

H.R. 739: Mr. CONNOLLY.

H.R. 755: Mr. GUTIERREZ, Mr. RODNEY DAVIS of Illinois, Ms. ESHOO, Mr. JOHNSON of Georgia, Ms. SCHWARTZ, Mr. KIND, Ms. DELAURO, Mr. NEAL, Ms. NORTON, and Mr. GENE GREEN of Texas.

H.R. 761: Mr. THOMPSON of Pennsylvania.

H.R. 763: Mr. COLLINS of Georgia, Mr. ADERHOLT, Mr. HUDSON, Mr. BRADY of Texas, and Mr. FLORES.

H.R. 764: Ms. EDWARDS and Mr. LOWENTHAL.

H.R. 769: Ms. KELLY of Illinois, Mr. OWENS, and Mr. RICHMOND.

H.R. 776: Mr. COLLINS of New York.

H.R. 778: Mr. DESANTIS.

H.R. 792: Mr. CÁRDENAS.

H.R. 794: Mr. ANDREWS, Ms. LEE of California, Mr. TONKO, and Mr. COHEN.

H.R. 805: Mr. LANGEVIN.

H.R. 819: Mr. FORBES and Ms. FOX.

H.R. 850: Mr. SHIMKUS, Mr. YARMUTH, Mr. FORTENBERRY, and Mr. TURNER.

H.R. 904: Mrs. BUSTOS and Mr. WOLF.

H.R. 911: Mr. PRICE of Georgia.

H.R. 920: Ms. MICHELLE LUJAN GRISHAM of New Mexico.

H.R. 921: Mr. PETRI.

H.R. 940: Mr. ROSS.

H.R. 958: Mrs. CAPPES.

H.R. 961: Mr. RAHALL.

H.R. 964: Mr. GRIJALVA, Ms. NORTON, and Ms. LEE of California.

H.R. 979: Mr. MATHESON.

H.R. 982: Mr. CHABOT.

H.R. 1010: Mr. SMITH of Washington.

H.R. 1015: Mr. DEFazio, Mrs. LOWEY, Mr. FRELINGHUYSEN, Mr. MCGOVERN, Mr. LYNCH, Mrs. CAROLYN B. MALONEY of New York, Mr. YARMUTH, Ms. PINGREE of Maine, Ms. SCHKOWSKY, and Mr. CONYERS.

H.R. 1024: Mr. CÁRDENAS, Ms. SHEA-PORTER, Mr. QUIGLEY, and Ms. DELBENE.

H.R. 1078: Mr. WALDEN.

H.R. 1094: Mr. SMITH of Washington, Ms. GABBARD, and Mr. SANFORD.

H.R. 1095: Mr. HORSFORD.

H.R. 1098: Ms. ESHOO.

H.R. 1129: Ms. DELBENE.

H.R. 1140: Mr. HECK of Nevada.

H.R. 1141: Ms. DELBENE.

H.R. 1146: Mr. COHEN, Ms. MICHELLE LUJAN GRISHAM of New Mexico, Mr. RUIZ, and Ms. DELBENE.

H.R. 1148: Ms. MICHELLE LUJAN GRISHAM of New Mexico.

H.R. 1149: Mr. CUMMINGS.

H.R. 1151: Ms. EDDIE BERNICE JOHNSON of Texas and Mr. CRAWFORD.

H.R. 1154: Mr. MCGOVERN and Ms. CLARKE.

H.R. 1155: Ms. MICHELLE LUJAN GRISHAM of New Mexico.

H.R. 1175: Mr. MCDERMOTT.

H.R. 1179: Mr. CUMMINGS and Mr. STIVERS.

H.R. 1213: Mr. JEFFRIES.

H.R. 1223: Ms. SINEMA.

H.R. 1240: Mr. CÁRDENAS.

H.R. 1250: Ms. EDWARDS and Mr. CRAWFORD.

H.R. 1254: Mr. ROE of Tennessee, Mr. CRAMER, Mr. JONES, and Mr. WESTMORELAND.

H.R. 1276: Mr. BISHOP of Utah, Mr. THOMPSON of California, Mr. BRADY of Pennsylvania, and Ms. BONAMICI.

