

(Mr. WHITEHOUSE) was added as a cosponsor of S. 442, a bill to impose a limitation on lifetime aggregate limits imposed by health plans.

S. 450

At the request of Mr. BAUCUS, the name of the Senator from Nebraska (Mr. NELSON) was added as a cosponsor of S. 450, a bill to understand and comprehensively address the oral health problems associated with methamphetamine use.

S. 475

At the request of Mr. BURR, the name of the Senator from Nebraska (Mr. JOHANNIS) was added as a cosponsor of S. 475, a bill to amend the Servicemembers Civil Relief Act to guarantee the equity of spouses of military personnel with regard to matters of residency, and for other purposes.

S. 478

At the request of Mr. DEMINT, the name of the Senator from Florida (Mr. MARTINEZ) was added as a cosponsor of S. 478, a bill to amend the National Labor Relations Act to ensure the right of employees to a secret-ballot election conducted by the National Labor Relations Board.

S. 487

At the request of Mr. HARKIN, the name of the Senator from New Hampshire (Mrs. SHAHEEN) was added as a cosponsor of S. 487, a bill to amend the Public Health Service Act to provide for human embryonic stem cell research.

S. 491

At the request of Mr. WEBB, the name of the Senator from Idaho (Mr. CRAPO) was added as a cosponsor of S. 491, a bill to amend the Internal Revenue Code of 1986 to allow Federal civilian and military retirees to pay health insurance premiums on a pretax basis and to allow a deduction for TRICARE supplemental premiums.

S. 495

At the request of Mr. CARDIN, the name of the Senator from Illinois (Mr. DURBIN) was added as a cosponsor of S. 495, a bill to increase public confidence in the justice system and address any unwarranted racial and ethnic disparities in the criminal process.

S. 496

At the request of Ms. CANTWELL, the name of the Senator from Rhode Island (Mr. WHITEHOUSE) was added as a cosponsor of S. 496, a bill to provide duty-free treatment for certain goods from designated Reconstruction Opportunity Zones in Afghanistan and Pakistan, and for other purposes.

S. 501

At the request of Mr. ROCKEFELLER, the name of the Senator from Michigan (Ms. STABENOW) was added as a cosponsor of S. 501, a bill to amend the Federal Food, Drug, and Cosmetic Act to prohibit the marketing of authorized generic drugs.

S. RES. 57

At the request of Mr. BAUCUS, the name of the Senator from California

(Mrs. BOXER) was added as a cosponsor of S. Res. 57, a resolution designating the first week of April 2009 as "National Asbestos Awareness Week".

AMENDMENT NO. 592

At the request of Mr. MCCAIN, the name of the Senator from Wyoming (Mr. ENZI) was added as a cosponsor of amendment No. 592 proposed to H.R. 1105, a bill making omnibus appropriations for the fiscal year ending September 30, 2009, and for other purposes.

AMENDMENT NO. 596

At the request of Mr. COBURN, the name of the Senator from Arizona (Mr. MCCAIN) was added as a cosponsor of amendment No. 596 proposed to H.R. 1105, a bill making omnibus appropriations for the fiscal year ending September 30, 2009, and for other purposes.

AMENDMENT NO. 601

At the request of Mr. VITTER, the names of the Senator from Oklahoma (Mr. INHOFE) and the Senator from South Carolina (Mr. DEMINT) were added as cosponsors of amendment No. 601 intended to be proposed to H.R. 1105, a bill making omnibus appropriations for the fiscal year ending September 30, 2009, and for other purposes.

AMENDMENT NO. 607

At the request of Mr. WICKER, the names of the Senator from Wyoming (Mr. ENZI), the Senator from Kentucky (Mr. BUNNING), the Senator from Oklahoma (Mr. INHOFE), the Senator from Oklahoma (Mr. COBURN), the Senator from Louisiana (Mr. VITTER), the Senator from Iowa (Mr. GRASSLEY), the Senator from South Dakota (Mr. THUNE), the Senator from Kansas (Mr. ROBERTS) and the Senator from South Carolina (Mr. DEMINT) were added as cosponsors of amendment No. 607 proposed to H.R. 1105, a bill making omnibus appropriations for the fiscal year ending September 30, 2009, and for other purposes.

AMENDMENT NO. 608

At the request of Mr. COBURN, the name of the Senator from Arizona (Mr. MCCAIN) was added as a cosponsor of amendment No. 608 proposed to H.R. 1105, a bill making omnibus appropriations for the fiscal year ending September 30, 2009, and for other purposes.

AMENDMENT NO. 610

At the request of Mr. COBURN, the name of the Senator from Arizona (Mr. MCCAIN) was added as a cosponsor of amendment No. 610 proposed to H.R. 1105, a bill making omnibus appropriations for the fiscal year ending September 30, 2009, and for other purposes.

AMENDMENT NO. 611

At the request of Mr. THUNE, the names of the Senator from Oklahoma (Mr. INHOFE) and the Senator from Wyoming (Mr. ENZI) were added as cosponsors of amendment No. 611 intended to be proposed to H.R. 1105, a bill making omnibus appropriations for the fiscal year ending September 30, 2009, and for other purposes.

## STATEMENTS ON INTRODUCED BILLS AND JOINT RESOLUTIONS

By Mr. DURBIN (for himself, Mr. GREGG, Mr. KENNEDY, Mr. BURR, Mr. DODD, Mr. ALEXANDER, and Mr. ISAKSON):

S. 510. A bill to amend the Federal Food, Drug, and Cosmetic Act with respect to the safety of the food supply; to the Committee on Health, Education, Labor, and Pensions.

Mr. DURBIN, Mr. President, today I rise to introduce the FDA Food Safety Modernization Act.

When I introduced this bill in the last Congress, we were in the middle of one of the largest food-borne illness outbreaks in the history of our country. Nearly 1500 people fell sick last spring and summer because of Salmonella Saintpaul, leading to a Government investigation that pointed the finger first at tomatoes and then at jalapeno peppers in Texas before settling on Serrano peppers in Mexico. In the meantime, more people got sick and the tomato industry lost up to hundreds of millions of dollars.

Less than a year later, we find ourselves in the middle of yet another nationwide outbreak: peanut butter tainted with Salmonella, the second case of its kind in 2 years. There is not a day that goes by that we don't hear about another recalled peanut butter product or another person sick with Salmonella. More than 660 people have been sickened, half of them children. At least nine people are dead. Over 2,600 products have been recalled, in a recall that goes back to March 2005 and could continue for at least another couple of years, making this one of the biggest food recalls in our Nation's history.

Unfortunately, these problems seem to be par for the course. In the last couple of years we have seen Salmonella in our peppers and peanut butter and E. coli in our spinach. Our food safety problems do not just start and stop at home: we have also seen chemically tainted pet food, milk products, and seafood from China.

These problems are only the tip of the iceberg. Every year, more than 76 million Americans become sick because of a food-borne illness, 325,000 are hospitalized, and 5,000 die.

It is clear that the Food and Drug Administration, who regulates these foods and 80 percent of our food supply, including virtually all food imports, can not keep up. The agency is underfunded and overwhelmed. It operates under an obsolete, largely reactive 1938 law. Its food safety program has not kept up with the dramatic changes in our food system, and it does a poor job of preventing and responding to food safety problems. As a result, consumers suffer and so do businesses something we can never afford, but especially in these trying economic times.

Our food safety system is in crisis and it is time that we act. That's why Senator GREGG and I are introducing

the FDA Food Safety Modernization Act, a bipartisan bill that gives the FDA the new authorities and resources it needs to stop food safety problems before they start.

For the first time in history, our bill gives the FDA a mandate to inspect: to increase the inspections at all food facilities, including annual inspections of high risk facilities. It requires the food industry to have in place plans that address identified hazards with the right preventive measures. It requires all testing and sampling for regulatory purposes to be done by labs accredited by the FDA, and requires those results to be sent to the agency. It also enables the FDA to more effectively respond to an outbreak by giving the agency new authorities to order recalls, shut down tainted facilities, and access records.

This bill is proof that food safety is not a Democratic issue or a Republican one. Everyone eats. All Americans have a right to know that the food we buy for our families and our pets is safe. We should not have to worry about getting sick, or worse. If there's a problem, our Government should be able to catch it and fix it before people die.

I thank Senators KENNEDY, DODD, KLOBUCHAR, BURR, ALEXANDER, and CHAMBLISS for joining me in this effort. I also want to thank the consumer, public health, and industry groups who have helped us craft a strong bill for their support: Consumer Federation of America, Center for Science in the Public Interest, Consumers Union, Trust for America's Health, Grocery Manufacturers of America, American Feed Industry Association, American Frozen Food Institute, Food Marketing Institute, National Fisheries Institute, and American Spice Trade Association.

This bill is a comprehensive, bipartisan effort that improves the FDA's ability to prevent, detect, and respond to food safety problems, whether this means Salmonella-tainted peanut butter from Georgia or melamine-spiked candy from China. It's the first step towards building a food safety system that is science and risk-based, accountable to consumers, more transparent, and focused on prevention. I urge my colleagues to support this bill.

Mr. President, I ask unanimous consent that the text of the bill be printed in the RECORD.

There being no objection, the text of the bill was ordered to be placed in the RECORD, as follows:

S. 510

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

**SECTION 1. SHORT TITLE; REFERENCES; TABLE OF CONTENTS.**

(a) **SHORT TITLE.**—This Act may be cited as the “FDA Food Safety Modernization Act”.

(b) **REFERENCES.**—Except as otherwise specified, whenever in this Act an amendment is expressed in terms of an amendment to a section or other provision, the reference shall be considered to be made to a section or other provision of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 301 et seq.).

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

Sec. 1. Short title; references; table of contents.

**TITLE I—IMPROVING CAPACITY TO PREVENT FOOD SAFETY PROBLEMS**

- Sec. 101. Inspections of records.
- Sec. 102. Registration of food facilities.
- Sec. 103. Hazard analysis and risk-based preventive controls.
- Sec. 104. Performance standards.
- Sec. 105. Standards for produce safety.
- Sec. 106. Protection against intentional adulteration.
- Sec. 107. Authority to collect fees.
- Sec. 108. National agriculture and food defense strategy.
- Sec. 109. Food and Agriculture Coordinating Councils.
- Sec. 110. Building domestic capacity.
- Sec. 111. Final rule for prevention of Salmonella Enteritidis in shell eggs during production.
- Sec. 112. Sanitary transportation of food.
- Sec. 113. Food allergy and anaphylaxis management.

**TITLE II—IMPROVING CAPACITY TO DETECT AND RESPOND TO FOOD SAFETY PROBLEMS**

- Sec. 201. Targeting of inspection resources for domestic facilities, foreign facilities, and ports of entry; annual report.
- Sec. 202. Recognition of laboratory accreditation for analyses of foods.
- Sec. 203. Integrated consortium of laboratory networks.
- Sec. 204. Enhancing traceback and record-keeping.
- Sec. 205. Surveillance.
- Sec. 206. Mandatory recall authority.
- Sec. 207. Administrative detention of food.
- Sec. 208. Decontamination and disposal standards and plans.

**TITLE III—IMPROVING THE SAFETY OF IMPORTED FOOD**

- Sec. 301. Foreign supplier verification program.
- Sec. 302. Voluntary qualified importer program.
- Sec. 303. Authority to require import certifications for food.
- Sec. 304. Prior notice of imported food shipments.
- Sec. 305. Review of a regulatory authority of a foreign country.
- Sec. 306. Building capacity of foreign governments with respect to food.
- Sec. 307. Inspection of foreign food facilities.
- Sec. 308. Accreditation of qualified third-party auditors and audit agents.
- Sec. 309. Foreign offices of the Food and Drug Administration.

**TITLE IV—MISCELLANEOUS PROVISIONS**

- Sec. 401. Funding for food safety.
- Sec. 402. Jurisdiction; authorities.

**TITLE I—IMPROVING CAPACITY TO PREVENT FOOD SAFETY PROBLEMS**

**SEC. 101. INSPECTIONS OF RECORDS.**

(a) **IN GENERAL.**—Section 414(a) (21 U.S.C. 350c(a)) is amended—

(1) by striking the heading and all follows through “of food is” and inserting the following: “RECORDS INSPECTION.—

“(1) **ADULTERATED FOOD.**—If the Secretary has a reasonable belief that an article of food, and any other article of food that the Secretary reasonably believes is likely to be affected in a similar manner, is”;

(2) by inserting “, and to any other article of food that the Secretary reasonably believes is likely to be affected in a similar manner,” after “relating to such article”;

(3) by striking the last sentence; and

(4) by inserting at the end the following:

“(2) **USE OF OR EXPOSURE TO FOOD OF CONCERN.**—If the Secretary believes that there is a reasonable probability that the use of or exposure to an article of food, and any other article of food that the Secretary reasonably believes is likely to be affected in a similar manner, will cause serious adverse health consequences or death to humans or animals, each person (excluding farms and restaurants) who manufactures, processes, packs, distributes, receives, holds, or imports such article shall, at the request of an officer or employee duly designated by the Secretary, permit such officer or employee, upon presentation of appropriate credentials and a written notice to such person, at reasonable times and within reasonable limits and in a reasonable manner, to have access to and copy all records relating to such article and to any other article of food that the Secretary reasonably believes is likely to be affected in a similar manner, that are needed to assist the Secretary in determining whether there is a reasonable probability that the use of or exposure to the food will cause serious adverse health consequences or death to humans or animals.

“(3) **APPLICATION.**—The requirement under paragraphs (1) and (2) applies to all records relating to the manufacture, processing, packing, distribution, receipt, holding, or importation of such article maintained by or on behalf of such person in any format (including paper and electronic formats) and at any location.”.

(b) **CONFORMING AMENDMENT.**—Section 704(a)(1)(B) (21 U.S.C. 374(a)(1)(B)) is amended by striking “section 414 when” and all that follows through “subject to” and inserting “section 414, when the standard for record inspection under paragraph (1) or (2) of section 414(a) applies, subject to”.

**SEC. 102. REGISTRATION OF FOOD FACILITIES.**

(a) **UPDATING OF FOOD CATEGORY REGULATIONS; BIENNIAL REGISTRATION RENEWAL.**—Section 415(a) (21 U.S.C. 350d(a)) is amended—

(1) in paragraph (2), by—

(A) striking “conducts business and” and inserting “conducts business, the e-mail address for the contact person of the facility or, in the case of a foreign facility, the United States agent for the facility, and”;

(B) inserting “, or any other food categories as determined appropriate by the Secretary, including by guidance)” after “Code of Federal Regulations”;

(2) by redesignating paragraphs (3) and (4) as paragraphs (4) and (5), respectively; and

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

“(3) **BIENNIAL REGISTRATION RENEWAL.**—During the period beginning on October 1 and ending on December 31 of each even-numbered year, a registrant that has submitted a registration under paragraph (1) shall submit to the Secretary a renewal registration containing the information described in paragraph (2). The Secretary shall provide for an abbreviated registration renewal process for any registrant that has not had any changes to such information since the registrant submitted the preceding registration or registration renewal for the facility involved.”.

(b) **SUSPENSION OF REGISTRATION.**—

(1) **IN GENERAL.**—Section 415 (21 U.S.C. 350d) is amended—

(A) in subsection (a)(2), by inserting after the first sentence the following: “The registration shall contain an assurance that the Secretary will be permitted to inspect such facility at the times and in the manner permitted by this Act.”;

(B) by redesignating subsections (b) and (c) as subsections (c) and (d), respectively; and

(C) by inserting after subsection (a) the following:

“(b) SUSPENSION OF REGISTRATION.—

“(1) IN GENERAL.—If the Secretary determines that food manufactured, processed, packed, or held by a facility registered under this section has a reasonable probability of causing serious adverse health consequences or death to humans or animals, the Secretary may by order suspend the registration of the facility under this section in accordance with this subsection.

“(2) HEARING ON SUSPENSION.—The Secretary shall provide the registrant subject to an order under paragraph (1) with an opportunity for an informal hearing, to be held as soon as possible but not later than 2 days after the issuance of the order, on the actions required for reinstatement of registration and why the registration that is subject to suspension should be reinstated. The Secretary shall reinstate a registration if the Secretary determines, based on evidence presented, that adequate grounds do not exist to continue the suspension of the registration.

“(3) POST-HEARING CORRECTIVE ACTION PLAN; VACATING OF ORDER.—

“(A) CORRECTIVE ACTION PLAN.—If, after providing opportunity for an informal hearing under paragraph (2), the Secretary determines that the suspension of registration remains necessary, the Secretary shall require the registrant to submit a corrective action plan to demonstrate how the registrant plans to correct the conditions found by the Secretary. The Secretary shall review such plan in a timely manner.

“(B) VACATING OF ORDER.—Upon a determination by the Secretary that adequate grounds do not exist to continue the suspension actions required by the order, or that such actions should be modified, the Secretary shall vacate the order or modify the order.

“(4) EFFECT OF SUSPENSION.—If the registration of a facility is suspended under this subsection, such facility shall not import food or offer to import food into the United States, or otherwise introduce food into interstate commerce in the United States.

“(5) REGULATIONS.—The Secretary shall promulgate regulations that describe the standards officials will use in making a determination to suspend a registration, and the format such officials will use to explain to the registrant the conditions found at the facility.

“(6) NO DELEGATION.—The authority conferred by this subsection to issue an order to suspend a registration or vacate an order of suspension shall not be delegated to any officer or employee other than the Commissioner.”.

(2) IMPORTED FOOD.—Section 801(l) (21 U.S.C. 381(l)) is amended by inserting “(or for which a registration has been suspended under such section)” after “section 415”.

(c) CONFORMING AMENDMENTS.—

(1) Section 301(d) (21 U.S.C. 331(d)) is amended by inserting “415,” after “404.”.

(2) Section 415(d), as redesignated by subsection (b), is amended by adding at the end before the period “for a facility to be registered, except with respect to the reinstatement of a registration that is suspended under subsection (b)”.

#### SEC. 103. HAZARD ANALYSIS AND RISK-BASED PREVENTIVE CONTROLS.

(a) IN GENERAL.—Chapter IV (21 U.S.C. 341 et seq.) is amended by adding at the end the following:

#### “SEC. 418. HAZARD ANALYSIS AND RISK-BASED PREVENTIVE CONTROLS.

“(a) IN GENERAL.—Each owner, operator, or agent in charge of a facility shall, in accordance with this section, evaluate the hazards that could affect food manufactured, proc-

essed, packed, or held by such facility, identify and implement preventive controls to significantly minimize or prevent their occurrence and provide assurances that such food is not adulterated under section 402 or misbranded under section 403(w), monitor the performance of those controls, and maintain records of this monitoring as a matter of routine practice.

“(b) HAZARD ANALYSIS.—The owner, operator, or agent in charge of a facility shall—

“(1) identify and evaluate known or reasonably foreseeable hazards that may be associated with the facility, including—

“(A) biological, chemical, physical, and radiological hazards, natural toxins, pesticides, drug residues, decomposition, parasites, allergens, and unapproved food and color additives; and

“(B) hazards that occur naturally, may be unintentionally introduced, or may be intentionally introduced, including by acts of terrorism; and

“(2) develop a written analysis of the hazards.

“(c) PREVENTIVE CONTROLS.—The owner, operator, or agent in charge of a facility shall identify and implement preventive controls, including at critical control points, if any, to provide assurances that—

“(1) hazards identified in the hazard analysis conducted under subsection (b) will be significantly minimized or prevented; and

“(2) the food manufactured, processed, packed, or held by such facility will not be adulterated under section 402 or misbranded under section 403(w).

“(d) MONITORING OF EFFECTIVENESS.—The owner, operator, or agent in charge of a facility shall monitor the effectiveness of the preventive controls implemented under subsection (c) to provide assurances that the outcomes described in subsection (c) shall be achieved.

“(e) CORRECTIVE ACTIONS.—The owner, operator, or agent in charge of a facility shall establish procedures that a facility will implement if the preventive controls implemented under subsection (c) are found to be ineffective through monitoring under subsection (d).

“(f) VERIFICATION.—The owner, operator, or agent in charge of a facility shall verify that—

“(1) the preventive controls implemented under subsection (c) are adequate to control the hazards identified under subsection (b);

“(2) the owner, operator, or agent is conducting monitoring in accordance with subsection (d);

“(3) the owner, operator, or agent is making appropriate decisions about corrective actions taken under subsection (e); and

“(4) there is documented, periodic reanalysis of the plan under subsection (i) to ensure that the plan is still relevant to the raw materials, as well as to conditions and processes in the facility, and to new and emerging threats.

“(g) RECORDKEEPING.—The owner, operator, or agent in charge of a facility shall maintain, for not less than 2 years, records documenting the monitoring of the preventive controls implemented under subsection (c), instances of nonconformance material to food safety, instances when corrective actions were implemented, and the efficacy of preventive controls and corrective actions.

“(h) WRITTEN PLAN AND DOCUMENTATION.—Each owner, operator, or agent in charge of a facility shall prepare a written plan that documents and describes the procedures used by the facility to comply with the requirements of this section, including analyzing the hazards under subsection (b) and identifying the preventive controls adopted to address those hazards under subsection (c). Such written plan, together with documenta-

tion that the plan is being implemented, shall be made promptly available to a duly authorized representative of the Secretary upon oral or written request.

“(i) REQUIREMENT TO REANALYZE.—Each owner, operator, or agent in charge of a facility shall conduct a reanalysis under subsection (b) whenever a significant change is made in the activities conducted at a facility operated by such owner, operator, or agent if the change creates a reasonable potential for a new hazard or a significant increase in a previously identified hazard or not less frequently than once every 3 years, whichever is earlier. Such reanalysis shall be completed and additional preventive controls needed to address the hazard identified, if any, shall be implemented before the change in activities at the facility is commenced. Such owner, operator, or agent shall revise the written plan required under subsection (h) if such a significant change is made or document the basis for the conclusion that no additional or revised preventive controls are needed. The Secretary may require a reanalysis under this section to respond to new hazards and developments in scientific understanding.

“(j) DEEMED COMPLIANCE OF SEAFOOD, JUICE, AND LOW-ACID CANNED FOOD FACILITIES IN COMPLIANCE WITH HACCP.—An owner, operator, or agent in charge of a facility required to comply with 1 of the following standards and regulations with respect to such facility shall be deemed to be in compliance with this section, with respect to such facility:

“(1) The Seafood Hazard Analysis Critical Control Points Program of the Food and Drug Administration.

“(2) The Juice Hazard Analysis Critical Control Points Program of the Food and Drug Administration.

“(3) The Thermally Processed Low-Acid Foods Packaged in Hermetically Sealed Containers standards of the Food and Drug Administration (or any successor standards).

“(k) EXCEPTION FOR FACILITIES IN COMPLIANCE WITH SECTION 419.—This section shall not apply to a facility that is subject to section 419.

“(l) AUTHORITY WITH RESPECT TO CERTAIN FACILITIES.—The Secretary may, by regulation, exempt or modify the requirements for compliance under this section with respect to facilities that are solely engaged in the production of food for animals other than man or the storage of packaged foods that are not exposed to the environment.

“(m) DEFINITIONS.—For purposes of this section:

“(1) CRITICAL CONTROL POINT.—The term ‘critical control point’ means a point, step, or procedure in a food process at which control can be applied and is essential to prevent or eliminate a food safety hazard or reduce it to an acceptable level.

“(2) FACILITY.—The term ‘facility’ means a domestic facility or a foreign facility that is required to register under section 415.

“(3) PREVENTIVE CONTROLS.—The term ‘preventive controls’ means those risk-based, reasonably appropriate procedures, practices, and processes that a person knowledgeable about the safe manufacturing, processing, packing, or holding of food would have employed to significantly minimize or prevent the hazards identified under the hazard analysis conducted under subsection (a) and that are consistent with the current scientific understanding of safe food manufacturing, processing, packing, or holding at the time of the analysis. Those procedures, practices, and processes may include the following:

“(A) Sanitation procedures for food contact surfaces and utensils and food-contact surfaces of equipment.

“(B) Supervisor, manager, and employee hygiene training.

“(C) An environmental monitoring program to verify the effectiveness of pathogen controls.

“(D) An allergen control program.

“(E) A recall contingency plan.

“(F) Good Manufacturing Practices (GMPs).

“(G) Supplier verification activities.”.

(b) REGULATIONS.—

(1) IN GENERAL.—The Secretary of Health and Human Services (referred to in this Act as the “Secretary”) shall promulgate regulations to establish science-based minimum standards for conducting a hazard analysis, documenting hazards, implementing preventive controls, and documenting the implementation of the preventive controls under section 418 of the Federal Food, Drug, and Cosmetic Act (as added by subsection (a)).

(2) CONTENT.—The regulations promulgated under paragraph (1) shall provide sufficient flexibility to be applicable in all situations, including in the operations of small businesses.

(3) RULE OF CONSTRUCTION.—Nothing in this subsection shall be construed to provide the Secretary with the authority to apply specific technologies, practices, or critical controls to an individual facility.

(4) REVIEW.—In promulgating the regulations under paragraph (1), the Secretary shall review regulatory hazard analysis and preventive control programs in existence on the date of enactment of this Act to ensure that the program under such section 418 is consistent, to the extent practicable, with applicable internationally recognized standards in existence on such date.

(c) GUIDANCE DOCUMENT.—The Secretary shall issue a guidance document related to hazard analysis and preventive controls required under section 418 of the Federal Food, Drug, and Cosmetic Act (as added by subsection (a)).

(d) PROHIBITED ACTS.—Section 301 (21 U.S.C. 331) is amended by adding at the end the following:

“(oo) The operation of a facility that manufacturers, processes, packs, or holds food for sale in the United States if the owner, operator, or agent in charge of such facility is not in compliance with section 418.”.

(e) NO EFFECT ON HACCP AUTHORITIES.—Nothing in the amendments made by this section limits the authority of the Secretary under the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 301 et seq.) or the Public Health Service Act (42 U.S.C. 201 et seq.) to revise, issue, or enforce product and category-specific regulations, such as the Seafood Hazard Analysis Critical Controls Points Program, the Juice Hazard Analysis Critical Control Program, and the Thermally Processed Low-Acid Foods Packaged in Hermetically Sealed Containers standards.

(f) EFFECTIVE DATE.—

(1) GENERAL RULE.—The amendments made by this section shall take effect 18 months after the date of enactment of this Act.

(2) EXCEPTIONS.—Notwithstanding paragraph (1)—

(A) the amendments made by this section shall apply to a small business (as defined by the Secretary) after the date that is 2 years after the date of enactment of this Act; and

(B) the amendments made by this section shall apply to a very small business (as defined by the Secretary) after the date that is 3 years after the date of enactment of this Act.

#### SEC. 104. PERFORMANCE STANDARDS.

The Secretary shall, not less frequently than every 2 years, review and evaluate relevant health data and other relevant information, including from toxicological and epidemiological studies and analyses, to determine the most significant food-borne con-

taminants and, when appropriate to reduce the risk of serious illness or death to humans or animals or to prevent the adulteration of the food under section 402 of the Federal Food, Drug, or Cosmetic Act, (21 U.S.C. 342) or to prevent the spread of communicable disease under section 361 of the Public Health Service Act (42 U.S.C. 264), shall issue contaminant-specific and science-based guidance documents, actions levels, or regulations. Such guidance, action levels, or regulations shall apply to products or product classes and shall not be written to be facility-specific.

#### SEC. 105. STANDARDS FOR PRODUCE SAFETY.

(a) IN GENERAL.—Chapter IV (21 U.S.C. 341 et seq.), as amended by section 103, is amended by adding at the end the following:

##### “SEC. 419. STANDARDS FOR PRODUCE SAFETY.

“(a) PROPOSED RULEMAKING.—

“(1) IN GENERAL.—Not later than 1 year after the date of enactment of the FDA Food Safety Modernization Act, the Secretary, in consultation with the Secretary of Agriculture and representatives of State departments of agriculture, shall publish a notice of proposed rulemaking to establish science-based minimum standards for the safe production and harvesting of those types of fruits and vegetables that are raw agricultural commodities for which the Secretary has determined that such standards minimize the risk of serious adverse health consequences or death.

“(2) PUBLIC INPUT.—During the comment period on the notice of proposed rulemaking under paragraph (1), the Secretary shall conduct not less than 3 public meetings in diverse geographical areas of the United States to provide persons in different regions an opportunity to comment.

“(3) CONTENT.—The proposed rulemaking under paragraph (1) shall—

“(A) include, with respect to growing, harvesting, sorting, and storage operations, minimum standards related to soil amendments, hygiene, packaging, temperature controls, animal encroachment, and water; and

“(B) consider hazards that occur naturally, may be unintentionally introduced, or may be intentionally introduced, including by acts of terrorism.

“(4) PRIORITIZATION.—The Secretary shall prioritize the implementation of the regulations for specific fruits and vegetables that are raw agricultural commodities that have been associated with food-borne illness outbreaks.

“(b) FINAL REGULATION.—

“(1) IN GENERAL.—Not later than 1 year after the close of the comment period for the proposed rulemaking under subsection (a), the Secretary shall adopt a final regulation to provide for minimum standards for those types of fruits and vegetables that are raw agricultural commodities for which the Secretary has determined that such standards minimize the risk of serious adverse health consequences or death.

“(2) FINAL REGULATION.—The final regulation shall—

“(A) provide a reasonable period of time for compliance, taking into account the needs of small businesses for additional time to comply;

“(B) provide for coordination of education and enforcement activities by State and local officials, as designated by the Governors of the respective States; and

“(C) include a description of the variance process under subsection (c) and the types of permissible variances the Secretary may grant.

“(c) CRITERIA.—

“(1) IN GENERAL.—The regulations adopted under subsection (b) shall—

“(A) set forth those procedures, processes, and practices as the Secretary determines to

be reasonably necessary to prevent the introduction of known or reasonably foreseeable biological, chemical, and physical hazards, including hazards that occur naturally, may be unintentionally introduced, or may be intentionally introduced, including by acts of terrorism, into fruits and vegetables that are raw agricultural commodities and to provide reasonable assurances that the produce is not adulterated under section 402; and

“(B) permit States and foreign countries from which food is imported into the United States, subject to paragraph (2), to request from the Secretary variances from the requirements of the regulations, where upon approval of the Secretary, the variance is considered permissible under the requirements of the regulations adopted under subsection (b)(2)(C) and where the State or foreign country determines that the variance is necessary in light of local growing conditions and that the procedures, processes, and practices to be followed under the variance are reasonably likely to ensure that the produce is not adulterated under section 402 to the same extent as the requirements of the regulation adopted under subsection (b).

“(2) APPROVAL OF VARIANCES.—A State or foreign country from which food is imported into the United States shall request a variance from the Secretary in writing. The Secretary may deny such a request as not reasonably likely to ensure that the produce is not adulterated under section 402 to the same extent as the requirements of the regulation adopted under subsection (b).

“(d) ENFORCEMENT.—The Secretary may coordinate with the Secretary of Agriculture and shall contract and coordinate with the agency or department designated by the Governor of each State to perform activities to ensure compliance with this section.

“(e) GUIDANCE.—Not later than 1 year after the date of enactment of the FDA Food Safety Modernization Act, the Secretary shall publish, after consultation with the Secretary of Agriculture and representatives of State departments of agriculture, updated good agricultural practices and guidance for the safe production and harvesting of specific types of fresh produce.

“(f) EXCEPTION FOR FACILITIES IN COMPLIANCE WITH SECTION 418.—This section shall not apply to a facility that is subject to section 418.”.

(b) PROHIBITED ACTS.—Section 301 (21 U.S.C. 331), as amended by section 103, is amended by adding at the end the following:

“(pp) The production or harvesting of produce not in accordance with minimum standards as provided by regulation under section 419(b) or a variance issued under section 419(c).”.

(c) NO EFFECT ON HACCP AUTHORITIES.—Nothing in the amendments made by this section limits the authority of the Secretary under the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 301 et seq.) or the Public Health Service Act (42 U.S.C. 201 et seq.) to revise, issue, or enforce product and category-specific regulations, such as the Seafood Hazard Analysis Critical Controls Points Program, the Juice Hazard Analysis Critical Control Program, and the Thermally Processed Low-Acid Foods Packaged in Hermetically Sealed Containers standards.

#### SEC. 106. PROTECTION AGAINST INTENTIONAL ADULTERATION.

(a) IN GENERAL.—Chapter IV (21 U.S.C. 341 et seq.), as amended by section 105, is amended by adding at the end the following:

##### “SEC. 420. PROTECTION AGAINST INTENTIONAL ADULTERATION.

“(a) IN GENERAL.—Not later than 24 months after the date of enactment of the FDA Food Safety Modernization Act, the

Secretary, in consultation with the Secretary of Homeland Security and the Secretary of Agriculture, shall promulgate regulations to protect against the intentional adulteration of food subject to this Act.

“(b) CONTENT OF REGULATIONS.—Regulations under subsection (a) shall only apply to food—

“(1) for which the Secretary has identified clear vulnerabilities (such as short shelf-life or susceptibility to intentional contamination at critical control points);

“(2) in bulk or batch form, prior to being packaged for the final consumer; and

“(3) for which there is a high risk of intentional contamination, as determined by the Secretary, that could cause serious adverse health consequences or death to humans or animals.

“(c) DETERMINATIONS.—In making the determination under subsection (b)(3), the Secretary shall—

“(1) conduct vulnerability assessments of the food system;

“(2) consider the best available understanding of uncertainties, risks, costs, and benefits associated with guarding against intentional adulteration at vulnerable points; and

“(3) determine the types of science-based mitigation strategies or measures that are necessary to protect against the intentional adulteration of food.

“(d) EXCEPTION.—This section shall not apply to food produced on farms, except for milk.

“(e) DEFINITION.—For purposes of this section, the term ‘farm’ has the meaning given that term in section 1.227 of title 21, Code of Federal Regulations (or any successor regulation).”

(b) GUIDANCE DOCUMENTS.—

(1) IN GENERAL.—Not later than 1 year after the date of enactment of this Act, the Secretary, in consultation with the Secretary of Homeland Security and the Secretary of Agriculture, shall issue guidance documents related to protection against the intentional adulteration of food, including mitigation strategies or measures to guard against such adulteration as required under section 420 of the Federal Food, Drug, and Cosmetic Act, as added by subsection (a).

(2) CONTENT.—The guidance document issued under paragraph (1) shall—

(A) specify how a person shall assess whether the person is required to implement mitigation strategies or measures intended to protect against the intentional adulteration of food;

(B) specify appropriate science-based mitigation strategies or measures to prepare and protect the food supply chain at specific vulnerable points, as appropriate;

(C) include a model assessment for a person to use under subparagraph (A);

(D) include examples of mitigation strategies or measures described in subparagraph (B); and

(E) specify situations in which the examples of mitigation strategies or measures described in subparagraph (D) are appropriate.

(3) LIMITED DISTRIBUTION.—In the interest of national security, the Secretary, in consultation with the Secretary of Homeland Security, may determine the time and manner in which the guidance documents issued under paragraph (1) are made public, including by releasing such documents to targeted audiences.

(c) PERIODIC REVIEW.—The Secretary shall periodically review and, as appropriate, update the regulation under subsection (a) and the guidance documents under subsection (b).

(d) PROHIBITED ACTS.—Section 301 (21 U.S.C. 331 et seq.), as amended by section 105, is amended by adding at the end the following:

“(qq) The failure to comply with section 420.”

**SEC. 107. AUTHORITY TO COLLECT FEES.**

(a) FEES FOR REINSPECTION, RECALL, AND IMPORTATION ACTIVITIES.—Subchapter C of chapter VII (21 U.S.C. 379f et seq.) is amended by inserting after section 740 the following:

**“PART 5—FEES RELATED TO FOOD**

**“SEC. 740A. AUTHORITY TO COLLECT AND USE FEES.**

“(A) IN GENERAL.—

“(1) PURPOSE AND AUTHORITY.—For fiscal year 2010 and each subsequent fiscal year, the Secretary shall, in accordance with this section, assess and collect fees from—

“(A) each domestic facility (as defined in section 415(b)) subject to a reinspection in such fiscal year, to cover reinspection-related costs for such year;

“(B) each domestic facility (as defined in section 415(b)) and importer subject to a food recall in such fiscal year, to cover food recall activities performed by the Secretary, including technical assistance, follow-up effectiveness checks, and public notifications, for such year;

“(C) each importer participating in the voluntary qualified importer program under section 806 in such year, to cover the administrative costs such program for such year; and

“(D) each importer subject to a reinspection in such fiscal year at a port of entry, to cover reinspection-related costs at ports of entry for such year.

“(2) DEFINITIONS.—For purposes of this section—

“(A) the term ‘reinspection’ means—

“(i) with respect to domestic facilities (as defined in section 415(b)), 1 or more inspections conducted under section 704 subsequent to an inspection conducted under such provision which identified noncompliance materially related to a food safety requirement of this Act, specifically to determine whether compliance has been achieved to the Secretary’s satisfaction; and

“(ii) with respect to importers, 1 or more examinations conducted under section 801 subsequent to an examination conducted under such provision which identified noncompliance materially related to a food safety requirement of this Act, specifically to determine whether compliance has been achieved to the Secretary’s satisfaction; and

“(B) the term ‘reinspection-related costs’ means all expenses, including administrative expenses, incurred in connection with—

“(i) arranging, conducting, and evaluating the results of reinspections; and

“(ii) assessing and collecting reinspection fees under this section.

“(b) ESTABLISHMENT OF FEES.—

“(1) IN GENERAL.—Subject to subsections (c) and (d), the Secretary shall establish the fees to be collected under this section for each fiscal year specified in subsection (a)(1), based on the methodology described under paragraph (2), and shall publish such fees in a Federal Register notice not later than 60 days before the start of each such year.

“(2) FEE METHODOLOGY.—

“(A) FEES.—Fees amounts established for collection—

“(i) under subparagraph (A) of subsection (a)(1) for a fiscal year shall be based on the Secretary’s estimate of 100 percent of the costs of the reinspection-related activities (including by type or level of reinspection activity, as the Secretary determines applicable) described in such subparagraph (A) for such year;

“(ii) under subparagraph (B) of subsection (a)(1) for a fiscal year shall be based on the Secretary’s estimate of 100 percent of the costs of the activities described in such subparagraph (B) for such year;

“(iii) under subparagraph (C) of subsection (a)(1) for a fiscal year shall be based on the Secretary’s estimate of 100 percent of the costs of the activities described in such subparagraph (C) for such year; and

“(iv) under subparagraph (D) of subsection (a)(1) for a fiscal year shall be based on the Secretary’s estimate of 100 percent of the costs of the activities described in such subparagraph (D) for such year.

“(B) OTHER CONSIDERATIONS.—

“(i) VOLUNTARY QUALIFIED IMPORTER PROGRAM.—

“(I) PARTICIPATION.—In establishing the fee amounts under subparagraph (A)(iii) for a fiscal year, the Secretary shall provide for the number of importers who have submitted to the Secretary a notice under section 806(e) informing the Secretary of the intent of such importer to participate in the program under section 806 in such fiscal year.

“(II) RECOUPMENT.—In establishing the fee amounts under subparagraph (A)(iii) for the first 5 fiscal years after the date of enactment of this section, the Secretary shall include in such fee a reasonable surcharge that provides a recoupment of the costs expended by the Secretary to establish and implement the first year of the program under section 806.

“(ii) CREDITING OF FEES.—In establishing the fee amounts under subparagraph (A) for a fiscal year, the Secretary shall provide for the crediting of fees from the previous year to the next year if the Secretary overestimated the amount of fees needed to carry out such activities, and consider the need to account for any adjustment of fees and such other factors as the Secretary determines appropriate.

“(3) USE OF FEES.—The Secretary shall make all of the fees collected pursuant to clause (i), (ii), (iii), and (iv) of paragraph (2)(A) available solely to pay for the costs referred to in such clause (i), (ii), (iii), and (iv) of paragraph (2)(A), respectively.

“(4) COMPLIANCE WITH INTERNATIONAL AGREEMENTS.—Nothing in this section shall be construed to authorize the assessment of any fee inconsistent with the agreement establishing the World Trade Organization or any other treaty or international agreement to which the United States is a party.

“(c) LIMITATIONS.—

“(1) IN GENERAL.—Fees under subsection (a) shall be refunded for a fiscal year beginning after fiscal year 2010 unless appropriations for the Center for Food Safety and Applied Nutrition and the Center for Veterinary Medicine and related activities of the Office of Regulatory Affairs at 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 Center for Food Safety and Applied Nutrition and the Center for Veterinary Medicine and related activities of the Office of Regulatory Affairs at the Food and Drug Administration for the preceding fiscal year (excluding the amount of fees appropriated for such fiscal year) multiplied by 1 plus 4.5 percent.

“(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, under subsection (a), notwithstanding the provisions of subsection (a) relating to the date fees are to be paid.

“(3) LIMITATION ON AMOUNT OF CERTAIN FEES.—

“(A) IN GENERAL.—Notwithstanding any other provision of this section and subject to

subparagraph (B), the Secretary may not collect fees in a fiscal year such that the amount collected—

“(i) under subparagraph (B) of subsection (a)(1) exceeds \$20,000,000; and

“(ii) under subparagraphs (A) and (D) of subsection (a)(1) exceeds \$25,000,000 combined.

“(B) EXCEPTION.—If a domestic facility (as defined in section 415(b)) or an importer becomes subject to a fee described in subparagraph (A), (B), or (D) of subsection (a)(1) after the maximum amount of fees has been collected by the Secretary under subparagraph (A), the Secretary may collect a fee from such facility or importer.

“(d) CREDITING AND AVAILABILITY OF FEES.—Fees authorized under subsection (a) shall be collected and available for obligation only to the extent and in the amount provided in appropriations Acts. Such fees are authorized to remain available until expended. Such sums as may be necessary may be transferred from the Food and Drug Administration salaries and expenses account without fiscal year limitation to such appropriation account for salaries and expenses with such fiscal year limitation. The sums transferred shall be available solely for the purpose of paying the operating expenses of the Food and Drug Administration employees and contractors performing activities associated with these food safety fees.

“(e) COLLECTION OF FEES.—

“(1) IN GENERAL.—The Secretary shall specify in the Federal Register notice described in subsection (b)(1) the time and manner in which fees assessed under this section shall be collected.

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

“(f) ANNUAL REPORT TO CONGRESS.—Not later than 120 days after each fiscal year for which fees are assessed under this section, the Secretary shall submit a report to the Committee on Health, Education, Labor, and Pensions of the United States Senate and the Committee on Energy and Commerce of the United States House of Representatives, to include a description of fees assessed and collected for each such year and a summary description of the entities paying such fees and the types of business in which such entities engage.

“(g) AUTHORIZATION OF APPROPRIATIONS.—For fiscal year 2010 and each fiscal year thereafter, 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 the other provisions of this section.”

(b) EXPORT CERTIFICATION FEES FOR FOODS AND ANIMAL FEED.—

(1) AUTHORITY FOR EXPORT CERTIFICATIONS FOR FOOD, INCLUDING ANIMAL FEED.—Section 801(e)(4)(A) (21 U.S.C. 381(e)(4)(A)) is amended—

(A) in the matter preceding clause (i), by striking “a drug” and inserting “a food, drug”;

(B) in clause (i) by striking “exported drug” and inserting “exported food, drug”;

(C) in clause (ii) by striking “the drug” each place it appears and inserting “the food, drug”.

(2) CLARIFICATION OF CERTIFICATION.—Section 801(e)(4) (21 U.S.C. 381(e)(4)) is amended by inserting after subparagraph (B) the following new subparagraph:

“(C) For purposes of this paragraph, a certification by the Secretary shall be made on

such basis, and in such form (including a publicly available listing) as the Secretary determines appropriate.”

#### SEC. 108. NATIONAL AGRICULTURE AND FOOD DEFENSE STRATEGY.

(a) DEVELOPMENT AND SUBMISSION OF STRATEGY.—

(1) IN GENERAL.—Not later than 1 year after the date of enactment of this Act, the Secretary of Health and Human Services and the Secretary of Agriculture, in coordination with the Secretary of Homeland Security, shall prepare and submit to the relevant committees of Congress, and make publicly available on the Internet Web site of the Department of Health and Human Services and the Department of Agriculture, the National Agriculture and Food Defense Strategy.

(2) IMPLEMENTATION PLAN.—The strategy shall include an implementation plan for use by the Secretaries described under paragraph (1) in carrying out the strategy.

(3) RESEARCH.—The strategy shall include a coordinated research agenda for use by the Secretaries described under paragraph (1) in conducting research to support the goals and activities described in paragraphs (1) and (2) of subsection (b).

(4) REVISIONS.—Not later than 4 years after the date on which the strategy is submitted to the relevant committees of Congress under paragraph (1), and not less frequently than every 4 years thereafter, the Secretary of Health and Human Services and the Secretary of Agriculture, in coordination with the Secretary of Homeland Security, shall revise and submit to the relevant committees of Congress the strategy.

(5) CONSISTENCY WITH EXISTING PLANS.—The strategy described in paragraph (1) shall be consistent with—

(A) the National Incident Management System;

(B) the National Response Framework;

(C) the National Infrastructure Protection Plan;

(D) the National Preparedness Goals; and

(E) other relevant national strategies.

(b) COMPONENTS.—

(1) IN GENERAL.—The strategy shall include a description of the process to be used by the Department of Health and Human Services, the Department of Agriculture, and the Department of Homeland Security—

(A) to achieve each goal described in paragraph (2); and

(B) to evaluate the progress made by Federal, State, local, and tribal governments towards the achievement of each goal described in paragraph (2).

(2) GOALS.—The strategy shall include a description of the process to be used by the Department of Health and Human Services, the Department of Agriculture, and the Department of Homeland Security to achieve the following goals:

(A) PREPAREDNESS GOAL.—Enhance the preparedness of the agriculture and food system by—

(i) conducting vulnerability assessments of the agriculture and food system;

(ii) mitigating vulnerabilities of the system;

(iii) improving communication and training relating to the system;

(iv) developing and conducting exercises to test decontamination and disposal plans;

(v) developing modeling tools to improve event consequence assessment and decision support; and

(vi) preparing risk communication tools and enhancing public awareness through outreach.

(B) DETECTION GOAL.—Improve agriculture and food system detection capabilities by—

(i) identifying contamination in food products at the earliest possible time; and

(ii) conducting surveillance to prevent the spread of diseases.

(C) EMERGENCY RESPONSE GOAL.—Ensure an efficient response to agriculture and food emergencies by—

(i) immediately investigating animal disease outbreaks and suspected food contamination;

(ii) preventing additional human illnesses;

(iii) organizing, training, and equipping animal, plant, and food emergency response teams of—

(I) the Federal Government; and

(II) State, local, and tribal governments;

(iv) designing, developing, and evaluating training and exercises carried out under agriculture and food defense plans; and

(v) ensuring consistent and organized risk communication to the public by—

(I) the Federal Government;

(II) State, local, and tribal governments; and

(III) the private sector.

(D) RECOVERY GOAL.—Secure agriculture and food production after an agriculture or food emergency by—

(i) working with the private sector to develop business recovery plans to rapidly resume agriculture and food production;

(ii) conducting exercises of the plans described in subparagraph (C) with the goal of long-term recovery results;

(iii) rapidly removing, and effectively disposing of—

(I) contaminated agriculture and food products; and

(II) infected plants and animals; and

(iv) decontaminating and restoring areas affected by an agriculture or food emergency.