- H.R. 1281: Mr. NADLER and Mr. GENE GREEN of Texas.
- H.R. 1284: Ms. SINEMA.
- H.R. 1304: Mr. COTTON.
- H.R. 1309: Mr. GRAVES of Missouri, Mr. BURGESS, Mr. CONNOLLY, and Mr. ROSKAM.
- H.R. 1318: Mr. HIGGINS and Mrs. DAVIS of California.
- H.R. 1331: Mr. STIVERS.
- H.R. 1332: Mr. ENYART.
- H.R. 1039: Mr. LOEBACK.
- H.R. 1346: Mr. ELLISON and Ms. LEE of California.
- H.R. 1355: Mr. COTTON and Mr. RADEL.
- H.R. 1359: Mr. BARR.
- H.R. 1404: Mr. MASSIE.
- H.R. 1416: Mr. THOMPSON of Pennsylvania, Mr. MURPHY of Florida, Mr. YOHO, Mr. FORTENBERRY, and Mr. GRAVES of Georgia.
- H.R. 1449: Mr. CHABOT, Mr. AL GREEN of Texas and Mrs. CAPITO.
- H.R. 1451: Ms. CLARKE, Ms. VELÁZQUEZ, Ms. MENG, Mr. MEEKS, Mrs. LOWEY, and Mr. CROWLEY.
- H.R. 1466: Mr. HOLT.
- H.R. 1502: Mr. ROSS.
- H.R. 1518: Mr. BISHOP of New York, Ms. CLARKE, Mr. SMITH of New Jersey, Ms. MCCOLLUM, Mrs. CAROLYN B. MALONEY of New York, Mr. GARY G. MILLER of California, Mr. SHUSTER, Mr. CÁRDENAS, and Ms. FRANKEL of Florida.
- H.R. 1521: Mr. PERLMUTTER and Mr. SWALWELL of California.
- H.R. 1528: Mr. NUGENT and Mr. SMITH of Washington.
- H.R. 1598: Ms. SINEMA.
- H.R. 1621: Mr. CÁRDENAS.
- H.R. 1640: Mr. MAFFEI.
- H.R. 1657: Mr. BENTIVOLIO.
- H.R. 1661: Mr. CARSON of Indiana.
- H.R. 1690: Mr. CONNOLLY and Mr. BERA of California.
- H.R. 1692: Ms. EDDIE BERNICE JOHNSON of Texas.
- H.R. 1693: Mrs. BROOKS of Indiana.
- H.R. 1699: Mr. CONYERS, Ms. TITUS, and Mr. PAYNE.
- H.R. 1701: Mr. CUELLAR.
- H.R. 1717: Mr. CRAMER, Mr. BUCHSHON, Mr. SALMON, Mr. ISRAEL, and Mr. PITTINGER.
- H.R. 1727: Mrs. BUSTOS.
- H.R. 1729: Mr. GARAMENDI, Mr. THOMPSON of California, Mr. PERLMUTTER, Mr. KILMER, Mr. BISHOP of New York, Mr. VAN HOLLEN, Mr. SWALWELL of California, Ms. SCHAKOWSKY, Ms. BROWNLEY of California, Mr. CARSON of Indiana, and Mrs. CHRISTENSEN.
- H.R. 1731: Mr. BUCHANAN, Ms. SPEIER, Ms. BORDALLO, Mr. RUPPERSBERGER, Mr. SMITH of Washington, Ms. SLAUGHTER, and Mr. MCGOVERN.
- H.R. 1739: Ms. DUCKWORTH, Mr. HASTINGS of Florida, and Mr. BERA of California.
- H.R. 1749: Mr. FALEOMAVAEGA and Mr. POCAN.
- H.R. 1771: Mr. BROOKS of Alabama and Ms. BORDALLO.
- H.R. 1775: Mr. MICHAUD.
- H.R. 1780: Mr. COTTON.
- H.R. 1785: Mr. MCDERMOTT.
- H.R. 1796: Mr. COHEN, Mr. RUNYAN, Ms. HANABUSA, Mr. BROOKS of Alabama, Mr. COURTNEY, Mr. KILDEE, Mrs. NEGRETE MCLEOD, Ms. FRANKEL of Florida, Mr. CONNOLLY, Mr. RUSH, Ms. NORTON, and Mr. RUPPERSBERGER.