#### SEC. 109. FOOD AND AGRICULTURE COORDINATING COUNCILS.

The Secretary of Homeland Security, in consultation with the Secretary of Health and Human Services and the Secretary of Agriculture, shall within 180 days of enactment of this Act, and annually thereafter, submit to the relevant committees of Congress, and make publicly available on the Internet Web site of the Department of Homeland Security, a report on the activities of the Food and Agriculture Government Coordinating Council and the Food and Agriculture Sector Coordinating Council, including the progress of such Councils on—

(1) facilitating partnerships between public and private entities to help unify and enhance the protection of the agriculture and food system of the United States;

(2) providing for the regular and timely interchange of information between each council relating to the security of the agriculture and food system (including intelligence information);

(3) identifying best practices and methods for improving the coordination among Federal, State, local, and private sector preparedness and response plans for agriculture and food defense; and

(4) recommending methods by which to protect the economy and the public health of the United States from the effects of—

(A) animal or plant disease outbreaks;

(B) food contamination; and

(C) natural disasters affecting agriculture and food.

#### SEC. 110. BUILDING DOMESTIC CAPACITY.

(a) IN GENERAL.—

(1) INITIAL REPORT.—The Secretary shall, not later than 2 years after the date of enactment of this Act, submit to Congress a comprehensive report that identifies programs and practices that are intended to promote the safety and security of food and to prevent outbreaks of food-borne illness and other food-related hazards that can be addressed through preventive activities. Such

report shall include a description of the following:

(A) Analysis of the need for regulations or guidance to industry.

(B) Outreach to food industry sectors, including through the Food and Agriculture Coordinating Councils referred to in section 109, to identify potential sources of emerging threats to the safety and security of the food supply and preventive strategies to address those threats.

(C) Systems to ensure the prompt distribution to the food industry of information and technical assistance concerning preventive strategies.

(D) Communication systems to ensure that information about specific threats to the safety and security of the food supply are rapidly and effectively disseminated.

(E) Surveillance systems and laboratory networks to rapidly detect and respond to food-borne illness outbreaks and other food-related hazards, including how such systems and networks are integrated.

(F) Outreach, education, and training provided to States and local governments to build State and local food safety and food defense capabilities, including progress implementing strategies developed under sections 108 and 205.

(G) The estimated resources needed to effectively implement the programs and practices identified in the report developed in this section over a 5-year period.

(2) BIENNIAL REPORTS.—On a biennial basis following the submission of the report under paragraph (1), the Secretary shall submit to Congress a report that—

(A) reviews previous food safety programs and practices;

(B) outlines the success of those programs and practices;

(C) identifies future programs and practices; and

(D) includes information related to any matter described in subparagraphs (A) through (G) of paragraph (1), as necessary.

(b) RISK-BASED ACTIVITIES.—The report developed under subsection (a)(1) shall describe methods that seek to ensure that resources available to the Secretary for food safety-related activities are directed at those actions most likely to reduce risks from food, including the use of preventive strategies and allocation of inspection resources. The Secretary shall promptly undertake those risk-based actions that are identified during the development of the report as likely to contribute to the safety and security of the food supply.

(c) CAPABILITY FOR LABORATORY ANALYSES; RESEARCH.—The report developed under subsection (a)(1) shall provide a description of methods to increase capacity to undertake analyses of food samples promptly after collection, to identify new and rapid analytical techniques, including techniques that can be employed at ports of entry and through Food Emergency Response Network laboratories, and to provide for well-equipped and staffed laboratory facilities.

(d) INFORMATION TECHNOLOGY.—The report developed under subsection (a)(1) shall include a description of such information technology systems as may be needed to identify risks and receive data from multiple sources, including foreign governments, State, local, and tribal governments, other Federal agencies, the food industry, laboratories, laboratory networks, and consumers. The information technology systems that the Secretary describes shall also provide for the integration of the facility registration system under section 415 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 350d), and the prior notice system under section 801(m) of such Act (21 U.S.C. 381(m)) with other information technology systems that are used by the

Federal Government for the processing of food offered for import into the United States.

(e) AUTOMATED RISK ASSESSMENT.—The report developed under subsection (a)(1) shall include a description of progress toward developing and improving an automated risk assessment system for food safety surveillance and allocation of resources.

(f) TRACEBACK AND SURVEILLANCE REPORT.—The Secretary shall include in the report developed under subsection (a)(1) an analysis of the Food and Drug Administration's performance in food-borne illness outbreaks during the 5-year period preceding the date of enactment of this Act involving fruits and vegetables that are raw agricultural commodities (as defined in section 201(r) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 321(r)) and recommendations for enhanced surveillance, outbreak response, and traceability. Such findings and recommendations shall address communication and coordination with the public, industry, and State and local governments, outbreak identification, and traceback.

(g) BIENNIAL FOOD SAFETY AND FOOD DEFENSE RESEARCH PLAN.—The Secretary and the Secretary of Agriculture shall, on a biennial basis, submit to Congress a joint food safety and food defense research plan which may include studying the long-term health effects of food-borne illness. Such biennial plan shall include a list and description of projects conducted during the previous 2-year period and the plan for projects to be conducted during the following 2-year period.

**SEC. 111. FINAL RULE FOR PREVENTION OF SALMONELLA ENTERITIDIS IN SHELL EGGS DURING PRODUCTION.**

Not later than 1 year after the date of enactment of this Act, the Secretary shall issue a final rule based on the proposed rule issued by the Commissioner of Food and Drugs entitled "Prevention of Salmonella Enteritidis in Shell Eggs During Production", 69 Fed. Reg. 56824, (September 22, 2004).

**SEC. 112. SANITARY TRANSPORTATION OF FOOD.**

Not later than 1 year after the date of enactment of this Act, the Secretary shall promulgate regulations described in section 416(b) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 350e(b)).

**SEC. 113. FOOD ALLERGY AND ANAPHYLAXIS MANAGEMENT.**

(a) DEFINITIONS.—In this section:

(1) EARLY CHILDHOOD EDUCATION PROGRAM.—The term "early childhood education program" means—

(A) a Head Start program or an Early Head Start program carried out under the Head Start Act (42 U.S.C. 9831 et seq.);

(B) a State licensed or regulated child care program or school; or

(C) a State prekindergarten program that serves children from birth through kindergarten.

(2) ESEA DEFINITIONS.—The terms "local educational agency", "secondary school", "elementary school", and "parent" have the meanings given the terms in section 9101 of the Elementary and Secondary Education Act of 1965 (20 U.S.C. 7801).

(3) SCHOOL.—The term "school" includes public—

(A) kindergartens;

(B) elementary schools; and

(C) secondary schools.

(4) SECRETARY.—The term "Secretary" means the Secretary of Health and Human Services.

(b) ESTABLISHMENT OF VOLUNTARY FOOD ALLERGY AND ANAPHYLAXIS MANAGEMENT GUIDELINES.—

(1) ESTABLISHMENT.—

(A) IN GENERAL.—Not later than 1 year after the date of enactment of this Act, the

Secretary, in consultation with the Secretary of Education, shall—

(i) develop guidelines to be used on a voluntary basis to develop plans for individuals to manage the risk of food allergy and anaphylaxis in schools and early childhood education programs; and

(ii) make such guidelines available to local educational agencies, schools, early childhood education programs, and other interested entities and individuals to be implemented on a voluntary basis only.

(B) APPLICABILITY OF FERPA.—Each plan described in subparagraph (A) that is developed for an individual shall be considered an education record for the purpose of the Family Educational Rights and Privacy Act of 1974 (20 U.S.C. 1232g).

(2) CONTENTS.—The voluntary guidelines developed by the Secretary under paragraph (1) shall address each of the following, and may be updated as the Secretary determines necessary:

(A) Parental obligation to provide the school or early childhood education program, prior to the start of every school year, with—

(i) documentation from their child's physician or nurse—

(I) supporting a diagnosis of food allergy, and any risk of anaphylaxis, if applicable;

(II) identifying any food to which the child is allergic;

(III) describing, if appropriate, any prior history of anaphylaxis;

(IV) listing any medication prescribed for the child for the treatment of anaphylaxis;

(V) detailing emergency treatment procedures in the event of a reaction;

(VI) listing the signs and symptoms of a reaction; and

(VII) assessing the child's readiness for self-administration of prescription medication; and

(ii) a list of substitute meals that may be offered to the child by school or early childhood education program food service personnel.

(B) The creation and maintenance of an individual plan for food allergy management, in consultation with the parent, tailored to the needs of each child with a documented risk for anaphylaxis, including any procedures for the self-administration of medication by such children in instances where—

(i) the children are capable of self-administering medication; and

(ii) such administration is not prohibited by State law.

(C) Communication strategies between individual schools or early childhood education programs and providers of emergency medical services, including appropriate instructions for emergency medical response.

(D) Strategies to reduce the risk of exposure to anaphylactic causative agents in classrooms and common school or early childhood education program areas such as cafeterias.

(E) The dissemination of general information on life-threatening food allergies to school or early childhood education program staff, parents, and children.

(F) Food allergy management training of school or early childhood education program personnel who regularly come into contact with children with life-threatening food allergies.

(G) The authorization and training of school or early childhood education program personnel to administer epinephrine when the nurse is not immediately available.

(H) The timely accessibility of epinephrine by school or early childhood education program personnel when the nurse is not immediately available.

(I) The creation of a plan contained in each individual plan for food allergy management

that addresses the appropriate response to an incident of anaphylaxis of a child while such child is engaged in extracurricular programs of a school or early childhood education program, such as non-academic outings and field trips, before- and after-school programs or before- and after-early child education program programs, and school-sponsored or early childhood education program-sponsored programs held on weekends.

(J) Maintenance of information for each administration of epinephrine to a child at risk for anaphylaxis and prompt notification to parents.

(K) Other elements the Secretary determines necessary for the management of food allergies and anaphylaxis in schools and early childhood education programs.

(3) RELATION TO STATE LAW.—Nothing in this section or the guidelines developed by the Secretary under paragraph (1) shall be construed to preempt State law, including any State law regarding whether students at risk for anaphylaxis may self-administer medication.

(C) SCHOOL-BASED FOOD ALLERGY MANAGEMENT GRANTS.—

(1) IN GENERAL.—The Secretary may award grants to local educational agencies to assist such agencies with implementing voluntary food allergy and anaphylaxis management guidelines described in subsection (b).

(2) APPLICATION.—

(A) IN GENERAL.—To be eligible to receive a grant under this subsection, a local educational agency shall submit an application to the Secretary at such time, in such manner, and including such information as the Secretary may reasonably require.

(B) CONTENTS.—Each application submitted under subparagraph (A) shall include—

(i) an assurance that the local educational agency has developed plans in accordance with the food allergy and anaphylaxis management guidelines described in subsection (b);

(ii) a description of the activities to be funded by the grant in carrying out the food allergy and anaphylaxis management guidelines, including—

(I) how the guidelines will be carried out at individual schools served by the local educational agency;

(II) how the local educational agency will inform parents and students of the guidelines in place;

(III) how school nurses, teachers, administrators, and other school-based staff will be made aware of, and given training on, when applicable, the guidelines in place; and

(IV) any other activities that the Secretary determines appropriate;

(iii) an itemization of how grant funds received under this subsection will be expended;

(iv) a description of how adoption of the guidelines and implementation of grant activities will be monitored; and

(v) an agreement by the local educational agency to report information required by the Secretary to conduct evaluations under this subsection.

(3) USE OF FUNDS.—Each local educational agency that receives a grant under this subsection may use the grant funds for the following:

(A) Purchase of materials and supplies, including limited medical supplies such as epinephrine and disposable wet wipes, to support carrying out the food allergy and anaphylaxis management guidelines described in subsection (b).

(B) In partnership with local health departments, school nurse, teacher, and personnel training for food allergy management.

(C) Programs that educate students as to the presence of, and policies and procedures

in place related to, food allergies and anaphylactic shock.

(D) Outreach to parents.

(E) Any other activities consistent with the guidelines described in subsection (b).

(4) DURATION OF AWARDS.—The Secretary may award grants under this subsection for a period of not more than 2 years. In the event the Secretary conducts a program evaluation under this subsection, funding in the second year of the grant, where applicable, shall be contingent on a successful program evaluation by the Secretary after the first year.

(5) LIMITATION ON GRANT FUNDING.—The Secretary may not provide grant funding to a local educational agency under this subsection after such local educational agency has received 2 years of grant funding under this subsection.

(6) MAXIMUM AMOUNT OF ANNUAL AWARDS.—A grant awarded under this subsection may not be made in an amount that is more than \$50,000 annually.

(7) PRIORITY.—In awarding grants under this subsection, the Secretary shall give priority to local educational agencies with the highest percentages of children who are counted under section 1124(c) of the Elementary and Secondary Education Act of 1965 (20 U.S.C. 6333(c)).

(8) MATCHING FUNDS.—

(A) IN GENERAL.—The Secretary may not award a grant under this subsection unless the local educational agency agrees that, with respect to the costs to be incurred by such local educational agency in carrying out the grant activities, the local educational agency shall make available (directly or through donations from public or private entities) non-Federal funds toward such costs in an amount equal to not less than 25 percent of the amount of the grant.

(B) DETERMINATION OF AMOUNT OF NON-FEDERAL CONTRIBUTION.—Non-Federal funds required under subparagraph (A) may be cash or in kind, including plant, equipment, or services. Amounts provided by the Federal Government, and any portion of any service subsidized by the Federal Government, may not be included in determining the amount of such non-Federal funds.

(9) ADMINISTRATIVE FUNDS.—A local educational agency that receives a grant under this subsection may use not more than 2 percent of the grant amount for administrative costs related to carrying out this subsection.

(10) PROGRESS AND EVALUATIONS.—At the completion of the grant period referred to in paragraph (4), a local educational agency shall provide the Secretary with information on how grant funds were spent and the status of implementation of the food allergy and anaphylaxis management guidelines described in subsection (b).

(11) SUPPLEMENT, NOT SUPPLANT.—Grant funds received under this subsection shall be used to supplement, and not supplant, non-Federal funds and any other Federal funds available to carry out the activities described in this subsection.

(12) AUTHORIZATION OF APPROPRIATIONS.—There is authorized to be appropriated to carry out this subsection \$30,000,000 for fiscal year 2010 and such sums as may be necessary for each of the 4 succeeding fiscal years.

(d) VOLUNTARY NATURE OF GUIDELINES.—

(1) IN GENERAL.—The food allergy and anaphylaxis management guidelines developed by the Secretary under subsection (b) are voluntary. Nothing in this section or the guidelines developed by the Secretary under subsection (b) shall be construed to require a local educational agency to implement such guidelines.

(2) EXCEPTION.—Notwithstanding paragraph (1), the Secretary may enforce an agreement by a local educational agency to implement food allergy and anaphylaxis

management guidelines as a condition of the receipt of a grant under subsection (c).

## TITLE II—IMPROVING CAPACITY TO DETECT AND RESPOND TO FOOD SAFETY PROBLEMS

### SEC. 201. TARGETING OF INSPECTION RESOURCES FOR DOMESTIC FACILITIES, FOREIGN FACILITIES, AND PORTS OF ENTRY; ANNUAL REPORT.

(a) TARGETING OF INSPECTION RESOURCES FOR DOMESTIC FACILITIES, FOREIGN FACILITIES, AND PORTS OF ENTRY.—Chapter IV (21 U.S.C. 341 et seq.), as amended by section 106, is amended by adding at the end the following:

#### “SEC. 421. TARGETING OF INSPECTION RESOURCES FOR DOMESTIC FACILITIES, FOREIGN FACILITIES, AND PORTS OF ENTRY; ANNUAL REPORT.

“(a) IDENTIFICATION AND INSPECTION OF FACILITIES.—

“(1) IDENTIFICATION.—The Secretary shall allocate resources to inspect facilities according to the risk profile of the facilities, which shall be based on the following factors:

“(A) The risk profile of the food manufactured, processed, packed, or held at the facility.

“(B) The facility’s history of food recalls, outbreaks, and violations of food safety standards.

“(C) The rigor of the facility’s hazard analysis and risk-based preventive controls.

“(D) Whether the food manufactured, processed, packed, handled, prepared, treated, distributed, or stored at the facility meets the criteria for priority under section 801(h)(1).

“(E) Whether the facility has received a certificate as described in section 809(b).

“(F) Any other criteria deemed necessary and appropriate by the Secretary for purposes of allocating inspection resources.

“(2) INSPECTIONS.—

“(A) IN GENERAL.—Beginning on the date of enactment of the FDA Food Safety Modernization Act, the Secretary shall increase the frequency of inspection of all facilities.

“(B) HIGH-RISK FACILITIES.—The Secretary shall increase the frequency of inspection of facilities identified under paragraph (1) as high-risk facilities such that—

“(i) for the first 2 years after the date of enactment of the FDA Food Safety Modernization Act, each high-risk facility is inspected not less often than once every 2 years; and

“(ii) for each succeeding year, each high-risk facility is inspected not less often than once each year.

“(C) NON-HIGH-RISK FACILITIES.—The Secretary shall ensure that each facility that is not identified under paragraph (1) as a high-risk facility is inspected not less often than once every 4 years.

“(b) IDENTIFICATION AND INSPECTION AT PORTS OF ENTRY.—The Secretary, in consultation with the Secretary of Homeland Security, shall allocate resources to inspect articles of food imported into the United States according to the risk profile of the article of food, which shall be based on the following factors:

“(1) The risk profile of the food imported.

“(2) The risk profile of the countries of origin and countries of transport of the food imported.

“(3) The history of food recalls, outbreaks, and violations of food safety standards of the food importer.

“(4) The rigor of the foreign supplier verification program under section 805.

“(5) Whether the food importer participates in the voluntary qualified importer program under section 806.

“(6) Whether the food meets the criteria for priority under section 801(h)(1).

“(7) Whether the food is from a facility that has received a certificate as described in section 809(b).

“(8) Any other criteria deemed appropriate by the Secretary for purposes of allocating inspection resources.

“(C) COORDINATION.—The Secretary shall improve coordination and cooperation with the Secretary of Agriculture to target food inspection resources.

“(d) FACILITY.—For purposes of this section, the term ‘facility’ means a domestic facility or a foreign facility that is required to register under section 415.”

(b) ANNUAL REPORT.—Section 903 (21 U.S.C. 393) is amended by adding at the end the following:

“(h) ANNUAL REPORT REGARDING FOOD.—Not later than February 1 of each year, the Secretary shall submit to Congress a report regarding—

“(1) information about food facilities including—

“(A) the appropriations used to inspect facilities registered pursuant to section 415 in the previous fiscal year;

“(B) the average cost of both a non-high-risk food facility inspection and a high-risk food facility inspection, if such a difference exists, in the previous fiscal year;

“(C) the number of domestic facilities and the number of foreign facilities registered pursuant to section 415 that the Secretary inspected in the previous fiscal year;

“(D) the number of domestic facilities and the number of foreign facilities registered pursuant to section 415 that the Secretary did not inspect in the previous fiscal year;

“(E) the number of high-risk facilities identified pursuant to section 421 that the Secretary inspected in the previous fiscal year; and

“(F) the number of high-risk facilities identified pursuant to section 421 that the Secretary did not inspect in the previous fiscal year;

“(2) information about food imports including—

“(A) the number of lines of food imported into the United States that the Secretary physically inspected or sampled in the previous fiscal year;

“(B) the number of lines of food imported into the United States that the Secretary did not physically inspect or sample in the previous fiscal year; and

“(C) the average cost of physically inspecting or sampling a food line subject to this Act that is imported or offered for import into the United States; and

“(3) information on the foreign offices established under section 309 of the FDA Food Safety Modernization Act including—

“(A) the number of foreign offices established; and

“(B) the number of personnel permanently stationed in each foreign office.

“(i) PUBLIC AVAILABILITY OF ANNUAL FOOD REPORTS.—The Secretary shall make the reports required under subsection (h) available to the public on the Internet Web site of the Food and Drug Administration.”

**SEC. 202. RECOGNITION OF LABORATORY ACCREDITATION FOR ANALYSES OF FOODS.**

(a) IN GENERAL.—Chapter IV (21 U.S.C. 341 et seq.), as amended by section 201, is amended by adding at the end the following:

**“SEC. 422. RECOGNITION OF LABORATORY ACCREDITATION FOR ANALYSES OF FOODS.**

“(a) RECOGNITION OF LABORATORY ACCREDITATION.—

“(1) IN GENERAL.—Not later than 2 years after the date of enactment of the FDA Food Safety Modernization Act, the Secretary shall—

“(A) provide for the recognition of accreditation bodies that accredit laboratories, in-

cluding laboratories run and operated by a State or locality, with a demonstrated capability to conduct analytical testing of food products; and

“(B) establish a publicly available registry of accreditation bodies, including the name of, contact information for, and other information deemed necessary by the Secretary about such bodies.

“(2) FOREIGN LABORATORIES.—Accreditation bodies may accredit laboratories that operate outside the United States, so long as such laboratories meet the accreditation standards applicable to domestic laboratories accredited under this section.

“(3) MODEL ACCREDITATION STANDARDS.—The Secretary shall develop model standards that an accreditation body shall require laboratories to meet in order to be included in the registry provided for under paragraph (1). In developing the model standards, the Secretary shall look to existing standards for guidance. The model standards shall include methods to ensure that—

“(A) appropriate sampling and analytical procedures are followed and reports of analyses are certified as true and accurate;

“(B) internal quality systems are established and maintained;

“(C) procedures exist to evaluate and respond promptly to complaints regarding analyses and other activities for which the laboratory is recognized;

“(D) individuals who conduct the analyses are qualified by training and experience to do so; and

“(E) any other criteria determined appropriate by the Secretary.

“(4) REVIEW OF ACCREDITATION.—To assure compliance with the requirements of this section, the Secretary shall—

“(A) periodically, or at least every 5 years, reevaluate accreditation bodies recognized under paragraph (1); and

“(B) promptly revoke the recognition of any accreditation body found not to be in compliance with the requirements of this section.

“(b) TESTING PROCEDURES.—

“(1) IN GENERAL.—Food testing shall be conducted by either Federal laboratories or non-Federal laboratories that have been accredited by an accreditation body on the registry established by the Secretary under subsection (a) whenever such testing is either conducted by or on behalf of an owner or consignee—

“(A) in support of admission of an article of food under section 801(a);

“(B) due to a specific testing requirement in this Act or implementing regulations, when applied to address an identified or suspected food safety problem;

“(C) under an Import Alert that requires successful consecutive tests; or

“(D) is so required by the Secretary as the Secretary deems appropriate to address an identified or suspected food safety problem.

“(2) RESULTS OF TESTING.—The results of any such testing shall be sent directly to the Food and Drug Administration. Such results may be submitted to the Food and Drug Administration through electronic means.

“(c) REVIEW BY SECRETARY.—If food sampling and testing performed by a laboratory run and operated by a State or locality that is accredited by an accreditation body on the registry established by the Secretary under subsection (a) result in a State recalling a food, the Secretary shall review the sampling and testing results for the purpose of determining the need for a national recall or other compliance and enforcement activities.

“(d) NO LIMIT ON SECRETARIAL AUTHORITY.—Nothing in this section shall be construed to limit the ability of the Secretary to review and act upon information from

food testing, including determining the sufficiency of such information and testing.”

(b) FOOD EMERGENCY RESPONSE NETWORK.—The Secretary, in coordination with the Secretary of Agriculture, the Secretary of Homeland Security, and State, local, and tribal governments shall, not later than 180 days after the date of enactment of this Act, and biennially thereafter, submit to the relevant committees of Congress, and make publicly available on the Internet Web site of the Department of Health and Human Services, a report on the progress in implementing a national food emergency response laboratory network that—

(1) provides ongoing surveillance, rapid detection, and surge capacity for large-scale food-related emergencies, including intentional adulteration of the food supply;

(2) coordinates the food laboratory capacities of State food laboratories, including the sharing of data between State laboratories to develop national situational awareness;

(3) provides accessible, timely, accurate, and consistent food laboratory services throughout the United States;

(4) develops and implements a methods repository for use by Federal, State, and local officials;

(5) responds to food-related emergencies; and

(6) is integrated with relevant laboratory networks administered by other Federal agencies.

**SEC. 203. INTEGRATED CONSORTIUM OF LABORATORY NETWORKS.**

(a) IN GENERAL.—The Secretary of Homeland Security, in consultation with the Secretary of Health and Human Services, the Secretary of Agriculture, and the Administrator of the Environmental Protection Agency, shall maintain an agreement through which relevant laboratory network members, as determined by the Secretary of Homeland Security, shall—

(1) agree on common laboratory methods in order to facilitate the sharing of knowledge and information relating to animal health, agriculture, and human health;

(2) identify the means by which each laboratory network member could work cooperatively—

(A) to optimize national laboratory preparedness; and

(B) to provide surge capacity during emergencies; and

(3) engage in ongoing dialogue and build relationships that will support a more effective and integrated response during emergencies.

(b) REPORTING REQUIREMENT.—The Secretary of Homeland Security shall, on a biennial basis, submit to the relevant committees of Congress, and make publicly available on the Internet Web site of the Department of Homeland Security, a report on the progress of the integrated consortium of laboratory networks, as established under subsection (a), in carrying out this section.

**SEC. 204. ENHANCING TRACEBACK AND RECORD-KEEPING.**

(a) IN GENERAL.—The Secretary, in consultation with the Secretary of Agriculture and representatives of State departments of health and agriculture, shall improve the capacity of the Secretary to effectively and rapidly track and trace, in the event of an outbreak, fruits and vegetables that are raw agricultural commodities.

(b) PILOT PROJECT.—

(1) IN GENERAL.—Not later than 9 months after the date of enactment of this Act, the Secretary shall establish a pilot project in coordination with the produce industry to explore and evaluate methods for rapidly and effectively tracking and tracing fruits and

vegetables that are raw agricultural commodities so that, if an outbreak occurs involving such a fruit or vegetable, the Secretary may quickly identify the source of the outbreak and the recipients of the contaminated food.

(2) **CONTENT.**—The Secretary shall select participants from the produce industry to run projects which overall shall include at least 3 different types of fruits or vegetables that have been the subject of outbreaks during the 5-year period preceding the date of enactment of this Act, and shall be selected in order to develop and demonstrate—

(A) methods that are applicable and appropriate for small businesses; and

(B) technologies, including existing technologies, that enhance traceback and trace forward.

(c) **REPORT.**—Not later than 18 months after the date of enactment of this Act, the Secretary shall report to Congress on the findings of the pilot project under subsection (b) together with recommendations for establishing more effective traceback and trace forward procedures for fruits and vegetables that are raw agricultural commodities.

(d) **TRACEBACK PERFORMANCE REQUIREMENTS.**—Not later than 24 months after the date of enactment of this Act, the Secretary shall publish a notice of proposed rulemaking to establish standards for the type of information, format, and timeframe for persons to submit records to aid the Secretary in effectively and rapidly tracking and tracing, in the event of an outbreak, fruits and vegetables that are raw agricultural commodities. Nothing in this section shall be construed as giving the Secretary the authority to prescribe specific technologies for the maintenance of records.

(e) **PUBLIC INPUT.**—During the comment period in the notice of proposed rulemaking under subsection (d), the Secretary shall conduct not less than 3 public meetings in diverse geographical areas of the United States to provide persons in different regions an opportunity to comment.

(f) **RAW AGRICULTURAL COMMODITY.**—In this section, the term “raw agricultural commodity” has the meaning given that term in section 201(r) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 321(r)).

#### SEC. 205. SURVEILLANCE.

(a) **DEFINITION OF FOOD-BORNE ILLNESS OUTBREAK.**—In this section, the term “food-borne illness outbreak” means the occurrence of 2 or more cases of a similar illness resulting from the ingestion of a food.

(b) **FOOD-BORNE ILLNESS SURVEILLANCE SYSTEMS.**—

(1) **IN GENERAL.**—The Secretary, acting through the Director of the Centers for Disease Control and Prevention, shall enhance food-borne illness surveillance systems to improve the collection, analysis, reporting, and usefulness of data on food-borne illnesses by—

(A) coordinating Federal, State and local food-borne illness surveillance systems, including complaint systems, and increasing participation in national networks of public health and food regulatory agencies and laboratories;

(B) facilitating sharing of findings on a more timely basis among governmental agencies, including the Food and Drug Administration, the Department of Agriculture, and State and local agencies, and with the public;

(C) developing improved epidemiological tools for obtaining quality exposure data, and microbiological methods for classifying cases;

(D) augmenting such systems to improve attribution of a food-borne illness outbreak to a specific food;

(E) expanding capacity of such systems, including working toward automatic electronic searches, for implementation of fingerprinting strategies for food-borne infectious agents, in order to identify new or rarely documented causes of food-borne illness and submit standardized information to a centralized database;

(F) allowing timely public access to aggregated, de-identified surveillance data;

(G) at least annually, publishing current reports on findings from such systems;

(H) establishing a flexible mechanism for rapidly initiating scientific research by academic institutions;

(I) integrating food-borne illness surveillance systems and data with other biosurveillance and public health situational awareness capabilities at the Federal, State, and local levels; and

(J) other activities as determined appropriate by the Secretary.

(2) **PARTNERSHIPS.**—The Secretary shall support and maintain a diverse working group of experts and stakeholders from Federal, State, and local food safety and health agencies, the food industry, consumer organizations, and academia. Such working group shall provide the Secretary, through at least annual meetings of the working group and an annual public report, advice and recommendations on an ongoing and regular basis regarding the improvement of food-borne illness surveillance and implementation of this section, including advice and recommendations on—

(A) the priority needs of regulatory agencies, the food industry, and consumers for information and analysis on food-borne illness and its causes;

(B) opportunities to improve the effectiveness of initiatives at the Federal, State, and local levels, including coordination and integration of activities among Federal agencies, and between the Federal, State, and local levels of government;

(C) improvement in the timeliness and depth of access by regulatory and health agencies, the food industry, academic researchers, and consumers to food-borne illness surveillance data collected by government agencies at all levels, including data compiled by the Centers for Disease Control and Prevention;

(D) key barriers to improvement in food-borne illness surveillance and its utility for preventing food-borne illness at Federal, State, and local levels;

(E) the capabilities needed for establishing automatic electronic searches of surveillance data; and

(F) specific actions to reduce barriers to improvement, implement the working group’s recommendations, and achieve the purposes of this section, with measurable objectives and timelines, and identification of resource and staffing needs.

(c) **IMPROVING FOOD SAFETY AND DEFENSE CAPACITY AT THE STATE AND LOCAL LEVEL.**—

(1) **IN GENERAL.**—The Secretary shall develop and implement strategies to leverage and enhance the food safety and defense capacities of State and local agencies in order to achieve the following goals:

(A) Improve food-borne illness outbreak response and containment.

(B) Accelerate food-borne illness surveillance and outbreak investigation, including rapid shipment of clinical isolates from clinical laboratories to appropriate State laboratories, and conducting more standardized illness outbreak interviews.

(C) Strengthen the capacity of State and local agencies to carry out inspections and enforce safety standards.

(D) Improve the effectiveness of Federal, State, and local partnerships to coordinate

food safety and defense resources and reduce the incidence of food-borne illness.

(E) Share information on a timely basis among public health and food regulatory agencies, with the food industry, with health care providers, and with the public.

(F) Strengthen the capacity of State and local agencies to achieve the goals described in section 108.

(2) **REVIEW.**—In developing of the strategies required by paragraph (1), the Secretary shall, not later than 1 year after the date of enactment of the FDA Food Safety Modernization Act, complete a review of State and local capacities, and needs for enhancement, which may include a survey with respect to—

(A) staffing levels and expertise available to perform food safety and defense functions;

(B) laboratory capacity to support surveillance, outbreak response, inspection, and enforcement activities;

(C) information systems to support data management and sharing of food safety and defense information among State and local agencies and with counterparts at the Federal level; and

(D) other State and local activities and needs as determined appropriate by the Secretary.

(d) **FOOD SAFETY CAPACITY BUILDING GRANTS.**—Section 317R(b) of the Public Health Service Act (42 U.S.C. 247b-20(b)) is amended—

(1) by striking “2002” and inserting “2010”; and

(2) by striking “2003 through 2006” and inserting “2011 through 2014”.

#### SEC. 206. MANDATORY RECALL AUTHORITY.

(a) **IN GENERAL.**—Chapter IV (21 U.S.C. 341 et seq.), as amended by section 202, is amended by adding at the end the following:

##### “SEC. 423. MANDATORY RECALL AUTHORITY.

“(a) **VOLUNTARY PROCEDURES.**—If the Secretary determines, based on information gathered through the reportable food registry under section 417 or through any other means, that there is a reasonable probability that an article of food (other than infant formula) is adulterated under section 402 or misbranded under section 403(w) and the use of or exposure to such article will cause serious adverse health consequences or death to humans or animals, the Secretary shall provide the responsible party (as defined in section 417) with an opportunity to cease distribution and recall such article.

“(b) **PREHEARING ORDER TO CEASE DISTRIBUTION AND GIVE NOTICE.**—If the responsible party refuses to or does not voluntarily cease distribution or recall such article within the time and in the manner prescribed by the Secretary (if so prescribed), the Secretary may, by order require, as the Secretary deems necessary, such person to—

“(1) immediately cease distribution of such article; or

“(2) immediately notify all persons—

“(A) manufacturing, processing, packing, transporting, distributing, receiving, holding, or importing and selling such article; and

“(B) to which such article has been distributed, transported, or sold, to immediately cease distribution of such article.

“(c) **HEARING ON ORDER.**—The Secretary shall provide the responsible party subject to an order under subsection (b) with an opportunity for an informal hearing, to be held as soon as possible but not later than 2 days after the issuance of the order, on the actions required by the order and on why the article that is the subject of the order should not be recalled.

“(d) **POST-HEARING RECALL ORDER AND MODIFICATION OF ORDER.**—

“(1) **AMENDMENT OF ORDER.**—If, after providing opportunity for an informal hearing

under subsection (c), the Secretary determines that removal of the article from commerce is necessary, the Secretary shall, as appropriate—

“(A) amend the order to require recall of such article or other appropriate action;

“(B) specify a timetable in which the recall shall occur;

“(C) require periodic reports to the Secretary describing the progress of the recall; and

“(D) provide notice to consumers to whom such article was, or may have been, distributed.

“(2) VACATING OF ORDER.—If, after such hearing, the Secretary determines that adequate grounds do not exist to continue the actions required by the order, or that such actions should be modified, the Secretary shall vacate the order or modify the order.

“(e) COOPERATION AND CONSULTATION.—The Secretary shall work with State and local public health officials in carrying out this section, as appropriate.

“(f) PUBLIC NOTIFICATION.—In conducting a recall under this section, the Secretary shall—

“(1) ensure that a press release is published regarding the recall, as well as alerts and public notices, as appropriate, in order to provide notification—

“(A) of the recall to consumers and retailers to whom such article was, or may have been, distributed; and

“(B) that includes, at a minimum—

“(i) the name of the article of food subject to the recall; and

“(ii) a description of the risk associated with such article; and

“(2) consult the policies of the Department of Agriculture regarding providing to the public a list of retail consignees receiving products involved in a Class I recall and shall consider providing such a list to the public, as determined appropriate by the Secretary.

“(g) NO DELEGATION.—The authority conferred by this section to order a recall or vacate a recall order shall not be delegated to any officer or employee other than the Commissioner.

“(h) EFFECT.—Nothing in this section shall affect the authority of the Secretary to request or participate in a voluntary recall.”.

(b) CIVIL PENALTY.—Section 303(f)(2)(A) (21 U.S.C. 333(f)(2)(A)) is amended by inserting “or any person who does not comply with a recall order under section 423” after “section 402(a)(2)(B)”.

(c) PROHIBITED ACTS.—Section 301 (21 U.S.C. 331 et seq.), as amended by section 106, is amended by adding at the end the following:

“(rr) The refusal or failure to follow an order under section 423.”.

#### SEC. 207. ADMINISTRATIVE DETENTION OF FOOD.

(a) IN GENERAL.—Section 304(h)(1)(A) (21 U.S.C. 334(h)(1)(A)) is amended by—

(1) striking “credible evidence or information indicating” and inserting “reason to believe”; and

(2) striking “presents a threat of serious adverse health consequences or death to humans or animals” and inserting “is adulterated or misbranded”.

(b) REGULATIONS.—Not later than 120 days after the date of enactment of this Act, the Secretary shall issue an interim final rule amending subpart K of part 1 of title 21, Code of Federal Regulations, to implement the amendment made by this section.

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

#### SEC. 208. DECONTAMINATION AND DISPOSAL STANDARDS AND PLANS.

(a) IN GENERAL.—The Administrator of the Environmental Protection Agency (referred

to in this section as the “Administrator”), in coordination with the Secretary of Health and Human Services, Secretary of Homeland Security, and Secretary of Agriculture, shall provide support for, and technical assistance to, State, local, and tribal governments in preparing for, assessing, decontaminating, and recovering from an agriculture or food emergency.

(b) DEVELOPMENT OF STANDARDS.—In carrying out subsection (a), the Administrator, in coordination with the Secretary of Health and Human Services, Secretary of Homeland Security, Secretary of Agriculture, and State, local, and tribal governments, shall develop and disseminate specific standards and protocols to undertake clean-up, clearance, and recovery activities following the decontamination and disposal of specific threat agents and foreign animal diseases.

(c) DEVELOPMENT OF MODEL PLANS.—In carrying out subsection (a), the Administrator, the Secretary of Health and Human Services, and the Secretary of Agriculture shall jointly develop and disseminate model plans for—

(1) the decontamination of individuals, equipment, and facilities following an intentional contamination of agriculture or food; and

(2) the disposal of large quantities of animals, plants, or food products that have been infected or contaminated by specific threat agents and foreign animal diseases.

(d) EXERCISES.—In carrying out subsection (a), the Administrator, in coordination with the entities described under subsection (b), shall conduct exercises at least annually to evaluate and identify weaknesses in the decontamination and disposal model plans described in subsection (c). Such exercises shall be carried out, to the maximum extent practicable, as part of the national exercise program under section 648(b)(1) of the Post-Katrina Emergency Management Reform Act of 2006 (6 U.S.C. 748(b)(1)).

(e) MODIFICATIONS.—Based on the exercises described in subsection (d), the Administrator, in coordination with the entities described in subsection (b), shall review and modify as necessary the plans described in subsection (c) not less frequently than biennially.

(f) PRIORITIZATION.—The Administrator, in coordination with the entities described in subsection (b), shall develop standards and plans under subsections (b) and (c) in an identified order of priority that takes into account—

(1) highest-risk biological, chemical, and radiological threat agents;

(2) agents that could cause the greatest economic devastation to the agriculture and food system; and

(3) agents that are most difficult to clean or remediate.

### TITLE III—IMPROVING THE SAFETY OF IMPORTED FOOD

#### SEC. 301. FOREIGN SUPPLIER VERIFICATION PROGRAM.

(a) IN GENERAL.—Chapter VIII (21 U.S.C. 381 et seq.) is amended by adding at the end the following:

#### “SEC. 805. FOREIGN SUPPLIER VERIFICATION PROGRAM.

“(a) IN GENERAL.—

“(1) VERIFICATION REQUIREMENT.—Each United States importer shall perform risk-based foreign supplier verification activities in accordance with regulations promulgated under subsection (c) for the purpose of verifying that the food imported by the importer or its agent is—

“(A) produced in compliance with the requirements of section 418 or 419, as appropriate; and

“(B) is not adulterated under section 402 or misbranded under section 403(w).

“(2) IMPORTER DEFINED.—For purposes of this section, the term ‘importer’ means, with respect to an article of food—

“(A) the United States owner or consignee of the article of food at the time of entry of such article into the United States; or

“(B) in the case when there is no United States owner or consignee as described in subparagraph (A), the United States agent or representative of a foreign owner or consignee of the article of food at the time of entry of such article into the United States.

“(b) GUIDANCE.—Not later than 1 year after the date of enactment of the FDA Food Safety Modernization Act, the Secretary shall issue guidance to assist United States importers in developing foreign supplier verification programs.

“(c) REGULATIONS.—

“(1) IN GENERAL.—Not later than 1 year after the date of enactment of the FDA Food Safety Modernization Act, the Secretary shall promulgate regulations to provide for the content of the foreign supplier verification program established under subsection (a). Such regulations shall, as appropriate, include a process for verification by a United States importer, with respect to each foreign supplier from which it obtains food, that the imported food is produced in compliance with the requirements of section 418 or 419, as appropriate, and is not adulterated under section 402 or misbranded under section 403(w).

“(2) VERIFICATION.—The regulations under paragraph (1) shall require that the foreign supplier verification program of each importer be adequate to provide assurances that each foreign supplier to the importer produces the imported food employing processes and procedures, including risk-based reasonably appropriate preventive controls, equivalent in preventing adulteration and reducing hazards as those required by section 418 or section 419, as appropriate.

“(3) ACTIVITIES.—Verification activities under a foreign supplier verification program under this section may include monitoring records for shipments, lot-by-lot certification of compliance, annual on-site inspections, checking the hazard analysis and risk-based preventive control plan of the foreign supplier, and periodically testing and sampling shipments.

“(d) RECORD MAINTENANCE AND ACCESS.—Records of a United States importer related to a foreign supplier verification program shall be maintained for a period of not less than 2 years and shall be made available promptly to a duly authorized representative of the Secretary upon request.

“(e) DEEMED COMPLIANCE OF SEAFOOD, JUICE, AND LOW-ACID CANNED FOOD FACILITIES IN COMPLIANCE WITH HACCP.—An owner, operator, or agent in charge of a facility required to comply with 1 of the following standards and regulations with respect to such facility shall be deemed to be in compliance with this section with respect to such facility:

“(1) The Seafood Hazard Analysis Critical Control Points Program of the Food and Drug Administration.

“(2) The Juice Hazard Analysis Critical Control Points Program of the Food and Drug Administration.

“(3) The Thermally Processed Low-Acid Foods Packaged in Hermetically Sealed Containers standards of the Food and Drug Administration (or any successor standards).

“(f) PUBLICATION OF LIST OF PARTICIPANTS.—The Secretary shall publish and maintain on the Internet Web site of the Food and Drug Administration a current list that includes the name of, location of, and other information deemed necessary by the Secretary about, importers participating under this section.”.

(b) PROHIBITED ACT.—Section 301 (21 U.S.C. 331), as amended by section 206, is amended by adding at the end the following:

“(ss) The importation or offering for importation of a food if the importer (as defined in section 805) does not have in place a foreign supplier verification program in compliance with such section 805.”

(c) IMPORTS.—Section 801(a) (21 U.S.C. 381(a)) is amended by adding “or the importer (as defined in section 805) is in violation of such section 805” after “or in violation of section 505”.

(d) EFFECTIVE DATE.—The amendments made by this section shall take effect 2 years after the date of enactment of this Act.

**SEC. 302. VOLUNTARY QUALIFIED IMPORTER PROGRAM.**

Chapter VIII (21 U.S.C. 381 et seq.), as amended by section 301, is amended by adding at the end the following:

**“SEC. 806. VOLUNTARY QUALIFIED IMPORTER PROGRAM.**

“(a) IN GENERAL.—Beginning not later than 1 year after the date of enactment of the FDA Food Safety Modernization Act, the Secretary shall—

“(1) establish a program, in consultation with the Department of Homeland Security, to provide for the expedited review and importation of food offered for importation by United States importers who have voluntarily agreed to participate in such program; and

“(2) issue a guidance document related to participation and compliance with such program.

“(b) VOLUNTARY PARTICIPATION.—An importer may request the Secretary to provide for the expedited review and importation of designated foods in accordance with the program procedures established by the Secretary.

“(c) ELIGIBILITY.—In order to be eligible, an importer shall be offering food for importation from a facility that has a certification described in section 809(b). In reviewing the applications and making determinations on such requests, the Secretary shall consider the risk of the food to be imported based on factors, such as the following:

“(1) The nature of the food to be imported.

“(2) The compliance history of the foreign supplier.

“(3) The capability of the regulatory system of the country of export to ensure compliance with United States food safety standards.

“(4) The compliance of the importer with the requirements of section 805.

“(5) The recordkeeping, testing, inspections and audits of facilities, traceability of articles of food, temperature controls, and sourcing practices of the importer.

“(6) The potential risk for intentional adulteration of the food.

“(7) Any other factor that the Secretary determines appropriate.

“(d) REVIEW AND REVOCATION.—Any importer qualified by the Secretary in accordance with the eligibility criteria set forth in this section shall be reevaluated not less often than once every 3 years and the Secretary shall promptly revoke the qualified importer status of any importer found not to be in compliance with such criteria.

“(e) NOTICE OF INTENT TO PARTICIPATE.—An importer that intends to participate in the program under this section in a fiscal year shall submit a notice to the Secretary of such intent at time and in a manner established by the Secretary.

“(f) FALSE STATEMENTS.—Any statement or representation made by an importer to the Secretary shall be subject to section 1001 of title 18, United States Code.

“(g) DEFINITION.—For purposes of this section, the term ‘importer’ means the person

that brings food, or causes food to be brought, from a foreign country into the customs territory of the United States.”

**SEC. 303. AUTHORITY TO REQUIRE IMPORT CERTIFICATIONS FOR FOOD.**

(a) IN GENERAL.—Section 801(a) (21 U.S.C. 381(a)) is amended by inserting after the third sentence the following: “With respect to an article of food, if importation of such food is subject to, but not compliant with, the requirement under subsection (p) that such food be accompanied by a certification or other assurance that the food meets some or all applicable requirements of this Act, then such article shall be refused admission.”

(b) ADDITION OF CERTIFICATION REQUIREMENT.—Section 801 (21 U.S.C. 381) is amended by adding at the end the following new subsection:

“(p) CERTIFICATIONS CONCERNING IMPORTED FOODS.—

“(1) IN GENERAL.—The Secretary, based on public health considerations, including risks associated with the food or its place of origin, may require as a condition of granting admission to an article of food imported or offered for import into the United States, that an entity specified in paragraph (2) provide a certification or such other assurances as the Secretary determines appropriate that the article of food complies with some or all applicable requirements of this Act, as specified by the Secretary. Such certification or assurances may be provided in the form of shipment-specific certificates, a listing of certified entities, or in such other form as the Secretary may specify. Such certification shall be used for designated food imported from countries with which the Food and Drug Administration has an agreement to establish a certification program.

“(2) CERTIFYING ENTITIES.—For purposes of paragraph (1), entities that shall provide the certification or assurances described in such paragraph are—

“(A) an agency or a representative of the government of the country from which the article of food at issue originated, as designated by such government or the Secretary; or

“(B) such other persons or entities accredited pursuant to section 809 to provide such certification or assurance.

“(3) RENEWAL AND REFUSAL OF CERTIFICATIONS.—The Secretary may—

“(A) require that any certification or other assurance provided by an entity specified in paragraph (2) be renewed by such entity at such times as the Secretary determines appropriate; and

“(B) refuse to accept any certification or assurance if the Secretary determines that such certification or assurance is no longer valid or reliable.

“(4) ELECTRONIC SUBMISSION.—The Secretary shall provide for the electronic submission of certifications under this subsection.

“(5) FALSE STATEMENTS.—Any statement or representation made by an entity described in paragraph (2) to the Secretary shall be subject to section 1001 of title 18, United States Code.”

(c) CONFORMING TECHNICAL AMENDMENT.—Section 801(b) (21 U.S.C. 381(b)) is amended in the second sentence by striking “with respect to an article included within the provision of the fourth sentence of subsection (a)” and inserting “with respect to an article described in subsection (a) relating to the requirements of sections 760 or 761.”

(d) NO LIMIT ON AUTHORITY.—Nothing in the amendments made by this section shall limit the authority of the Secretary to conduct random inspections of imported food or to take such other steps as the Secretary deems appropriate to determine the admissibility of imported food.