- H.R. 1797: Mr. FARENTHOLD, Mr. MCHENRY, Mr. DUFFY, and Mr. PETERSON.
- H.R. 1798: Mr. SALMON and Mr. PETRI.
- H.R. 1805: Mrs. BEATTY, Ms. SHEA-PORTER, Mr. CICILLINE, Mr. SWALWELL of California, and Ms. SINEMA.
- H.R. 1809: Ms. SINEMA, Mr. SWALWELL of California, and Ms. CASTOR of Florida.
- H.R. 1825: Mr. YODER, Mr. COTTON, Mr. HOLDING, and Mr. BARLETTA.
- H.R. 1827: Mr. QUIGLEY and Mr. LANGEVIN.
- H.R. 1829: Mr. GUTHRIE and Mr. MURPHY of Pennsylvania.
- H.R. 1830: Mr. CASSIDY, Mr. BERA of California, Ms. MATSUI, Mrs. BUSTOS, Mr. ENYART, Mr. GARY G. MILLER of California, Mr. LAMALFA, Ms. BONAMICI, Ms. FUDGE, Mr. SARBANES, and Mr. DESANTIS.
- H.R. 1843: Mr. RANGEL, Mr. HONDA, Mr. CICILLINE, Ms. MOORE, Mr. TAKANO, Mr. SCHIFF, Mr. CONYERS, Ms. FUDGE, Mrs. DAVIS of California, Mr. WAXMAN, Mr. SWALWELL of California, Mr. CLAY, Ms. BASS, Ms. MCCOLLUM, Ms. NORTON, Ms. ROYBAL-ALLARD, Mr. PAYNE, Mr. ELLISON, Ms. JACKSON LEE, and Mr. POLIS.
- H.R. 1848: Mr. CARSON of Indiana, Mr. CAMPBELL, and Mr. GRIFFIN of Arkansas.
- H.R. 1864: Ms. KELLY of Illinois, Mr. LATHAM, Mrs. WAGNER, Mrs. BEATTY, Mr. MURPHY of Florida, Ms. MENG, Mr. HUDSON, Ms. MICHELLE LUJAN GRISHAM of New Mexico, Mr. HORSFORD, Mrs. NEGRETE MCLEOD, Mr. O'ROURKE, Ms. ESHOO, Ms. SINEMA, Mr. RUSH, Ms. ROS-LEHTINEN, Mr. GIBSON, Mr. SEAN PATRICK MALONEY of New York, Ms. SHEA-PORTER, Mr. POCAN, Mr. MAFFEI, Mr. SWALWELL of California, Mr. GALLEGRO, Mrs. MILLER of Michigan, Mr. KILDEE, Mr. MILLER of Florida, Mr. WENSTRUP, Ms. JENKINS, Mr. TIERNEY, Mrs. ROBY, and Mr. GARDNER.
- H.R. 1868: Mr. MCCLINTOCK.
- H.R. 1869: Mr. COFFMAN, Mr. MICHAUD, Mr. BROOKS of Alabama, and Mr. HUFFMAN.
- H.R. 1878: Ms. SHEA-PORTER and Mr. KILMER.
- H.R. 1882: Mr. RIGELL.
- H.R. 1893: Mr. MICHAUD.
- H.R. 1907: Mr. DEFAZIO, Mr. ENYART, Mr. LOWENTHAL, and Mrs. BEATTY.
- H.R. 1919: Mr. VEASEY, Mr. WALBERG, and Mrs. WALORSKI.
- H.R. 1921: Mr. DEFAZIO, Mr. TONKO, Mrs. CAROLYN B. MALONEY of New York, Mr. HOLT, Mr. MORAN, Ms. MENG, Mr. BLUMENAUER, Ms. SLAUGHTER, Mr. HUFFMAN, Ms. SCHAKOWSKY, Ms. ESHOO, Mr. LARSON of Connecticut, and Mr. PRICE of North Carolina.
- H.R. 1946: Ms. DEGETTE.
- H.R. 1950: Mr. RADEL.
- H.R. 1962: Mr. STUTZMAN, Mr. ENYART, Mr. MESSER, Mr. MARCHANT, Ms. ESHOO, and Ms. MCCOLLUM.
- H.R. 1971: Mrs. BLACKBURN, Mr. VELA, Mr. WELCH, and Mr. LOEBACK.
- H.R. 1976: Mrs. DAVIS of California.