**SEC. 304. PRIOR NOTICE OF IMPORTED FOOD SHIPMENTS.**

(a) IN GENERAL.—Section 801(m)(1) (21 U.S.C. 381(m)(1)) is amended by inserting “any country to which the article has been refused entry;” after “the country from which the article is shipped;”.

(b) REGULATIONS.—Not later than 120 days after the date of enactment of this Act, the Secretary shall issue an interim final rule amending subpart I of part 1 of title 21, Code of Federal Regulations, to implement the amendment made by this section.

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

**SEC. 305. REVIEW OF A REGULATORY AUTHORITY OF A FOREIGN COUNTRY.**

Chapter VIII (21 U.S.C. 381 et seq.), as amended by section 302, is amended by adding at the end the following:

**“SEC. 807. REVIEW OF A REGULATORY AUTHORITY OF A FOREIGN COUNTRY.**

“The Secretary may review information from a country outlining the statutes, regulations, standards, and controls of such country, and conduct on-site audits in such country to verify the implementation of those statutes, regulations, standards, and controls. Based on such review, the Secretary shall determine whether such country can provide reasonable assurances that the food supply of the country is equivalent in safety to food manufactured, processed, packed, or held in the United States.”

**SEC. 306. BUILDING CAPACITY OF FOREIGN GOVERNMENTS WITH RESPECT TO FOOD.**

(a) IN GENERAL.—The Secretary shall, not later than 2 years of the date of enactment of this Act, develop a comprehensive plan to expand the technical, scientific, and regulatory capacity of foreign governments, and their respective food industries, from which foods are exported to the United States.

(b) CONSULTATION.—In developing the plan under subsection (a), the Secretary shall consult with the Secretary of Agriculture, Secretary of State, Secretary of the Treasury, and the Secretary of Commerce, representatives of the food industry, appropriate foreign government officials, and non-governmental organizations that represent the interests of consumers, and other stakeholders.

(c) PLAN.—The plan developed under subsection (a) shall include, as appropriate, the following:

(1) Recommendations for bilateral and multilateral arrangements and agreements, including provisions to provide for responsibility of exporting countries to ensure the safety of food.

(2) Provisions for electronic data sharing.

(3) Provisions for mutual recognition of inspection reports.

(4) Training of foreign governments and food producers on United States requirements for safe food.

(5) Recommendations to harmonize requirements under the Codex Alimentarius.

(6) Provisions for the multilateral acceptance of laboratory methods and detection techniques.

**SEC. 307. INSPECTION OF FOREIGN FOOD FACILITIES.**

Chapter VIII (21 U.S.C. 381 et seq.), as amended by section 305, is amended by inserting at the end the following:

**“SEC. 808. INSPECTION OF FOREIGN FOOD FACILITIES.**

“(a) INSPECTION.—The Secretary—

“(1) may enter into arrangements and agreements with foreign governments to facilitate the inspection of foreign facilities registered under section 415; and

“(2) shall direct resources to inspections of foreign facilities, suppliers, and food types,

especially such facilities, suppliers, and food types that present a high risk (as identified by the Secretary), to help ensure the safety and security of the food supply of the United States.

“(b) EFFECT OF INABILITY TO INSPECT.—Notwithstanding any other provision of law, food shall be refused admission into the United States if it is from a foreign facility registered under section 415 of which the owner, operator, or agent in charge of the facility, or the government of the foreign country, refuses to permit entry of United States inspectors, upon request, to inspect such facility. For purposes of this subsection, such an owner, operator, or agent in charge shall be considered to have refused an inspection if such owner, operator, or agent in charge refuses such a request to inspect a facility more than 48 hours after such request is submitted.”

**SEC. 308. ACCREDITATION OF THIRD-PARTY AUDITORS AND AUDIT AGENTS.**

Chapter VIII (21 U.S.C. 381 et seq.), as amended by section 307, is amended by adding at the end the following:

**“SEC. 809. ACCREDITATION OF THIRD-PARTY AUDITORS AND AUDIT AGENTS.**

“(a) DEFINITIONS.—In this section:

“(1) ACCREDITED AUDIT AGENT.—The term ‘accredited audit agent’ means an audit agent accredited by an accreditation body under this section.

“(2) AUDIT AGENT.—The term ‘audit agent’ means an individual who is qualified to conduct food safety audits, and who may be an employee or an agent of a third-party auditor.

“(3) ACCREDITATION BODY.—The term ‘accreditation body’ means a recognized authority that performs accreditation of third-party auditors and audit agents.

“(4) ACCREDITED THIRD-PARTY AUDITOR.—The term ‘accredited third-party auditor’ means a third-party auditor accredited by an accreditation body under this section.

“(5) CONSULTATIVE AUDIT.—The term ‘consultative audit’ means an audit of an eligible entity—

“(A) to determine whether such entity is in compliance with the provisions of this Act and with applicable industry standards and practices; and

“(B) the results of which are for internal facility purposes only.

“(6) ELIGIBLE ENTITY.—The term ‘eligible entity’ means a foreign entity, including foreign facilities registered under section 415, in the food import supply chain that chooses to be audited by an accredited third-party auditor or audit agent.

“(7) REGULATORY AUDIT.—The term ‘regulatory audit’ means an audit of an eligible entity—

“(A) to determine whether such entity is in compliance with the provisions of this Act; and

“(B) the results of which determine—

“(i) whether an entity is eligible to receive a certification under section 801(p); and

“(ii) whether the entity is eligible to participate in the voluntary qualified importer program under section 806.

“(8) THIRD-PARTY AUDITOR.—The term ‘third-party auditor’ means a foreign government, foreign cooperative, or any other qualified third party, as the Secretary determines appropriate, that conducts audits of eligible entities to certify that such eligible entities meet the applicable requirements of this section.

“(b) ACCREDITATION SYSTEM.—

“(1) ACCREDITATION BODIES.—

“(A) RECOGNITION OF ACCREDITATION BODIES.—Beginning not later than 2 years after the date of enactment of the FDA Food Safety Modernization Act, the Secretary shall es-

tablish a system for the recognition of accreditation bodies that accredit third-party auditors and audit agents to certify that eligible entities meet the applicable requirements of this Act.

“(B) NOTIFICATION.—Each accreditation body recognized by the Secretary shall submit to the Secretary a list of all accredited third-party auditors and audit agents accredited by such body.

“(C) REVOCATION OF RECOGNITION AS AN ACCREDITATION BODY.—The Secretary shall promptly revoke the recognition of any accreditation body found not to be in compliance with the requirements of this section.

“(2) MODEL ACCREDITATION STANDARDS.—The Secretary shall develop model standards, including audit report requirements, and each recognized accreditation body shall ensure that third-party auditors and audit agents meet such standards in order to qualify as an accredited third-party auditor or audit agent under this section. In developing the model standards, the Secretary shall look to standards in place on the date of the enactment of this section for guidance, to avoid unnecessary duplication of efforts and costs.

“(c) THIRD-PARTY AUDITORS AND AUDIT AGENCIES.—

“(1) REQUIREMENTS FOR ACCREDITATION AS A THIRD-PARTY AUDITOR OR AUDIT AGENT.—

“(A) FOREIGN GOVERNMENTS.—Prior to accrediting a foreign government as an accredited third-party auditor, the accreditation body shall perform such reviews and audits of food safety programs, systems, and standards of the government as the Secretary deems necessary to determine that the foreign government is capable of adequately ensuring that eligible entities certified by such government meet the requirements of this Act with respect to food manufactured, processed, packed, or held for import to the United States.

“(B) FOREIGN COOPERATIVES AND OTHER THIRD PARTIES.—Prior to accrediting a foreign cooperative that aggregates the products of growers or processors, or any other third party that the Secretary determines appropriate to be an accredited third-party auditor or audit agent, the accreditation body shall perform such reviews and audits of the training and qualifications of auditors used by that cooperative or party and conduct such reviews of internal systems and such other investigation of the cooperative or party as the Secretary deems necessary to determine that each eligible entity certified by the cooperative or party has systems and standards in use to ensure that such entity meets the requirements of this Act.

“(2) REQUIREMENT TO ISSUE CERTIFICATION OF ELIGIBLE ENTITIES.—

“(A) IN GENERAL.—An accreditation body may not accredit a third-party auditor or audit agent unless such third-party auditor or audit agent agrees to issue a written and electronic certification to accompany each food shipment for import into the United States from an eligible entity certified by the third-party auditor or audit agent, subject to requirements set forth by the Secretary. The Secretary shall consider such certificates when targeting inspection resources under section 421.

“(B) PURPOSE OF CERTIFICATION.—The Secretary shall use evidence of certification provided by accredited third-party auditors and audit agents—

“(i) to determine the eligibility of an importer to receive a certification under section 801(p); and

“(ii) determine the eligibility of an importer to participate in the voluntary qualified importer program under section 806.

“(3) AUDIT REPORT REQUIREMENTS.—

“(A) REQUIREMENTS IN GENERAL.—As a condition of accreditation, an accredited third-party auditor or audit agent shall prepare the audit report for an audit, in a form and manner designated by the Secretary, which shall include—

“(i) the identity of the persons at the audited eligible entity responsible for compliance with food safety requirements;

“(ii) the dates of the audit;

“(iii) the scope of the audit; and

“(iv) any other info required by the Secretary that relate to or may influence an assessment of compliance with this Act.

“(B) SUBMISSION OF REPORTS TO THE SECRETARY.—

“(i) IN GENERAL.—Following any accreditation of a third-party auditor or audit agent, the Secretary may, at any time, require the accredited third-party auditor or audit agent to submit to the Secretary an onsite audit report and such other reports or documents required as part of the audit process, for any eligible entity certified by the third-party auditor or audit agent. Such report may include documentation that the eligible entity is in compliance with any applicable registration requirements.

“(ii) LIMITATION.—The requirement under clause (i) shall not include any report or other documents resulting from a consultative audit by the accredited third-party auditor or audit agent, except that the Secretary may access the results of a consultative audit in accordance with section 414.

“(4) REQUIREMENTS OF AUDIT AGENTS.—

“(A) RISKS TO PUBLIC HEALTH.—If, at any time during an audit, an accredited audit agent discovers a condition that could cause or contribute to a serious risk to the public health, the audit agent shall immediately notify the Secretary of—

“(i) the identification of the eligible entity subject to the audit; and

“(ii) such condition.

“(B) TYPES OF AUDITS.—An accredited audit agent may perform consultative and regulatory audits of eligible entities.

“(C) LIMITATIONS.—An accredited audit agent may not perform a regulatory audit of an eligible entity if such agent has performed a consultative audit or a regulatory audit of such eligible entity during the previous 24-month period.

“(5) CONFLICTS OF INTEREST.—

“(A) THIRD-PARTY AUDITORS.—An accredited third-party auditor shall—

“(i) not be owned, managed, or controlled by any person that owns or operates an eligible entity to be certified by such auditor;

“(ii) in carrying out audits of eligible entities under this section, have procedures to ensure against the use of any officer or employee of such auditor that has a financial conflict of interest regarding an eligible entity to be certified by such auditor; and

“(iii) annually make available to the Secretary disclosures of the extent to which such auditor and the officers and employees of such auditor have maintained compliance with clauses (i) and (ii) relating to financial conflicts of interest.

“(B) AUDIT AGENTS.—An accredited audit agent shall—

“(i) not own or operate an eligible entity to be certified by such agent;

“(ii) in carrying out audits of eligible entities under this section, have procedures to ensure that such agent does not have a financial conflict of interest regarding an eligible entity to be certified by such agent; and

“(iii) annually make available to the Secretary disclosures of the extent to which such agent has maintained compliance with clauses (i) and (ii) relating to financial conflicts of interest.

“(C) REGULATIONS.—The Secretary shall promulgate regulations not later than 18 months after the date of enactment of the FDA Food Safety Modernization Act to ensure that there are protections against conflicts of interest between an accredited third-party auditor or audit agent and the eligible entity to be certified by such auditor or audit agent. Such regulations shall include—

“(i) requiring that audits performed under this section be unannounced;

“(ii) a structure, including timing and public disclosure, for fees paid by eligible entities to accredited third-party auditors or audit agents to decrease the potential for conflicts of interest; and

“(iii) appropriate limits on financial affiliations between an accredited third-party auditor or audit agent and any person that owns or operates an eligible entity to be certified by such auditor or audit agent.

“(6) WITHDRAWAL OF ACCREDITATION.—The Secretary shall withdraw accreditation from an accredited third-party auditor or audit agent—

“(A) if food from an eligible entity certified by such third-party auditor or audit agent is linked to an outbreak of human or animal illness;

“(B) following a performance audit and finding by the Secretary that the third-party auditor or audit agent no longer meets the requirements for accreditation; or

“(C) following a refusal to allow United States officials to conduct such audits and investigations as may be necessary to ensure continued compliance with the requirements set forth in this section.

“(7) NEUTRALIZING COSTS.—The Secretary shall establish a method, similar to the method used by the Department of Agriculture, by which accredited third-party auditors and audit agents reimburse the Food and Drug Administration for the work performed to establish and administer the accreditation system under this section. The Secretary shall make operating this program revenue-neutral and shall not generate surplus revenue from such a reimbursement mechanism.

“(d) RECERTIFICATION OF ELIGIBLE ENTITIES.—An eligible entity shall apply for annual recertification by an accredited third-party auditor or audit agent if such entity—

“(1) intends to participate in voluntary qualified importer program under section 806; or

“(2) must provide to the Secretary a certification under section 801(p) for any food from such entity.

“(e) FALSE STATEMENTS.—Any statement or representation made—

“(1) by an employee or agent of an eligible entity to an accredited third-party auditor or audit agent; or

“(2) by an accredited third-party auditor or an audit agent to the Secretary, shall be subject to section 1001 of title 18, United States Code.

“(f) MONITORING.—To ensure compliance with the requirements of this section, the Secretary shall—

“(1) periodically, or at least once every 4 years, reevaluate the accreditation bodies described in subsection (b)(1);

“(2) periodically, or at least once every 4 years, audit the performance of each accredited third-party auditor and audit agent, through the review of audit reports by such auditors and audit agents, the compliance history as available of eligible entities certified by such auditors and audit agents, and any other measures deemed necessary by the Secretary;

“(3) at any time, conduct an onsite audit of any eligible entity certified by an accredited third-party auditor or audit agent, with or

without the auditor or audit agent present; and

“(4) take any other measures deemed necessary by the Secretary.

“(g) PUBLICLY AVAILABLE REGISTRY.—The Secretary shall establish a publicly available registry of accreditation bodies and of accredited third-party auditors and audit agents, including the name of, contact information for, and other information deemed necessary by the Secretary about such bodies, auditors, and agents.

“(h) LIMITATIONS.—

“(1) NO EFFECT ON SECTION 704 INSPECTIONS.—The audits performed under this section shall not be considered inspections under section 704.

“(2) NO EFFECT ON INSPECTION AUTHORITY.—Nothing in this section affects the authority of the Secretary to inspect any eligible entity pursuant to this Act.”

#### SEC. 309. FOREIGN OFFICES OF THE FOOD AND DRUG ADMINISTRATION.

(a) IN GENERAL.—The Secretary shall by October 1, 2010, establish an office of the Food and Drug Administration in not less than 5 foreign countries selected by the Secretary, to provide assistance to the appropriate governmental entities of such countries with respect to measures to provide for the safety of articles of food and other products regulated by the Food and Drug Administration exported by such country to the United States, including by directly conducting risk-based inspections of such articles and supporting such inspections by such governmental entity.

(b) CONSULTATION.—In establishing the foreign offices described in subsection (a), the Secretary shall consult with the Secretary of State and the United States Trade Representative.

(c) REPORT.—Not later than October 1, 2011, the Secretary shall submit to Congress a report on the basis for the selection by the Secretary of the foreign countries in which the Secretary established offices under subsection (a), the progress which such offices have made with respect to assisting the governments of such countries in providing for the safety of articles of food and other products regulated by the Food and Drug Administration exported to the United States, and the plans of the Secretary for establishing additional foreign offices of the Food and Drug Administration, as appropriate.

#### TITLE IV—MISCELLANEOUS PROVISIONS

##### SEC. 401. FUNDING FOR FOOD SAFETY.

(a) IN GENERAL.—There are authorized to be appropriated to carry out the activities of the Center for Food Safety and Applied Nutrition, the Center for Veterinary Medicine, and related field activities in the Office of Regulatory Affairs of the Food and Drug Administration—

(1) \$825,000,000 for fiscal year 2010; and

(2) such sums as may be necessary for fiscal years 2011 through 2014.

(b) INCREASED NUMBER OF FIELD STAFF.—To carry out the activities of the Center for Food Safety and Applied Nutrition, the Center for Veterinary Medicine, and related field activities of the Office of Regulatory Affairs of the Food and Drug Administration, the Secretary of Health and Human Services shall increase the field staff of such Centers and Office with a goal of not fewer than—

(1) 3,800 staff members in fiscal year 2010;

(2) 4,000 staff members in fiscal year 2011;

(3) 4,200 staff members in fiscal year 2012;

(4) 4,600 staff members in fiscal year 2013; and

(5) 5,000 staff members in fiscal year 2014.

##### SEC. 402. JURISDICTION; AUTHORITIES.

Nothing in this Act, or an amendment made by this Act, shall be construed to—

(1) alter the jurisdiction between the Secretary of Agriculture and the Secretary of

Health and Human Services, under applicable statutes and regulations;

(2) limit the authority of the Secretary of Health and Human Services to issue regulations related to the safety of food under—

(A) the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 301 et seq.) as in effect on the day before the date of enactment of this Act; or

(B) the Public Health Service Act (42 U.S.C. 301 et seq.) as in effect on the day before the date of enactment of this Act; or

(3) impede, minimize, or affect the authority of the Secretary of Agriculture to prevent, control, or mitigate a plant or animal health emergency, or a food emergency involving products regulated under the Federal Meat Inspection Act, the Poultry Products Inspection Act, or the Egg Products Inspection Act.

By Mr. AKAKA:

S. 514. A bill to amend title 38, United States Code, to enhance vocational rehabilitation benefits for veterans, and for other purposes; to the Committee on Veterans' Affairs.

Mr. AKAKA. Mr. President, I am introducing today the proposed Veterans Rehabilitation and Training Improvements Act of 2009. This measure would improve the program of rehabilitation and training for veterans who suffer from service-connected disabilities by offering an increase in the amount of subsistence allowances, reimbursing certain incidental costs, and repealing the limit on the number of individuals who may be enrolled in a program of Independent Living services.

Under current law, veterans who are enrolled in a program of rehabilitation under Chapter 31 receive a monthly subsistence allowance. This, in addition to the payment of the costs of the program of rehabilitation, is intended to offer the veteran a means of paying for basic living expenses while pursuing their training or education.

With the enactment of the new Post 9-11 GI Bill last year, P.L. 110-323, which adopted a tuition-and-fees plus a living allowance approach to the payment of benefits under the educational assistance program, I am concerned that there may be an inequity between the vocational rehabilitation and education programs and that individuals who would truly benefit from enrollment in a program of rehabilitation and employment under Chapter 31 will be tempted to enroll in the Chapter 33 education program in order to take advantage of the higher living allowance. Those who would make such an election might forgo valuable counseling, employment and placement, and other assistance from which they might benefit.

To address this concern, the measure I am introducing today would modify the Chapter 31 program by offering a subsistence allowance to enrollees equal to the national average for the Department of Defense's Basic Allowance for Housing, BAH, for members of the military at the E-5 level, adjusted for marital status. This is similar, although not identical to, the approach of the new chapter 33 program which

adopted a regionalized BAH approach based on the address of the institution.

This is intended to help ensure that individuals who could best benefit from enrollment in the Chapter 31 program are not faced with a disincentive to do so.

With regard to the second issue, VA is permitted to pay certain costs associated with enrollment of an individual in a program of rehabilitation—for example, fees, equipment, and supplies. However, there are other costs that an individual might incur that are not covered by VA and these costs could represent a substantial barrier to the successful completion of a program. An example could be that of a single young mother with young children who—in order to attend classes—needs child care. Another example might be a veteran who lost both legs in service and needs a new suit in order to make the most favorable impression at the interview with a prospective employer.

The legislation I am introducing today would require VA to issue regulations providing for the reimbursement of incidental costs associated with obstacles that pose substantial barriers to successful completion of a program. I believe that this will substantially increase the ability of many individuals to finish their rehabilitation programs and be placed in rewarding jobs.

I also believe we need to repeal the cap on the number of individuals who may be enrolled in a program of Independent Living services under the Chapter 31 program. Current law provides that individuals for whom a determination is made that a program of rehabilitation leading to employment is not reasonably feasible may be eligible for enrollment in a program of independent living services which is designed to help the individual achieve a maximum level of independence in daily life. However, the number of veterans who in any one year may enroll in these programs is capped at 2,600.

Even though the VA has testified in the past that this enrollment cap does not present any problem for the effective conduct of the program, I remain concerned—despite the fact that last year Congress raised the cap from 2,500 to 2,600 in P.L. 110-389—that the effect of the cap is to put downward pressure on VA's enrollment of eligible veterans in this very important program. This is of particular concern when so many of today's returning servicemembers suffer from disabilities that may require extensive periods of rehabilitation and assistance in achieving independence in their daily lives that can result from such conditions as traumatic brain injury or PTSD.

Disabled veterans are transitioning from military service into an economy that is changing, challenging, and contracting at historic rates. My bill will give these veterans more of the help they need by increasing program flexibility and boosting the living stipend for disabled veterans undergoing rehabilitation.

While there will be costs associated with this legislation, the veterans who are served by the chapter 31 rehabilitation and employment program are the highest priority for our Nation—individuals who have incurred service-connected disabilities in service to the country. This truly is one of the costs of war that must be borne.

I look forward to working with my colleagues in moving this legislation through the Congress.

Mr. President, I ask unanimous consent that the text of the bill be printed in the RECORD.

There being no objection, the text of the bill was ordered to be placed in the RECORD, as follows:

S. 514

*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 “Veterans Rehabilitation and Training Improvements Act of 2009”

**SEC. 2. SUBSISTENCE ALLOWANCE FOR VETERANS PARTICIPATING IN A PROGRAM OF REHABILITATION.**

(a) MODIFICATION OF AMOUNT OF SUBSISTENCE ALLOWANCE.—Subsection (b) of section 3108 of title 38, United States Code, is amended to read as follows:

“(b) Except as otherwise provided in this section, the amount of the subsistence allowance to be paid to a veteran under this chapter for a month during which the veteran participates in a rehabilitation program under this chapter shall be the amount equal to the national average of the amount of basic allowance for housing payable under section 403 of title 37 for that month for a member of the uniformed services in pay grade E-5 with or without dependents, as applicable.”

(b) EFFECTIVE DATE.—The amendment made by subsection (a) shall take effect on October 1, 2009, and shall apply with respect to subsistence allowances payable under chapter 31 of title 38, United States Code, for months beginning on or after that date.

**SEC. 3. REIMBURSEMENT FOR COSTS OF PARTICIPATION IN A PROGRAM OF REHABILITATION FOLLOWING SUCCESSFUL COMPLETION OF PROGRAM OF REHABILITATION.**

Section 3108 of title 38, United States Code, is amended by adding at the end the following new subsection:

“(j)(1) The Secretary may, under such regulations as the Secretary shall prescribe for purposes of this subsection, pay to each veteran who successfully completes participation in a rehabilitation program under this chapter an amount to reimburse the veteran for costs incurred by veteran as a direct consequence of participation in the program. The costs for which payment may be made under this subsection may include child care expenses, costs for clothing for interviews for employment, and such other costs as the Secretary may prescribe in such regulations. The amounts payable in reimbursement for any such costs shall be the amounts determined in accordance with such regulations.

“(2) Any payment of costs in reimbursement of a veteran under this subsection is in addition to the subsistence allowance payable to the veteran under this section.”

**SEC. 4. REPEAL OF LIMITATION ON NUMBER OF VETERANS ENROLLED IN PROGRAMS OF INDEPENDENT LIVING SERVICES AND ASSISTANCE.**

Section 3120 of title 38, United States Code, is amended—

- (1) by striking subsection (e); and
- (2) by redesignating subsection (f) as subsection (e).

By Mr. LEAHY (for himself, Mr. HATCH, Mr. SCHUMER, Mr. CRAPO, Mr. WHITEHOUSE, Mr. RISCH, and Mrs. GILLIBRAND):

S. 515. A bill to amend title 35, United States Code, to provide for patent reform; to the Committee on the Judiciary.

Mr. LEAHY. Mr. President, ingenuity and innovation have been a cornerstone of the American economy from the time Thomas Jefferson issued the first patent to today.

The Founding Fathers recognized the importance of promoting innovation, and the Constitution explicitly grants Congress the power to “promote the progress and science and useful arts, by securing for limited times to . . . inventors the exclusive right to their respective . . . discoveries.” The discoveries made by American inventors and research institutions, commercialized by our companies, and protected and promoted by our patent laws have made our system the envy of the world.

The legislation I introduce today with Senator HATCH, and many others and from across the political spectrum, will keep America in its longstanding position at the pinnacle of innovation. This bill will establish a more efficient and streamlined patent system that will improve patent quality and limit unnecessary and counterproductive litigation costs, while making sure no party's access to court is denied.

Innovation and economic development are not uniquely Democratic or Republican objectives. I have been working on the Patent Reform Act on a bipartisan basis with Senator HATCH and others for several years—and Senator HATCH and I worked on various patent issues for many years before that.

Last Congress, I introduced, along with Senator HATCH, the Patent Reform Act of 2007, which is the precursor to the legislation we introduce today. That bill was the subject of consideration and amendments over four weeks of mark-up sessions in the Senate Judiciary Committee. After the Judiciary Committee voted to approve the bill in July 2007, we continued to hold numerous meetings, briefings, and stakeholder roundtables—again, on a bipartisan basis.

The legislation we introduce today picks up where we left off in those discussions. We have made some changes from the Committee-approved bill in response to concerns we heard from groups ranging from labor unions to small inventors to manufacturers. We have removed the requirement that all patent applications be published 18 months after they are filed and we have removed the requirement for Applicant Quality Submissions. We have also adopted the House approach to improving the current inter partes reexamination process, rather than creating a new second window post-grant review.

Perhaps the most hotly debated topic in the patent reform debate last Congress was the damages provision. The reasonable royalty language in the bill we introduce today is identical to the language approved by the Judiciary Committee last Congress. While I strongly support this language, I am prepared to continue the conversation and debate from the last Congress in order to find the best language we can.

There have been several positive developments since the Committee voted to report the legislation in July 2007. Senator SPECTER has made constructive suggestions about a “gate keeping” role for the court in damage calculations. The Supreme Court’s *Quanta* decision may offer a useful way of describing the truly inventive feature of a patent. There is much work to do on this provision and I am optimistic that by continuing to work together, we will find the right language.

During consideration of the Patent Reform Act of 2007 in Committee last Congress, I offered an amendment, which was adopted, to codify the inequitable conduct doctrine. Senator HATCH has asked that the provision be removed on introduction this year. I understand that the issue of inequitable conduct is very important to Senator HATCH, and I will work with him to address any statutory changes.

It has been more than 50 years since Congress significantly updated the patent system. In the decades since, our economy has changed dramatically. No longer is the economy defined only by assembly lines and brick-and-mortar production. We are living in the Information Age, and the products and processes that are being patented are changing as quickly as the times themselves.

A patent system developed for a 1952 economy, needs to be reconsidered in light of 21st century realities, while staying true to our constitutional imperative. The patent laws that were sufficiently robust for promoting innovation and economic development are now actually impeding growth, harming innovators and raising prices on consumers.

The array of voices heard in this debate—representing virtually all sectors of the economy and all interests in the patent system—have certainly not been uniform, but three major areas of concern with the current patent system can be distilled from their discussions.

First, there is significant concern that the U.S. Patent and Trademark Office, PTO, is issuing low quality patents. Patent examiners are facing a difficult task given the explosion in the number of applications and the increasing complexity of those applications. When Congress last overhauled the patent system in 1952, the PTO received approximately 60,000 patent applications; in 2006, it received 440,000. Clearly, this puts a strain on the system and understandably affects the quality of patents issued.

Second, the costs and uncertainty associated with patent litigation have escalated in recent years, and are creating an unbearable drag on innovation. Damage awards are inconsistent and too often fail to focus on the value of the invention to the infringing product. This disconnect and uncertainty is a problem that also leads to unreasonable posturing during licensing negotiations.

Third, as business and competition become more global, patent applicants are increasingly filing patent applications in other countries for protection of their inventions. The filing system in the United States, known as “first-to-invent,” differs from that in other patent-issuing jurisdictions, which have “first-to-file” systems. This causes confusion and inefficiencies for American companies and innovators.

The Patent Reform Act of 2009 promotes innovation, and will improve our economy, by addressing these impediments to growth. As the administration endeavors to guide the economy out of the recession, as payrolls shrink and the jobless rate rises, Congress cannot afford to sit idly by while innovation—the engine of our economy—is impeded by outdated laws.

Our legislation ensures that, in the Information Age, we have the legal landscape necessary for our innovators to flourish. It will improve the quality of patents and remove the ambiguity from the process of litigating patent claims, which will promote innovation stifled by the current system. As innovation is encouraged, and excessive litigation costs are removed, competition will increase and the consumer cost of products will fall. In this way, the bill directly benefits both creators and consumers of inventive products.

Patent reform is ultimately about economic development. It is about jobs, it is about innovation, and it is about consumers. All benefit under a patent system that reduces unnecessary costs, removes inefficiencies, and holds true to the vision of our Founders that Congress should establish a national policy that promotes the progress of science and the useful arts.

When Thomas Jefferson issued that first patent in 1790—a patent that went to a Vermonter—no one could have predicted how the American economy would develop and what changes would be needed for the law to keep pace, but the purpose then remains the purpose today—promoting progress.

As I said when I introduced the Patent Reform Act last Congress: If we are to maintain our position at the forefront of the world’s economy, if we are to continue to lead the world in innovation and production, if we are to continue to benefit from the ideas of the most creative citizens, then we must have a patent system that produces high quality patents, that limits counterproductive litigation over those patents, and that makes the entire system more streamlined and efficient.

Now is the time to bolster our role as the world leader in innovation. Now is

the time to create jobs at home. Now is the time for Congress to act on patent reform.

Mr. President, I ask unanimous consent that the text of the bill be printed in the RECORD.

There being no objection, the text of the bill was ordered to be printed in the RECORD, as follows:

S. 515

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

**SECTION 1. SHORT TITLE; TABLE OF CONTENTS.**

(a) SHORT TITLE.—This Act may be cited as the “Patent Reform Act of 2009”.

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

- Sec. 1. Short title; table of contents.
- Sec. 2. Right of the first inventor to file.
- Sec. 3. Inventor’s oath or declaration.
- Sec. 4. Right of the inventor to obtain damages.
- Sec. 5. Post-grant procedures and other quality enhancements.
- Sec. 6. Definitions; patent trial and appeal board.
- Sec. 7. Preissuance submissions by third parties.
- Sec. 8. Venue and jurisdiction.
- Sec. 9. Patent and trademark office regulatory authority.
- Sec. 10. Residency of Federal Circuit judges.
- Sec. 11. Micro-entity defined.
- Sec. 12. Technical amendments.
- Sec. 13. Effective date; rule of construction.
- Sec. 14. Severability.

**SEC. 2. RIGHT OF THE FIRST INVENTOR TO FILE.**

(a) DEFINITIONS.—Section 100 of title 35, United States Code, is amended by adding at the end the following:

“(f) The term ‘inventor’ means the individual or, if a joint invention, the individuals collectively who invented or discovered the subject matter of the invention.

“(g) The terms ‘joint inventor’ and ‘co-inventor’ mean any 1 of the individuals who invented or discovered the subject matter of a joint invention.

“(h) The ‘effective filing date of a claimed invention’ is—

“(1) the filing date of the patent or the application for the patent containing the claim to the invention; or

“(2) if the patent or application for patent is entitled to a right of priority of any other application under section 119, 365(a), or 365(b) or to the benefit of an earlier filing date in the United States under section 120, 121, or 365(c), the filing date of the earliest such application in which the claimed invention is disclosed in the manner provided by the first paragraph of section 112.

“(i) The term ‘claimed invention’ means the subject matter defined by a claim in a patent or an application for a patent.

“(j) The term ‘joint invention’ means an invention resulting from the collaboration of inventive endeavors of 2 or more persons working toward the same end and producing an invention by their collective efforts.”.

(b) CONDITIONS FOR PATENTABILITY.—

(1) IN GENERAL.—Section 102 of title 35, United States Code, is amended to read as follows:

**“§ 102. Conditions for patentability; novelty**

“(a) NOVELTY; PRIOR ART.—A patent for a claimed invention may not be obtained if—

“(1) the claimed invention was patented, described in a printed publication, or in public use, on sale, or otherwise available to the public—

“(A) more than 1 year before the effective filing date of the claimed invention; or

“(B) 1 year or less before the effective filing date of the claimed invention, other than

through disclosures made by the inventor or a joint inventor or by others who obtained the subject matter disclosed directly or indirectly from the inventor or a joint inventor; or

“(2) the claimed invention was described in a patent issued under section 151, or in an application for patent published or deemed published under section 122(b), in which the patent or application, as the case may be, names another inventor and was effectively filed before the effective filing date of the claimed invention.

“(b) EXCEPTIONS.—

“(1) PRIOR INVENTOR DISCLOSURE EXCEPTION.—Subject matter that would otherwise qualify as prior art based upon a disclosure under subparagraph (B) of subsection (a)(1) shall not be prior art to a claimed invention under that subparagraph if the subject matter had, before such disclosure, been publicly disclosed by the inventor or a joint inventor or others who obtained the subject matter disclosed directly or indirectly from the inventor or a joint inventor.

“(2) DERIVATION, PRIOR DISCLOSURE, AND COMMON ASSIGNMENT EXCEPTIONS.—Subject matter that would otherwise qualify as prior art only under subsection (a)(2), after taking into account the exception under paragraph (1), shall not be prior art to a claimed invention if—

“(A) the subject matter was obtained directly or indirectly from the inventor or a joint inventor;

“(B) the subject matter had been publicly disclosed by the inventor or a joint inventor or others who obtained the subject matter disclosed, directly or indirectly, from the inventor or a joint inventor before the effective filing date of the application or patent set forth under subsection (a)(2); or

“(C) the subject matter and the claimed invention, not later than the effective filing date of the claimed invention, were owned by the same person or subject to an obligation of assignment to the same person.

“(3) JOINT RESEARCH AGREEMENT EXCEPTION.—

“(A) IN GENERAL.—Subject matter and a claimed invention shall be deemed to have been owned by the same person or subject to an obligation of assignment to the same person in applying the provisions of paragraph (2) if—

“(i) the claimed invention was made by or on behalf of parties to a joint research agreement that was in effect on or before the effective filing date of the claimed invention;

“(ii) the claimed invention was made as a result of activities undertaken within the scope of the joint research agreement; and

“(iii) the application for patent for the claimed invention discloses or is amended to disclose the names of the parties to the joint research agreement.

“(B) For purposes of subparagraph (A), the term ‘joint research agreement’ means a written contract, grant, or cooperative agreement entered into by 2 or more persons or entities for the performance of experimental, developmental, or research work in the field of the claimed invention.

“(4) PATENTS AND PUBLISHED APPLICATIONS EFFECTIVELY FILED.—A patent or application for patent is effectively filed under subsection (a)(2) with respect to any subject matter described in the patent or application—

“(A) as of the filing date of the patent or the application for patent; or

“(B) if the patent or application for patent is entitled to claim a right of priority under section 119, 365(a), or 365(b) or to claim the benefit of an earlier filing date under section 120, 121, or 365(c), based upon 1 or more prior filed applications for patent, as of the filing

date of the earliest such application that describes the subject matter.”

(2) CONFORMING AMENDMENT.—The item relating to section 102 in the table of sections for chapter 10 of title 35, United States Code, is amended to read as follows:

“102. Conditions for patentability; novelty.”

(c) CONDITIONS FOR PATENTABILITY; NON-OBVIOUS SUBJECT MATTER.—Section 103 of title 35, United States Code, is amended to read as follows:

“§ 103. Conditions for patentability; non-obvious subject matter

“A patent for a claimed invention may not be obtained though the claimed invention is not identically disclosed as set forth in section 102, if the differences between the claimed invention and the prior art are such that the claimed invention as a whole would have been obvious before the effective filing date of the claimed invention to a person having ordinary skill in the art to which the claimed invention pertains. Patentability shall not be negated by the manner in which the invention was made.”

(d) REPEAL OF REQUIREMENTS FOR INVENTIONS MADE ABROAD.—Section 104 of title 35, United States Code, and the item relating to that section in the table of sections for chapter 10 of title 35, United States Code, are repealed.

(e) REPEAL OF STATUTORY INVENTION REGISTRATION.—

(1) IN GENERAL.—Section 157 of title 35, United States Code, and the item relating to that section in the table of sections for chapter 14 of title 35, United States Code, are repealed.

(2) REMOVAL OF CROSS REFERENCES.—Section 111(b)(8) of title 35, United States Code, is amended by striking “sections 115, 131, 135, and 157” and inserting “sections 131 and 135”.

(f) EARLIER FILING DATE FOR INVENTOR AND JOINT INVENTOR.—Section 120 of title 35, United States Code, is amended by striking “which is filed by an inventor or inventors named” and inserting “which names an inventor or joint inventor”.

(g) CONFORMING AMENDMENTS.—

(1) RIGHT OF PRIORITY.—Section 172 of title 35, United States Code, is amended by striking “and the time specified in section 102(d)”.

(2) LIMITATION ON REMEDIES.—Section 287(c)(4) of title 35, United States Code, is amended by striking “the earliest effective filing date of which is prior to” and inserting “which has an effective filing date before”.

(3) INTERNATIONAL APPLICATION DESIGNATING THE UNITED STATES: EFFECT.—Section 363 of title 35, United States Code, is amended by striking “except as otherwise provided in section 102(e) of this title”.

(4) PUBLICATION OF INTERNATIONAL APPLICATION: EFFECT.—Section 374 of title 35, United States Code, is amended by striking “sections 102(e) and 154(d)” and inserting “section 154(d)”.

(5) PATENT ISSUED ON INTERNATIONAL APPLICATION: EFFECT.—The second sentence of section 375(a) of title 35, United States Code, is amended by striking “Subject to section 102(e) of this title, such” and inserting “Such”.

(6) LIMIT ON RIGHT OF PRIORITY.—Section 119(a) of title 35, United States Code, is amended by striking “; but no patent shall be granted” and all that follows through “one year prior to such filing”.

(7) INVENTIONS MADE WITH FEDERAL ASSISTANCE.—Section 202(c) of title 35, United States Code, is amended—

(A) in paragraph (2)—

(i) by striking “publication, on sale, or public use,” and all that follows through “obtained in the United States” and inserting “the 1-year period referred to in section

102(a) would end before the end of that 2-year period”; and

(ii) by striking “the statutory” and inserting “that 1-year”; and

(B) in paragraph (3), by striking “any statutory bar date that may occur under this title due to publication, on sale, or public use” and inserting “the expiration of the 1-year period referred to in section 102(a)”.

(h) REPEAL OF INTERFERING PATENT REMEDIES.—Section 291 of title 35, United States Code, and the item relating to that section in the table of sections for chapter 29 of title 35, United States Code, are repealed.

(i) ACTION FOR CLAIM TO PATENT ON DERIVED INVENTION.—Section 135 of title 35, United States Code, is amended to read as follows:

“(a) DISPUTE OVER RIGHT TO PATENT.—

“(1) INSTITUTION OF DERIVATION PROCEEDING.—An applicant may request institution of a derivation proceeding to determine the right of the applicant to a patent by filing a request which sets forth with particularity the basis for finding that an earlier applicant derived the claimed invention from the applicant requesting the proceeding and, without authorization, filed an application claiming such invention. Any such request may only be made within 12 months after the date of first publication of an application containing a claim that is the same or is substantially the same as the claimed invention, must be made under oath, and must be supported by substantial evidence. Whenever the Director determines that patents or applications for patent naming different individuals as the inventor interfere with one another because of a dispute over the right to patent under section 101, the Director shall institute a derivation proceeding for the purpose of determining which applicant is entitled to a patent.

“(2) DETERMINATION BY PATENT TRIAL AND APPEAL BOARD.—In any proceeding under this subsection, the Patent Trial and Appeal Board—

“(A) shall determine the question of the right to patent;

“(B) in appropriate circumstances, may correct the naming of the inventor in any application or patent at issue; and

“(C) shall issue a final decision on the right to patent.

“(3) DERIVATION PROCEEDING.—The Board may defer action on a request to initiate a derivation proceeding until 3 months after the date on which the Director issues a patent to the applicant that filed the earlier application.

“(4) EFFECT OF FINAL DECISION.—The final decision of the Patent Trial and Appeal Board, if adverse to the claim of an applicant, shall constitute the final refusal by the United States Patent and Trademark Office on the claims involved. The Director may issue a patent to an applicant who is determined by the Patent Trial and Appeal Board to have the right to patent. The final decision of the Board, if adverse to a patentee, shall, if no appeal or other review of the decision has been or can be taken or had, constitute cancellation of the claims involved in the patent, and notice of such cancellation shall be endorsed on copies of the patent distributed after such cancellation by the United States Patent and Trademark Office.

“(b) SETTLEMENT.—Parties to a derivation proceeding may terminate the proceeding by filing a written statement reflecting the agreement of the parties as to the correct inventors of the claimed invention in dispute. Unless the Patent Trial and Appeal Board finds the agreement to be inconsistent with the evidence of record, it shall take action consistent with the agreement. Any written settlement or understanding of the parties

shall be filed with the Director. At the request of a party to the proceeding, the agreement or understanding shall be treated as business confidential information, shall be kept separate from the file of the involved patents or applications, and shall be made available only to Government agencies on written request, or to any person on a showing of good cause.

“(c) ARBITRATION.—Parties to a derivation proceeding, within such time as may be specified by the Director by regulation, may determine such contest or any aspect thereof by arbitration. Such arbitration shall be governed by the provisions of title 9 to the extent such title is not inconsistent with this section. The parties shall give notice of any arbitration award to the Director, and such award shall, as between the parties to the arbitration, be dispositive of the issues to which it relates. The arbitration award shall be unenforceable until such notice is given. Nothing in this subsection shall preclude the Director from determining patentability of the invention involved in the derivation proceeding.”

(j) ELIMINATION OF REFERENCES TO INTERFERENCES.—(1) Sections 6, 41, 134, 141, 145, 146, 154, 305, and 314 of title 35, United States Code, are each amended by striking “Board of Patent Appeals and Interferences” each place it appears and inserting “Patent Trial and Appeal Board”.

(2) Sections 141, 146, and 154 of title 35, United States Code, are each amended—

(A) by striking “an interference” each place it appears and inserting “a derivation proceeding”; and

(B) by striking “interference” each additional place it appears and inserting “derivation proceeding”.

(3) The section heading for section 134 of title 35, United States Code, is amended to read as follows:

“§ 134. Appeal to the Patent Trial and Appeal Board”.

(4) The section heading for section 135 of title 35, United States Code, is amended to read as follows:

“§ 135. Derivation proceedings”.

(5) The section heading for section 146 of title 35, United States Code, is amended to read as follows:

“§ 146. Civil action in case of derivation proceeding”.

(6) Section 154(b)(1)(C) of title 35, United States Code, is amended by striking “INTERFERENCES” and inserting “DERIVATION PROCEEDINGS”.

(7) The item relating to section 6 in the table of sections for chapter 1 of title 35, United States Code, is amended to read as follows:

“6. Patent Trial and Appeal Board.”.

(8) The items relating to sections 134 and 135 in the table of sections for chapter 12 of title 35, United States Code, are amended to read as follows:

“134. Appeal to the Patent Trial and Appeal Board.

“135. Derivation proceedings.”.

(9) The item relating to section 146 in the table of sections for chapter 13 of title 35, United States Code, is amended to read as follows:

“146. Civil action in case of derivation proceeding.”.

(10) CERTAIN APPEALS.—Section 1295(a)(4)(A) of title 28, United States Code, is amended to read as follows:

“(A) the Patent Trial and Appeal Board of the United States Patent and Trademark Office with respect to patent applications, interference proceedings (commenced before the date of enactment of the Patent Reform

Act of 2009), derivation proceedings, and post-grant review proceedings, at the instance of an applicant for a patent or any party to a patent interference (commenced before the effective date of the Patent Reform Act of 2009), derivation proceeding, or post-grant review proceeding, and any such appeal shall waive any right of such applicant or party to proceed under section 145 or 146 of title 35;”.

(k) SEARCH AND EXAMINATION FUNCTIONS.—Section 131 of title 35, United States Code, is amended by—

(1) by striking “The Director shall cause” and inserting “(a) IN GENERAL.—The Director shall cause”; and

(2) by adding at the end the following:

“(b) SEARCH AND EXAMINATION FUNCTIONS.—To the extent consistent with United States obligations under international agreements, examination and search duties for the grant of a United States patent are sovereign functions which shall be performed within the United States by United States citizens who are employees of the United States Government.”.

### SEC. 3. INVENTOR'S OATH OR DECLARATION.

(a) INVENTOR'S OATH OR DECLARATION.—

(1) IN GENERAL.—Section 115 of title 35, United States Code, is amended to read as follows:

#### “§ 115. Inventor's oath or declaration

“(a) NAMING THE INVENTOR; INVENTOR'S OATH OR DECLARATION.—An application for patent that is filed under section 111(a), that commences the national stage under section 363, or that is filed by an inventor for an invention for which an application has previously been filed under this title by that inventor shall include, or be amended to include, the name of the inventor of any claimed invention in the application. Except as otherwise provided in this section, an individual who is the inventor or a joint inventor of a claimed invention in an application for patent shall execute an oath or declaration in connection with the application.

“(b) REQUIRED STATEMENTS.—An oath or declaration under subsection (a) shall contain statements that—

“(1) the application was made or was authorized to be made by the affiant or declarant; and

“(2) such individual believes himself or herself to be the original inventor or an original joint inventor of a claimed invention in the application.

“(c) ADDITIONAL REQUIREMENTS.—The Director may specify additional information relating to the inventor and the invention that is required to be included in an oath or declaration under subsection (a).

“(d) SUBSTITUTE STATEMENT.—

“(1) IN GENERAL.—In lieu of executing an oath or declaration under subsection (a), the applicant for patent may provide a substitute statement under the circumstances described in paragraph (2) and such additional circumstances that the Director may specify by regulation.

“(2) PERMITTED CIRCUMSTANCES.—A substitute statement under paragraph (1) is permitted with respect to any individual who—

“(A) is unable to file the oath or declaration under subsection (a) because the individual—

“(i) is deceased;

“(ii) is under legal incapacity; or

“(iii) cannot be found or reached after diligent effort; or

“(B) is under an obligation to assign the invention but has refused to make the oath or declaration required under subsection (a).

“(3) CONTENTS.—A substitute statement under this subsection shall—

“(A) identify the individual with respect to whom the statement applies;

“(B) set forth the circumstances representing the permitted basis for the filing of the substitute statement in lieu of the oath or declaration under subsection (a); and

“(C) contain any additional information, including any showing, required by the Director.

“(e) MAKING REQUIRED STATEMENTS IN ASSIGNMENT OF RECORD.—An individual who is under an obligation of assignment of an application for patent may include the required statements under subsections (b) and (c) in the assignment executed by the individual, in lieu of filing such statements separately.

“(f) TIME FOR FILING.—A notice of allowance under section 151 may be provided to an applicant for patent only if the applicant for patent has filed each required oath or declaration under subsection (a) or has filed a substitute statement under subsection (d) or recorded an assignment meeting the requirements of subsection (e).