- H.R. 1979: Mr. KENNEDY, Ms. DEGETTE, and Mr. ELLISON.
- H.R. 1981: Mr. BERA of California.
- H.R. 1994: Mr. GINGREY of Georgia.
- H.R. 1995: Mr. CONYERS and Mr. DEFAZIO.
- H.R. 1998: Ms. EDDIE BERNICE JOHNSON of Texas, Ms. NORTON, Ms. SPEIER, Ms. SCHAKOWSKY, Mr. LANGEVIN, Mr. SCHIFF, Mr. COHEN, Mr. RANGEL, Mr. NADLER, Mr. PRICE of North Carolina, Mrs. DAVIS of California, Mr. NEAL, Mr. DEUTCH, and Mr. HASTINGS of Florida.
- H.R. 1999: Ms. KUSTER and Mr. CÁRDENAS.
- H.R. 2000: Mr. CONNOLLY, Ms. PINGREE of Maine, Mr. MURPHY of Florida, and Mr. RUPPERSBERGER.
- H.R. 2002: Mr. MORAN, Mr. VISCLOSKEY, and Mr. CALVERT.
- H.R. 2005: Mr. HOLT.
- H.R. 2009: Mr. ROGERS of Alabama, Mr. KINGSTON, Mr. RADEL, Mr. BUCHANAN, and Mr. FRANKS of Arizona.
- H.R. 2014: Ms. SCHAKOWSKY and Mr. HANNA.
- H.R. 2016: Mr. KILDEE.
- H.R. 2019: Mr. ROONEY, Mr. HUNTER, Mr. RENACCI, Mrs. BLACK, Mr. REICHERT, Mr. ENYART, Mr. MORAN, and Mr. GRIMM.
- H.R. 2022: Mr. HOLDING, Mr. FLEISCHMANN, and Mr. MESSER.
- H.R. 2023: Mr. GRIJALVA.
- H.R. 2026: Mrs. CAPITO, Mr. MULVANEY, Mr. NOLAN, and Mr. FLEMING.
- H.R. 2027: Mr. THORNBERRY, Mr. HALL, and Ms. SINEMA.
- H.R. 2036: Mr. COHEN.
- H.R. 2060: Ms. SHEA-PORTER and Mr. SWALWELL of California.
- H.R. 2086: Mr. PERLMUTTER.
- H.R. 2088: Mr. SWALWELL of California and Ms. PINGREE of Maine.
- H.R. 2089: Mr. BENTIVOLIO.
- H.R. 2092: Mrs. WAGNER.
- H.R. 2093: Mr. CRAWFORD, Mr. KLINE, Mr. RIBBLE, Mr. FINCHER, and Mr. GINGREY of Georgia.
- H.R. 2099: Mr. BUCHANAN.
- H.R. 2115: Mr. NUGENT.
- H.R. 2116: Ms. MOORE and Mr. CONYERS.
- H.R. 2131: Mr. KINZINGER of Illinois and Mr. WESTMORELAND.
- H.R. 2134: Ms. MOORE.
- H.R. 2144: Mr. WITTMAN.
- H.R. 2174: Ms. SLAUGHTER.
- H.R. 2182: Ms. EDDIE BERNICE JOHNSON of Texas, Mr. SWALWELL of California, Mr. JOHNSON of Georgia, and Mr. CLEAVER.
- H.R. 2188: Ms. TSONGAS.
- H.R. 2215: Ms. CHU, Mr. RANGEL, Mr. ELLISON, and Ms. LEE of California.
- H.J. Res. 40: Mr. LOWENTHAL.
- H.J. Res. 43: Ms. LEE of California, Mr. TAKANO, Mrs. DAVIS of California, Ms. DEGETTE, Mr. CARNEY, Mr. BUCHANAN, Mr. MCGOVERN, Mr. MARKEY, Mr. TIERNEY, Ms. SHEA-PORTER, Mr. RYAN of Ohio, Mr. BLUMENAUER, Mr. CARTWRIGHT, Mr. CONNOLLY, and Mr. POCAN.
- H.J. Res. 44: Mr. LOWENTHAL.
- H.J. Res. 47: Mr. RAHALL, Mr. PALAZZO, Mr. SIMPSON, Mr. HUELSKAMP, and Mr. KLINE.
- H. Con. Res. 23: Mr. RODNEY DAVIS of Illinois and Mr. OWENS.
- H. Con. Res. 30: Mr. CARTWRIGHT and Mr. BERA of California.
- H. Res. 30: Ms. BROWN of Florida and Mr. YARMOUTH.
- H. Res. 35: Mr. MICA and Mr. SENSENBRENNER.
- H. Res. 36: Mr. LAMBORN.
- H. Res. 63: Mr. FARR, Mr. CÁRDENAS, Mr. BUCHANAN, Mr. HASTINGS of Florida, Ms. WILSON of Florida, Mr. JOHNSON of Georgia, Ms. BORDALLO, Mrs. BUSTOS, Ms. SPEIER, Mr. MCGOVERN, Mr. LYNCH, Mr. LEVIN, Mr. CLAY, Mr. BISHOP of Utah, Mrs. CAROLYN B. MALONEY of New York, Mr. CHABOT, Mr. COHEN, Mr. BISHOP of New York, and Ms. LORETTA SANCHEZ of California.
- H. Res. 75: Mr. COFFMAN, Mr. HANNA, and Mr. LOEBACK.
- H. Res. 90: Mr. CASTRO of Texas and Mr. KILMER.
- H. Res. 101: Mr. TONKO.
- H. Res. 104: Mr. KENNEDY, Mr. CARSON of Indiana, Ms. NORTON, Mr. RUSH, Mr. THOMPSON of Pennsylvania, and Mr. HIMES.
- H. Res. 109: Mr. BROOKS of Alabama.
- H. Res. 112: Mr. HECK of Washington.
- H. Res. 118: Mr. TAKANO.
- H. Res. 190: Mr. RUIZ and Mr. CONNOLLY.
- H. Res. 195: Ms. EDWARDS.
- H. Res. 211: Mr. SALMON.
- H. Res. 213: Ms. SCHAKOWSKY, Ms. DELBENE, Mr. PAYNE, Ms. ESTY, Mr. MCDERMOTT, Mr. CONYERS, and Mr. KILDEE.
- H. Res. 220: Mr. NADLER, Ms. LORETTA SANCHEZ of California, Mr. MORAN, Mrs. MCCARTHY of New York, Mr. RANGEL, and Mr. MCGOVERN.
- H. Res. 229: Mr. SCHOCK.
- H. Res. 234: Ms. LEE of California, Mr. CLAY, and Ms. JACKSON LEE.
- H. Res. 236: Mr. JOYCE and Mr. VELA.
- H. Res. 237: Mr. HASTINGS of Florida.

AMENDMENTS

Under clause 8 of rule XVIII, proposed amendments were submitted as follows:

H.R. 2216

OFFERED BY: MR. GRIFFITH OF VIRGINIA
 AMENDMENT No. 1. Page 18, line 8, strike "\$35,000 per unit" and insert "\$15,000 per unit".

June 3, 2013

CONGRESSIONAL RECORD—HOUSE

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H.R. 2216

OFFERED BY: MR. FARR

AMENDMENT NO. 2. At the end of the bill (before the short title), insert the following:

SEC. _____. None of the funds made available by this Act may be used to implement Veterans Health Administration directive

2011-004 regarding "Access to clinical programs for veterans participating in State-approved marijuana programs".

H.R. 2216

OFFERED BY: MR. ROTHFUS

AMENDMENT NO. 3. At the end of the bill (before the short title), insert the following:

Sec. _____. None of the funds made available by this Act may be used by the Secretary of Veterans Affairs to pay a performance award under section 5384 of title 5, United States Code.