“(g) EARLIER-FILED APPLICATION CONTAINING REQUIRED STATEMENTS OR SUBSTITUTE STATEMENT.—The requirements under this section shall not apply to an individual with respect to an application for patent in which the individual is named as the inventor or a joint inventor and that claims the benefit under section 120 or 365(c) of the filing of an earlier-filed application, if—

“(1) an oath or declaration meeting the requirements of subsection (a) was executed by the individual and was filed in connection with the earlier-filed application;

“(2) a substitute statement meeting the requirements of subsection (d) was filed in the earlier filed application with respect to the individual; or

“(3) an assignment meeting the requirements of subsection (e) was executed with respect to the earlier-filed application by the individual and was recorded in connection with the earlier-filed application.

“(h) SUPPLEMENTAL AND CORRECTED STATEMENTS; FILING ADDITIONAL STATEMENTS.—

“(1) IN GENERAL.—Any person making a statement required under this section may withdraw, replace, or otherwise correct the statement at any time. If a change is made in the naming of the inventor requiring the filing of 1 or more additional statements under this section, the Director shall establish regulations under which such additional statements may be filed.

“(2) SUPPLEMENTAL STATEMENTS NOT REQUIRED.—If an individual has executed an oath or declaration under subsection (a) or an assignment meeting the requirements of subsection (e) with respect to an application for patent, the Director may not thereafter require that individual to make any additional oath, declaration, or other statement equivalent to those required by this section in connection with the application for patent or any patent issuing thereon.

“(3) SAVINGS CLAUSE.—No patent shall be invalid or unenforceable based upon the failure to comply with a requirement under this section if the failure is remedied as provided under paragraph (1).

“(i) ACKNOWLEDGMENT OF PENALTIES.—Any declaration or statement filed pursuant to this section shall contain an acknowledgment that any willful false statement made in such declaration or statement is punishable under section 1001 of title 18 by fine or imprisonment of not more than 5 years, or both.”.

(2) RELATIONSHIP TO DIVISIONAL APPLICATIONS.—Section 121 of title 35, United States Code, is amended by striking “If a divisional application” and all that follows through “inventor.”.

(3) REQUIREMENTS FOR NONPROVISIONAL APPLICATIONS.—Section 111(a) of title 35, United States Code, is amended—

(A) in paragraph (2)(C), by striking “by the applicant” and inserting “or declaration”;

(B) in the heading for paragraph (3), by striking “AND OATH”;

(C) by striking “and oath” each place it appears.

(4) CONFORMING AMENDMENT.—The item relating to section 115 in the table of sections for chapter 11 of title 35, United States Code, is amended to read as follows:

“115. Inventor’s oath or declaration.”.

(b) FILING BY OTHER THAN INVENTOR.—Section 118 of title 35, United States Code, is amended to read as follows:

**“§ 118. Filing by other than inventor**

“A person to whom the inventor has assigned or is under an obligation to assign the invention may make an application for patent. A person who otherwise shows sufficient proprietary interest in the matter may make an application for patent on behalf of and as agent for the inventor on proof of the pertinent facts and a showing that such action is appropriate to preserve the rights of the parties. If the Director grants a patent on an application filed under this section by a person other than the inventor, the patent shall be granted to the real party in interest and upon such notice to the inventor as the Director considers to be sufficient.”.

(c) SPECIFICATION.—Section 112 of title 35, United States Code, is amended—

(1) in the first paragraph—

(A) by striking “The specification” and inserting “(a) IN GENERAL.—The specification”;

(B) by striking “of carrying out his invention” and inserting “or joint inventor of carrying out the invention”;

(2) in the second paragraph—

(A) by striking “The specifications” and inserting “(b) CONCLUSION.—The specifications”;

(B) by striking “applicant regards as his invention” and inserting “inventor or a joint inventor regards as the invention”;

(3) in the third paragraph, by striking “A claim” and inserting “(c) FORM.—A claim”;

(4) in the fourth paragraph, by striking “Subject to the following paragraph,” and inserting “(d) REFERENCE IN DEPENDENT FORMS.—Subject to subsection (e),”;

(5) in the fifth paragraph, by striking “A claim” and inserting “(e) REFERENCE IN MULTIPLE DEPENDENT FORM.—A claim”;

(6) in the last paragraph, by striking “An element” and inserting “(f) ELEMENT IN CLAIM FOR A COMBINATION.—An element”.

**SEC. 4. RIGHT OF THE INVENTOR TO OBTAIN DAMAGES.**

(a) DAMAGES.—Section 284 of title 35, United States Code, is amended to read as follows:

**“§ 284. Damages**

“(a) IN GENERAL.—Upon finding for the claimant the court shall award the claimant damages adequate to compensate for the infringement but in no event less than a reasonable royalty for the use made of the invention by the infringer, together with interest and costs as fixed by the court, subject to the provisions of this section.

“(b) DETERMINATION OF DAMAGES; EVIDENCE CONSIDERED; PROCEDURE.—The court may receive expert testimony as an aid to the determination of damages or of what royalty would be reasonable under the circumstances. The admissibility of such testimony shall be governed by the rules of evidence governing expert testimony. When the damages are not found by a jury, the court shall assess them.

“(c) STANDARD FOR CALCULATING REASONABLE ROYALTY.—

“(1) IN GENERAL.—The court shall determine, based on the facts of the case and after

adducing any further evidence the court deems necessary, which of the following methods shall be used by the court or the jury in calculating a reasonable royalty pursuant to subsection (a). The court shall also identify the factors that are relevant to the determination of a reasonable royalty, and the court or jury, as the case may be, shall consider only those factors in making such determination.

“(A) ENTIRE MARKET VALUE.—Upon a showing to the satisfaction of the court that the claimed invention’s specific contribution over the prior art is the predominant basis for market demand for an infringing product or process, damages may be based upon the entire market value of that infringing product or process.

“(B) ESTABLISHED ROYALTY BASED ON MARKETPLACE LICENSING.—Upon a showing to the satisfaction of the court that the claimed invention has been the subject of a nonexclusive license for the use made of the invention by the infringer, to a number of persons sufficient to indicate a general marketplace recognition of the reasonableness of the licensing terms, if the license was secured prior to the filing of the case before the court, and the court determines that the infringer’s use is of substantially the same scope, volume, and benefit of the rights granted under such license, damages may be determined on the basis of the terms of such license. Upon a showing to the satisfaction of the court that the claimed invention has sufficiently similar noninfringing substitutes in the relevant market, which have themselves been the subject of such nonexclusive licenses, and the court determines that the infringer’s use is of substantially the same scope, volume, and benefit of the rights granted under such licenses, damages may be determined on the basis of the terms of such licenses.

“(C) VALUATION CALCULATION.—Upon a determination by the court that the showings required under subparagraphs (A) and (B) have not been made, the court shall conduct an analysis to ensure that a reasonable royalty is applied only to the portion of the economic value of the infringing product or process properly attributable to the claimed invention’s specific contribution over the prior art. In the case of a combination invention whose elements are present individually in the prior art, the contribution over the prior art may include the value of the additional function resulting from the combination, as well as the enhanced value, if any, of some or all of the prior art elements as part of the combination, if the patentee demonstrates that value.

“(2) ADDITIONAL FACTORS.—Where the court determines it to be appropriate in determining a reasonable royalty under paragraph (1), the court may also consider, or direct the jury to consider, any other relevant factors under applicable law.

“(d) INAPPLICABILITY TO OTHER DAMAGES ANALYSIS.—The methods for calculating a reasonable royalty described in subsection (c) shall have no application to the calculation of an award of damages that does not necessitate the determination of a reasonable royalty as a basis for monetary relief sought by the claimant.

“(e) WILLFUL INFRINGEMENT.—

“(1) INCREASED DAMAGES.—A court that has determined that an infringer has willfully infringed a patent or patents may increase damages up to 3 times the amount of the damages found or assessed under subsection (a), except that increased damages under this paragraph shall not apply to provisional rights under section 154(d).

“(2) PERMITTED GROUNDS FOR WILLFULNESS.—A court may find that an infringer has willfully infringed a patent only if the

patent owner presents clear and convincing evidence that acting with objective recklessness—

“(A) after receiving written notice from the patentee—

“(i) alleging acts of infringement in a manner sufficient to give the infringer an objectively reasonable apprehension of suit on such patent, and

“(ii) identifying with particularity each claim of the patent, each product or process that the patent owner alleges infringes the patent, and the relationship of such product or process to such claim,

the infringer, after a reasonable opportunity to investigate, thereafter performed 1 or more of the alleged acts of infringement;

“(B) the infringer intentionally copied the patented invention with knowledge that it was patented; or

“(C) after having been found by a court to have infringed that patent, the infringer engaged in conduct that was not colorably different from the conduct previously found to have infringed the patent, and which resulted in a separate finding of infringement of the same patent.

“(3) LIMITATIONS ON WILLFULNESS.—

“(A) IN GENERAL.—A court may not find that an infringer has willfully infringed a patent under paragraph (2) for any period of time during which the infringer had an informed good faith belief that the patent was invalid or unenforceable, or would not be infringed by the conduct later shown to constitute infringement of the patent.

“(B) GOOD FAITH ESTABLISHED.—An informed good faith belief within the meaning of subparagraph (A) may be established by—

“(i) reasonable reliance on advice of counsel;

“(ii) evidence that the infringer sought to modify its conduct to avoid infringement once it had discovered the patent; or

“(iii) other evidence a court may find sufficient to establish such good faith belief.

“(C) RELEVANCE OF NOT PRESENTING CERTAIN EVIDENCE.—The decision of the infringer not to present evidence of advice of counsel is not relevant to a determination of willful infringement under paragraph (2).

“(4) LIMITATION ON PLEADING.—Before the date on which a court determines that the patent in suit is not invalid, is enforceable, and has been infringed by the infringer, a patentee may not plead and a court may not determine that an infringer has willfully infringed a patent. The court’s determination of an infringer’s willfulness shall be made without a jury.”.

(b) REPORT TO CONGRESSIONAL COMMITTEES.—

(1) IN GENERAL.—Not later than 2 years after the date of enactment of this Act, the Director shall report to the Committee on the Judiciary of the Senate and the Committee on the Judiciary of the House of Representatives, the findings and recommendations of the Director on the operation of prior user rights in selected countries in the industrialized world. The report shall include the following:

(A) A comparison between patent laws of the United States and the laws of other industrialized countries, including the European Union, Japan, Canada, and Australia.

(B) An analysis of the effect of prior user rights on innovation rates in the selected countries.

(C) An analysis of the correlation, if any, between prior user rights and start-up enterprises and the ability to attract venture capital to start new companies.

(D) An analysis of the effect of prior user rights, if any, on small businesses, universities, and individual inventors.

(E) An analysis of legal and constitutional issues, if any, that arise from placing trade secret law in patent law.

(2) CONSULTATION WITH OTHER AGENCIES.—In preparing the report required under paragraph (1), the Director shall consult with the Secretary of State and the Attorney General.

(C) DEFENSE TO INFRINGEMENT BASED ON EARLIER INVENTOR.—Section 273(b)(6) of title 35, United States Code, is amended to read as follows:

“(6) PERSONAL DEFENSE.—The defense under this section may be asserted only by the person who performed or caused the performance of the acts necessary to establish the defense as well as any other entity that controls, is controlled by, or is under common control with such person and, except for any transfer to the patent owner, the right to assert the defense shall not be licensed or assigned or transferred to another person except as an ancillary and subordinate part of a good faith assignment or transfer for other reasons of the entire enterprise or line of business to which the defense relates. Notwithstanding the preceding sentence, any person may, on its own behalf, assert a defense based on the exhaustion of rights provided under paragraph (3), including any necessary elements thereof.”

(d) EFFECTIVE DATE.—The amendments made by this section shall apply to any civil action commenced on or after the date of enactment of this Act.

#### SEC. 5. POST-GRANT PROCEDURES AND OTHER QUALITY ENHANCEMENTS.

(a) CITATION OF PRIOR ART.—Section 301 of title 35, United States Code, is amended to read as follows:

##### “§ 301. Citation of prior art

“(a) IN GENERAL.—Any person at any time may cite to the Office in writing—

“(1) prior art consisting of patents, printed publications, or evidence that the claimed invention was in public use or sale in the United States more than 1 year prior to the date of the application for patent in the United States, which that person believes to have a bearing on the patentability of any claim of a particular patent; or

“(2) written statements of the patent owner filed in a proceeding before a Federal court or the Patent and Trademark Office in which the patent owner takes a position on the scope of one or more patent claims.

“(b) SUBMISSIONS PART OF OFFICIAL FILE.—If the person citing prior art or written submissions under subsection (a) explains in writing the pertinence and manner of applying the prior art or written submission to at least one claim of the patent, the citation of the prior art or documentary evidence (as the case may be) and the explanation thereof shall become a part of the official file of the patent.

“(c) PROCEDURES FOR WRITTEN STATEMENTS.—

“(1) SUBMISSION OF ADDITIONAL MATERIALS.—A party that submits written statements under subsection (a)(2) in a proceeding shall include any other documents, pleadings, or evidence from the proceeding that address the patent owner’s statements or the claims addressed by the written statements.

“(2) LIMITATION ON USE OF STATEMENTS.—Written statements submitted under subsection (a)(2) shall not be considered for any purpose other than to determine the proper meaning of the claims that are the subject of the request in a proceeding ordered pursuant to section 304 or 313. Any such written statements, and any materials submitted under paragraph (1), that are subject to an applicable protective order shall be redacted to exclude information subject to the order.

“(d) IDENTITY WITHHELD.—Upon the written request of the person making the cita-

tion under subsection (a), the person’s identity shall be excluded from the patent file and kept confidential.”

(b) REQUEST FOR REEXAMINATION.—The first sentence of section 302 of title 35, United States Code, is amended to read as follows: “Any person at any time may file a request for reexamination by the Office of any claim on a patent on the basis of any prior art or documentary evidence cited under paragraph (1) or (3) of subsection (a) of section 301 of this title.”

(c) REEXAMINATION.—Section 303(a) of title 35, United States Code, is amended to read as follows:

“(a) Within three months following the filing of a request for reexamination under section 302, the Director shall determine whether a substantial new question of patentability affecting any claim of the patent concerned is raised by the request, with or without consideration of other patents or printed publications. On the Director’s own initiative, and at any time, the Director may determine whether a substantial new question of patentability is raised by patents, publications, or other evidence discovered by the Director, is cited under section 301, or is cited by any person other than the owner of the patent under section 302 or section 311. The existence of a substantial new question of patentability is not precluded by the fact that a patent, printed publication, or other evidence was previously considered by the Office.”

(d) REQUEST FOR INTER PARTES REEXAMINATION.—Section 311(a) of title 35, United States Code, is amended to read as follows:

“(a) IN GENERAL.—Any third-party requester at any time may file a request for inter partes reexamination by the Office of a patent on the basis of any prior art or documentary evidence cited under paragraph (1) or (3) of subsection (a) of section 301 of this title.”

(e) CONDUCT OF INTER PARTES PROCEEDINGS.—Section 314 of title 35, United States Code, is amended—

(1) in the first sentence of subsection (a), by striking “conducted according to the procedures established for initial examination under the provisions of sections 132 and 133” and inserting “heard by an administrative patent judge in accordance with procedures which the Director shall establish”;

(2) in subsection (b), by striking paragraph (2) and inserting the following:

“(2) The third-party requester shall have the opportunity to file written comments on any action on the merits by the Office in the inter partes reexamination proceeding, and on any response that the patent owner files to such an action, if those written comments are received by the Office within 60 days after the date of service on the third-party requester of the Office action or patent owner response, as the case may be.”; and

(3) by adding at the end the following:

“(d) ORAL HEARING.—At the request of a third party requestor or the patent owner, the administrative patent judge shall conduct an oral hearing, unless the judge finds cause lacking for such hearing.”

(f) ESTOPPEL.—Section 315(c) of title 35, United States Code, is amended by striking “or could have raised”.

(g) REEXAMINATION PROHIBITED AFTER DISTRICT COURT DECISION.—Section 317(b) of title 35, United States Code, is amended—

(1) in the subsection heading, by striking “FINAL DECISION” and inserting “DISTRICT COURT DECISION”; and

(2) by striking “Once a final decision has been entered” and inserting “Once the judgment of the district court has been entered”.

(h) POST-GRANT OPPOSITION PROCEDURES.—

(1) IN GENERAL.—Part III of title 35, United States Code, is amended by adding at the end the following new chapter:

#### “CHAPTER 32—POST-GRANT REVIEW PROCEDURES

“Sec.

“321. Petition for post-grant review.

“322. Timing and bases of petition.

“323. Requirements of petition.

“324. Prohibited filings.

“325. Submission of additional information; showing of sufficient grounds.

“326. Conduct of post-grant review proceedings.

“327. Patent owner response.

“328. Proof and evidentiary standards.

“329. Amendment of the patent.

“330. Decision of the Board.

“331. Effect of decision.

“332. Settlement.

“333. Relationship to other pending proceedings.

“334. Effect of decisions rendered in civil action on post-grant review proceedings.

“335. Effect of final decision on future proceedings.

“336. Appeal.

##### “§ 321. Petition for post-grant review

“Subject to sections 322, 324, 332, and 333, a person who is not the patent owner may file with the Office a petition for cancellation seeking to institute a post-grant review proceeding to cancel as unpatentable any claim of a patent on any ground that could be raised under paragraph (2) or (3) of section 282(b) (relating to invalidity of the patent or any claim). The Director shall establish, by regulation, fees to be paid by the person requesting the proceeding, in such amounts as the Director determines to be reasonable.

##### “§ 322. Timing and bases of petition

“A post-grant proceeding may be instituted under this chapter pursuant to a cancellation petition filed under section 321 only if—

“(1) the petition is filed not later than 12 months after the issuance of the patent or a reissue patent, as the case may be; or

“(2) the patent owner consents in writing to the proceeding.

##### “§ 323. Requirements of petition

“A cancellation petition filed under section 321 may be considered only if—

“(1) the petition is accompanied by payment of the fee established by the Director under section 321;

“(2) the petition identifies the cancellation petitioner;

“(3) for each claim sought to be canceled, the petition sets forth in writing the basis for cancellation and provides the evidence in support thereof, including copies of patents and printed publications, or written testimony of a witness attested to under oath or declaration by the witness, or any other information that the Director may require by regulation; and

“(4) the petitioner provides copies of the petition, including any evidence submitted with the petition and any other information submitted under paragraph (3), to the patent owner or, if applicable, the designated representative of the patent owner.

##### “§ 324. Prohibited filings

“A post-grant review proceeding may not be instituted under section 322 if the petition for cancellation requesting the proceeding—

“(1) identifies the same cancellation petitioner and the same patent as a previous petition for cancellation filed under such section; or

“(2) is based on the best mode requirement contained in section 112.

##### “§ 325. Submission of additional information; showing of sufficient grounds

“(a) IN GENERAL.—The cancellation petitioner shall file such additional information

with respect to the petition as the Director may require. For each petition submitted under section 321, the Director shall determine if the written statement, and any evidence submitted with the request, establish that a substantial question of patentability exists for at least one claim in the patent. The Director may initiate a post-grant review proceeding if the Director determines that the information presented provides sufficient grounds to believe that there is a substantial question of patentability concerning one or more claims of the patent at issue.

“(b) NOTIFICATION; DETERMINATIONS NOT REVIEWABLE.—The Director shall notify the patent owner and each petitioner in writing of the Director’s determination under subsection (a), including a determination to deny the petition. The Director shall make that determination in writing not later than 60 days after receiving the petition. Any determination made by the Director under subsection (a), including whether or not to institute a post-grant review proceeding or to deny the petition, shall not be reviewable.

**“§ 326. Conduct of post-grant review proceedings**

“(a) IN GENERAL.—The Director shall prescribe regulations, in accordance with section 2(b)(2)—

“(1) establishing and governing post-grant review proceedings under this chapter and their relationship to other proceedings under this title;

“(2) establishing procedures for the submission of supplemental information after the petition for cancellation is filed; and

“(3) setting forth procedures for discovery of relevant evidence, including that such discovery shall be limited to evidence directly related to factual assertions advanced by either party in the proceeding, and the procedures for obtaining such evidence shall be consistent with the purpose and nature of the proceeding.

In carrying out paragraph (3), the Director shall bear in mind that discovery must be in the interests of justice.

“(b) POST-GRANT REGULATIONS.—Regulations under subsection (a)(1)—

“(1) shall require that the final determination in a post-grant proceeding issue not later than one year after the date on which the post-grant review proceeding is instituted under this chapter, except that, for good cause shown, the Director may extend the 1-year period by not more than six months;

“(2) shall provide for discovery upon order of the Director;

“(3) shall provide for publication of notice in the Federal Register of the filing of a petition for post-grant review under this chapter, for publication of the petition, and documents, orders, and decisions relating to the petition, on the website of the Patent and Trademark Office, and for filings under seal exempt from publication requirements;

“(4) shall prescribe sanctions for abuse of discovery, abuse of process, or any other improper use of the proceeding, such as to harass or to cause unnecessary delay or unnecessary increase in the cost of the proceeding;

“(5) may provide for protective orders governing the exchange and submission of confidential information; and

“(6) shall ensure that any information submitted by the patent owner in support of any amendment entered under section 329 is made available to the public as part of the prosecution history of the patent.

“(c) CONSIDERATIONS.—In prescribing regulations under this section, the Director shall consider the effect on the economy, the integrity of the patent system, and the efficient administration of the Office.

“(d) CONDUCT OF PROCEEDING.—The Patent Trial and Appeal Board shall, in accordance

with section 6(b), conduct each post-grant review proceeding authorized by the Director.

**“§ 327. Patent owner response**

“After a post-grant proceeding under this chapter has been instituted with respect to a patent, the patent owner shall have the right to file, within a time period set by the Director, a response to the cancellation petition. The patent owner shall file with the response, through affidavits or declarations, any additional factual evidence and expert opinions on which the patent owner relies in support of the response.

**“§ 328. Proof and evidentiary standards**

“(a) IN GENERAL.—The presumption of validity set forth in section 282 shall not apply in a challenge to any patent claim under this chapter.

“(b) BURDEN OF PROOF.—The party advancing a proposition under this chapter shall have the burden of proving that proposition by a preponderance of the evidence.

**“§ 329. Amendment of the patent**

“(a) IN GENERAL.—In response to a challenge in a petition for cancellation, the patent owner may file one motion to amend the patent in one or more of the following ways:

“(1) Cancel any challenged patent claim.

“(2) For each challenged claim, propose a substitute claim.

“(3) Amend the patent drawings or otherwise amend the patent other than the claims.

“(b) ADDITIONAL MOTIONS.—Additional motions to amend may be permitted only for good cause shown.

“(c) SCOPE OF CLAIMS.—An amendment under this section may not enlarge the scope of the claims of the patent or introduce new matter.

**“§ 330. Decision of the Board**

“If the post-grant review proceeding is instituted and not dismissed under this chapter, the Patent Trial and Appeal Board shall issue a final written decision addressing the patentability of any patent claim challenged and any new claim added under section 329.

**“§ 331. Effect of decision**

“(a) IN GENERAL.—If the Patent Trial and Appeal Board issues a final decision under section 330 and the time for appeal has expired or any appeal proceeding has terminated, the Director shall issue and publish a certificate canceling any claim of the patent finally determined to be unpatentable and incorporating in the patent by operation of the certificate any new claim determined to be patentable.

“(b) NEW CLAIMS.—Any new claim held to be patentable and incorporated into a patent in a post-grant review proceeding shall have the same effect as that specified in section 252 for reissued patents on the right of any person who made, purchased, offered to sell, or used within the United States, or imported into the United States, anything patented by such new claim, or who made substantial preparations therefor, before a certificate under subsection (a) of this section is issued.

**“§ 332. Settlement**

“(a) IN GENERAL.—A post-grant review proceeding shall be terminated with respect to any petitioner upon the joint request of the petitioner and the patent owner, unless the Patent Trial and Appeal Board has issued a written decision before the request for termination is filed. If the post-grant review proceeding is terminated with respect to a petitioner under this paragraph, no estoppel shall apply to that petitioner. If no petitioner remains in the proceeding, the panel of administrative patent judges assigned to the proceeding shall terminate the proceeding.

“(b) AGREEMENT IN WRITING.—Any agreement or understanding between the patent owner and a petitioner, including any collateral agreements referred to in the agreement or understanding, that is made in connection with or in contemplation of the termination of a post-grant review proceeding, must be in writing. A post-grant review proceeding as between the parties to the agreement or understanding may not be terminated until a copy of the agreement or understanding, including any such collateral agreements, has been filed in the Office. If any party filing such an agreement or understanding requests, the agreement or understanding shall be kept separate from the file of the post-grant review proceeding, and shall be made available only to Government agencies on written request, or to any person on a showing of good cause.

**“§ 333. Relationship to other proceedings**

“(a) IN GENERAL.—Notwithstanding subsection 135(a), sections 251 and 252, and chapter 30, the Director may determine the manner in which any reexamination proceeding, reissue proceeding, interference proceeding (commenced with respect to an application for patent filed before the effective date provided in section 3(k) of the Patent Reform Act of 2009), derivation proceeding, or post-grant review proceeding, that is pending during a post-grant review proceeding, may proceed, including providing for stay, transfer, consolidation, or termination of any such proceeding.

“(b) STAYS.—The Director may stay a post-grant review proceeding if a pending civil action for infringement of a patent addresses the same or substantially the same questions of patentability raised against the patent in a petition for the post-grant review proceeding.

“(c) EFFECT OF COMMENCEMENT OF PROCEEDING.—The commencement of a post-grant review proceeding—

“(1) shall not limit in any way the right of the patent owner to commence an action for infringement of the patent; and

“(2) shall not be cited as evidence relating to the validity of any claim of the patent in any proceeding before a court or the International Trade Commission concerning the patent.

**“§ 334. Effect of decisions rendered in civil action on post-grant review proceedings**

“If a final decision is entered against a party in a civil action arising in whole or in part under section 1338 of title 28 establishing that the party has not sustained its burden of proving the invalidity of any patent claim—

“(1) that party to the civil action and the privies of that party may not thereafter request a post-grant review proceeding on that patent claim on the basis of any grounds, under the provisions of section 321, which that party or the privies of that party raised or could have raised; and

“(2) the Director may not thereafter maintain a post-grant review proceeding that was requested, before the final decision was so entered, by that party or the privies of that party on the basis of such grounds.

**“§ 335. Effect of final decision on future proceedings**

“If a final decision under section 330 is favorable to the patentability of any original or new claim of the patent challenged by the cancellation petitioner, the cancellation petitioner may not thereafter, based on any ground that the cancellation petitioner raised during the post-grant review proceeding—

“(1) request or pursue a reexamination of such claim under chapter 31;

“(2) request or pursue a derivation proceeding with respect to such claim;

“(3) request or pursue a post-grant review proceeding under this chapter with respect to such claim;

“(4) assert the invalidity of any such claim in any civil action arising in whole or in part under section 1338 of title 28; or

“(5) assert the invalidity of any such claim in defense to an action brought under section 337 of the Tariff Act of 1930 (19 U.S.C. 1337).

#### “§ 336. Appeal

“A party dissatisfied with the final determination of the Patent Trial and Appeal Board in a post-grant proceeding under this chapter may appeal the determination under sections 141 through 144. Any party to the post-grant proceeding shall have the right to be a party to the appeal.”

(i) CONFORMING AMENDMENT.—The table of chapters for part III of title 35, United States Code, is amended by adding at the end the following:

#### “32. Post-Grant Review Proceedings .. 321”.

(j) REPEAL.—Section 4607 of the Intellectual Property and Communications Omnibus Reform Act of 1999, as enacted by section 1000(a)(9) of Public Law 106–113, is repealed.

#### (k) EFFECTIVE DATES.—

(1) IN GENERAL.—The amendments and repeal made by this section shall take effect at the end of the 1-year period beginning on the date of the enactment of this Act.

(2) APPLICABILITY TO EX PARTE AND INTER PARTES PROCEEDINGS.—Notwithstanding any other provision of law, sections 301 and 311 through 318 of title 35, United States Code, as amended by this section, shall apply to any patent that issues before, on, or after the effective date under paragraph (1) from an original application filed on any date.

(3) APPLICABILITY TO POST-GRANT PROCEEDINGS.—The amendments made by subsections (h) and (i) shall apply to patents issued on or after the effective date under paragraph (1).

(1) REGULATIONS.—The Under Secretary of Commerce for Intellectual Property and Director of the United States Patent and Trademark Office (in this subsection referred to as the “Director”) shall, not later than the date that is 1 year after the date of the enactment of this Act, issue regulations to carry out chapter 32 of title 35, United States Code, as added by subsection (h) of this section.

#### SEC. 6. DEFINITIONS; PATENT TRIAL AND APPEAL BOARD.

(a) DEFINITIONS.—Section 100 of title 35, United States Code, (as amended by section 2 of this Act) is further amended—

(1) in subsection (e), by striking “or inter partes reexamination under section 311”; and

(2) by adding at the end the following:

“(k) The term ‘cancellation petitioner’ means the real party in interest requesting cancellation of any claim of a patent under chapter 31 of this title and the privies of the real party in interest.”

(b) PATENT TRIAL AND APPEAL BOARD.—Section 6 of title 35, United States Code, is amended to read as follows:

#### “§ 6. Patent Trial and Appeal Board

“(a) ESTABLISHMENT AND COMPOSITION.—There shall be in the Office a Patent Trial and Appeal Board. The Director, the Deputy Director, the Commissioner for Patents, the Commissioner for Trademarks, and the administrative patent judges shall constitute the Patent Trial and Appeal Board. The administrative patent judges shall be persons of competent legal knowledge and scientific ability who are appointed by the Secretary of Commerce. Any reference in any Federal law, Executive order, rule, regulation, or delegation of authority, or any document or act pertaining to the Board of Patent Appeals and Interferences is deemed to refer to the Patent Trial and Appeal Board.

“(b) DUTIES.—The Patent Trial and Appeal Board shall—

“(1) on written appeal of an applicant, review adverse decisions of examiners upon application for patents;

“(2) on written appeal of a patent owner, review adverse decisions of examiners upon patents in reexamination proceedings under chapter 30;

“(3) conduct derivation proceedings under subsection 135(a); and

“(4) conduct post-grant opposition proceedings under chapter 32.

Each appeal and derivation proceeding shall be heard by at least 3 members of the Patent Trial and Appeal Board, who shall be designated by the Director. Only the Patent Trial and Appeal Board may grant rehearings. The Director shall assign each post-grant review proceeding to a panel of 3 administrative patent judges. Once assigned, each such panel of administrative patent judges shall have the responsibilities under chapter 32 in connection with post-grant review proceedings.”

#### SEC. 7. PREISSUANCE SUBMISSIONS BY THIRD PARTIES.

Section 122 of title 35, United States Code, is amended by adding at the end the following:

“(e) PREISSUANCE SUBMISSIONS BY THIRD PARTIES.—

“(1) IN GENERAL.—Any person may submit for consideration and inclusion in the record of a patent application, any patent, published patent application, or other publication of potential relevance to the examination of the application, if such submission is made in writing before the earlier of—

“(A) the date a notice of allowance under section 151 is mailed in the application for patent; or

“(B) either—

“(i) 6 months after the date on which the application for patent is published under section 122, or

“(ii) the date of the first rejection under section 132 of any claim by the examiner during the examination of the application for patent, whichever occurs later.

“(2) OTHER REQUIREMENTS.—Any submission under paragraph (1) shall—

“(A) set forth a concise description of the asserted relevance of each submitted document;

“(B) be accompanied by such fee as the Director may prescribe; and

“(C) include a statement by the person making such submission affirming that the submission was made in compliance with this section.”

#### SEC. 8. VENUE AND JURISDICTION.

(a) VENUE FOR PATENT CASES.—Section 1400 of title 28, United States Code, is amended by striking subsection (b) and inserting the following:

“(b) Notwithstanding section 1391 of this title, in any civil action arising under any Act of Congress relating to patents, a party shall not manufacture venue by assignment, incorporation, or otherwise to invoke the venue of a specific district court.

“(c) Notwithstanding section 1391 of this title, any civil action for patent infringement or any action for declaratory judgment may be brought only in a judicial district—

“(1) where the defendant has its principal place of business or in the location or place in which the defendant is incorporated or formed, or, for foreign corporations with a United States subsidiary, where the defendant’s primary United States subsidiary has its principal place of business or is incorporated or formed;

“(2) where the defendant has committed substantial acts of infringement and has a

regular and established physical facility that the defendant controls and that constitutes a substantial portion of the operations of the defendant;

“(3) where the primary plaintiff resides, if the primary plaintiff in the action is—

“(A) an institution of higher education as defined under section 101(a) of the Higher Education Act of 1965 (20 U.S.C. 1001(a)); or

“(B) a nonprofit organization that—

“(i) qualifies for treatment under section 501(c)(3) of the Internal Revenue Code (26 U.S.C. 501(c)(3));

“(ii) is exempt from taxation under section 501(a) of such Code; and

“(iii) serves as the patent and licensing organization for an institution of higher education as defined under section 101(a) of the Higher Education Act of 1965 (20 U.S.C. 1001(a)); or

“(4) where the plaintiff resides, if the sole plaintiff in the action is an individual inventor who is a natural person and who qualifies at the time such action is filed as a micro-entity pursuant to section 123 of title 35.

“(d) If a plaintiff brings a civil action for patent infringement or declaratory judgment relief under subsection (c), then the defendant may request the district court to transfer that action to another district or division where, in the court’s determination—

“(1) any of the parties has substantial evidence or witnesses that otherwise would present considerable evidentiary burdens to the defendant if such transfer were not granted;

“(2) such transfer would not cause undue hardship to the plaintiff; and

“(3) venue would be otherwise appropriate under section 1391 of this title.”

(b) INTERLOCUTORY APPEALS.—Subsection (c)(2) of section 1292 of title 28, United States Code, is amended by adding at the end the following:

“(3) of an appeal from an interlocutory order or decree determining construction of claims in a civil action for patent infringement under section 271 of title 35.

Application for an appeal under paragraph (3) shall be made to the court within 10 days after entry of the order or decree. The district court shall have discretion whether to approve the application and, if so, whether to stay proceedings in the district court during the pendency of such appeal.”

(c) TECHNICAL AMENDMENTS RELATING TO VENUE.—Sections 32, 145, 146, 154(b)(4)(A), and 293 of title 35, United States Code, and section 21(b)(4) of the Act entitled “An Act to provide for the registration and protection of trademarks used in commerce, to carry out the provisions of certain international conventions, and for other purposes”, approved July 5, 1946 (commonly referred to as the “Trademark Act of 1946” or the “Lanham Act”); 15 U.S.C. 1071(b)(4), are each amended by striking “United States District Court for the District of Columbia” each place that term appears and inserting “United States District Court for the Eastern District of Virginia”.

#### SEC. 9. PATENT AND TRADEMARK OFFICE REGULATORY AUTHORITY.

##### (a) FEE SETTING.—

(1) IN GENERAL.—The Director shall have authority to set or adjust by rule any fee established or charged by the Office under sections 41 and 376 of title 35, United States Code or under section 31 of the Trademark Act of 1946 (15 U.S.C. 1113) for the filing or processing of any submission to, and for all other services performed by or materials furnished by, the Office, provided that such fee amounts are set to reasonably compensate the Office for the services performed.

(2) REDUCTION OF FEES IN CERTAIN FISCAL YEARS.—In any fiscal year, the Director—

(A) shall consult with the Patent Public Advisory Committee and the Trademark Public Advisory Committee on the advisability of reducing any fees described in paragraph (1); and

(B) after that consultation may reduce such fees.

(3) **ROLE OF THE PUBLIC ADVISORY COMMITTEE.**—The Director shall—

(A) submit to the Patent or Trademark Public Advisory Committee, or both, as appropriate, any proposed fee under paragraph (1) not less than 45 days before publishing any proposed fee in the Federal Register;

(B) provide the relevant advisory committee described in subparagraph (A) a 30-day period following the submission of any proposed fee, on which to deliberate, consider, and comment on such proposal, and require that—

(i) during such 30-day period, the relevant advisory committee hold a public hearing related to such proposal; and

(ii) the Director shall assist the relevant advisory committee in carrying out such public hearing, including by offering the use of Office resources to notify and promote the hearing to the public and interested stakeholders;

(C) require the relevant advisory committee to make available to the public a written report detailing the comments, advice, and recommendations of the committee regarding any proposed fee;

(D) consider and analyze any comments, advice, or recommendations received from the relevant advisory committee before setting or adjusting any fee; and

(E) notify, through the Chair and Ranking Member of the Senate and House Judiciary Committees, the Congress of any final decision regarding proposed fees.

(4) **PUBLICATION IN THE FEDERAL REGISTER.**—

(A) **IN GENERAL.**—Any rules prescribed under this subsection shall be published in the Federal Register.

(B) **RATIONALE.**—Any proposal for a change in fees under this section shall—

(i) be published in the Federal Register; and

(ii) include, in such publication, the specific rationale and purpose for the proposal, including the possible expectations or benefits resulting from the proposed change.

(C) **PUBLIC COMMENT PERIOD.**—Following the publication of any proposed fee in the Federal Register pursuant to subparagraph (A), the Director shall seek public comment for a period of not less than 45 days.

(5) **CONGRESSIONAL COMMENT PERIOD.**—Following the notification described in paragraph (3)(E), Congress shall have not more than 45 days to consider and comment on any proposed fee under paragraph (1). No proposed fee shall be effective prior to the end of such 45-day comment period.

(6) **RULE OF CONSTRUCTION.**—No rules prescribed under this subsection may diminish—

(A) an applicant's rights under this title or the Trademark Act of 1946; or

(B) any rights under a ratified treaty.

(b) **FEES FOR PATENT SERVICES.**—Division B of Public Law 108-447 is amended in title VIII of the Departments of Commerce, Justice and State, the Judiciary and Related Agencies Appropriations Act, 2005, in section 801(a) by striking “During fiscal years 2005, 2006 and 2007”, and inserting “Until such time as the Director sets or adjusts the fees otherwise.”.

(c) **ADJUSTMENT OF TRADEMARK FEES.**—Division B of Public Law 108-447 is amended in title VIII of the Departments of Commerce, Justice and State, the Judiciary and Related Agencies Appropriations Act, 2005, in section 802(a) by striking “During fiscal years 2005, 2006 and 2007”, and inserting “Until such

time as the Director sets or adjusts the fees otherwise.”.

(d) **EFFECTIVE DATE, APPLICABILITY, AND TRANSITIONAL PROVISION.**—Division B of Public Law 108-447 is amended in title VIII of the Departments of Commerce, Justice and State, the Judiciary and Related Agencies Appropriations Act, 2005, in section 803(a) by striking “and shall apply only with respect to the remaining portion of fiscal year 2005, 2006 and 2007.”.

(e) **RULE OF CONSTRUCTION.**—Nothing in this section shall be construed to affect any other provision of Division B of Public Law 108-447, including section 801(c) of title VII of the Departments of Commerce, Justice and State, the Judiciary and Related Agencies Appropriations Act, 2005.

(f) **DEFINITIONS.**—In this section:

(1) **DIRECTOR.**—The term “Director” means the Director of the United States Patent and Trademark Office.

(2) **OFFICE.**—The term “Office” means the United States Patent and Trademark Office.

(3) **TRADEMARK ACT OF 1946.**—The term “Trademark Act of 1946” means an Act entitled “Act to provide for the registration and protection of trademarks used in commerce, to carry out the provisions of certain international conventions, and for other purposes”, approved July 5, 1946 (15 U.S.C. 1051 et seq.) (commonly referred to as the Trademark Act of 1946 or the Lanham Act).

#### **SEC. 10. RESIDENCY OF FEDERAL CIRCUIT JUDGES.**

(a) **RESIDENCY.**—The second sentence of section 44(c) of title 28, United States Code, is repealed.

(b) **FACILITIES.**—Section 44 of title 28, United States Code, is amended by adding at the end the following:

“(e)(1) The Director of the Administrative Office of the United States Courts shall provide—

“(A) a judge of the Federal judicial circuit who lives within 50 miles of the District of Columbia with appropriate facilities and administrative support services in the District of the District of Columbia; and

“(B) a judge of the Federal judicial circuit who does not live within 50 miles of the District of Columbia with appropriate facilities and administrative support services—

“(i) in the district and division in which that judge resides; or

“(ii) if appropriate facilities are not available in the district and division in which that judge resides, in the district and division closest to the residence of that judge in which such facilities are available, as determined by the Director.

“(2) Nothing in this subsection may be construed to authorize or require the construction of new facilities.”.

#### **SEC. 11. MICRO-ENTITY DEFINED.**

Chapter 11 of title 35, United States Code, is amended by adding at the end the following new section:

##### **“§ 123. Micro-entity defined**

“(a) **IN GENERAL.**—For purposes of this title, the term ‘micro-entity’ means an applicant who makes a certification under either subsections (b) or (c).

“(b) **UNASSIGNED APPLICATION.**—For an unassigned application, each applicant shall certify that the applicant—

“(1) qualifies as a small entity, as defined in regulations issued by the Director;

“(2) has not been named on 5 or more previously filed patent applications;

“(3) has not assigned, granted, or conveyed, and is not under an obligation by contract or law to assign, grant, or convey, a license or any other ownership interest in the particular application; and

“(4) does not have a gross income, as defined in section 61(a) of the Internal Revenue

Code (26 U.S.C. 61(a)), exceeding 2.5 times the average gross income, as reported by the Department of Labor, in the calendar year immediately preceding the calendar year in which the examination fee is being paid.

“(c) **ASSIGNED APPLICATION.**—For an assigned application, each applicant shall certify that the applicant—

“(1) qualifies as a small entity, as defined in regulations issued by the Director, and meets the requirements of subsection (b)(4);

“(2) has not been named on 5 or more previously filed patent applications; and

“(3) has assigned, granted, conveyed, or is under an obligation by contract or law to assign, grant, or convey, a license or other ownership interest in the particular application to an entity that has 5 or fewer employees and that such entity has a gross income, as defined in section 61(a) of the Internal Revenue Code (26 U.S.C. 61(a)), that does not exceed 2.5 times the average gross income, as reported by the Department of Labor, in the calendar year immediately preceding the calendar year in which the examination fee is being paid.

“(d) **INCOME LEVEL ADJUSTMENT.**—The gross income levels established under subsections (b) and (c) shall be adjusted by the Director on October 1, 2009, and every year thereafter, to reflect any fluctuations occurring during the previous 12 months in the Consumer Price Index, as determined by the Secretary of Labor.”.

#### **SEC. 12. TECHNICAL AMENDMENTS.**

(a) **JOINT INVENTIONS.**—Section 116 of title 35, United States Code, is amended—

(1) in the first paragraph, by striking “When” and inserting “(a) JOINT INVENTIONS.—When”;

(2) in the second paragraph, by striking “If a joint inventor” and inserting “(b) OMITTED INVENTOR.—If a joint inventor”;

(3) in the third paragraph, by striking “Whenever” and inserting “(c) CORRECTION OF ERRORS IN APPLICATION.—Whenever”.

(b) **FILING OF APPLICATION IN FOREIGN COUNTRY.**—Section 184 of title 35, United States Code, is amended—

(1) in the first paragraph, by striking “Except when” and inserting “(a) FILING IN FOREIGN COUNTRY.—Except when”;

(2) in the second paragraph, by striking “The term” and inserting “(b) APPLICATION.—The term”;

(3) in the third paragraph, by striking “The scope” and inserting “(c) SUBSEQUENT MODIFICATIONS, AMENDMENTS, AND SUPPLEMENTS.—The scope”.

(c) **REISSUE OF DEFECTIVE PATENTS.**—Section 251 of title 35, United States Code, is amended—

(1) in the first paragraph, by striking “Whenever” and inserting “(a) IN GENERAL.—Whenever”;

(2) in the second paragraph, by striking “The Director” and inserting “(b) MULTIPLE REISSUED PATENTS.—The Director”;

(3) in the third paragraph, by striking “The provision” and inserting “(c) APPLICABILITY OF THIS TITLE.—The provisions”;

(4) in the last paragraph, by striking “No reissued patent” and inserting “(d) REISSUE PATENT ENLARGING SCOPE OF CLAIMS.—No reissued patent”.

(d) **EFFECT OF REISSUE.**—Section 253 of title 35, United States Code, is amended—

(1) in the first paragraph, by striking “Whenever” and inserting “(a) IN GENERAL.—Whenever”;

(2) in the second paragraph, by striking “in like manner” and inserting “(b) ADDITIONAL DISCLAIMER OR DEDICATION.—In the manner set forth in subsection (a).”.

(e) **CORRECTION OF NAMED INVENTOR.**—Section 256 of title 35, United States Code, is amended—

(1) in the first paragraph, by striking “Whenever” and inserting “(a) CORRECTION.—Whenever”; and

(2) in the second paragraph, by striking “The error” and inserting “(b) PATENT VALID IF ERROR CORRECTED.—The error”.

(f) PRESUMPTION OF VALIDITY.—Section 282 of title 35, United States Code, is amended—

(1) in the first undesignated paragraph, by striking “A patent” and inserting “(a) IN GENERAL.—A patent”;

(2) in the second undesignated paragraph, by striking “The following” and inserting “(b) DEFENSES.—The following”; and

(3) in the third undesignated paragraph, by striking “In actions” and inserting “(c) NOTICE OF ACTIONS; ACTIONS DURING EXTENSION OF PATENT TERM.—In actions”.

**SEC. 13. EFFECTIVE DATE; RULE OF CONSTRUCTION.**

(a) EFFECTIVE DATE.—Except as otherwise provided in this Act, the provisions of this Act shall take effect 12 months after the date of the enactment of this Act and shall apply to any patent issued on or after that effective date.

(b) CONTINUITY OF INTENT UNDER THE CREATE ACT.—The enactment of section 102(b)(3) of title 35, United States Code, under section (2)(b) of this Act is done with the same intent to promote joint research activities that was expressed, including in the legislative history, through the enactment of the Cooperative Research and Technology Enhancement Act of 2004 (Public Law 108-453; the “CREATE Act”), the amendments of which are stricken by section 2(c) of this Act. The United States Patent and Trademark Office shall administer section 102(b)(3) of title 35, United States Code, in a manner consistent with the legislative history of the CREATE Act that was relevant to its administration by the United States Patent and Trademark Office.

**SEC. 14. SEVERABILITY.**

If any provision of this Act or of any amendment or repeal made by this Act, or the application of such a provision to any person or circumstance, is held to be invalid or unenforceable, the remainder of this Act and the amendments and repeals made by this Act, and the application of this Act and such amendments and repeals to any other person or circumstance, shall not be affected by such holding.

Mr. HATCH. Mr. President, I rise to introduce with Senate Judiciary Committee chairman PATRICK LEAHY the Patent Reform Act of 2009, S. 515. I consider introduction of this bill to be a milestone in the progress we have made so far in the effort to reform our patent system—a system that has not been updated significantly since 1952. There is no doubt we have come a long way in our pursuit to accomplish comprehensive patent law reform. Reform is so vitally necessary to keep our nation competitive in our technologically advanced global economy, especially during these difficult economic times.

I have always believed that passing patent reform legislation would be a multi-Congress endeavor. The Hatch-Leahy patent bill, S. 3818, formally started the legislative process in 2006. We continued the momentum in the 110th Congress by introducing S. 1145, the Patent Reform Act of 2007. In June 2007, my colleagues and I on the Senate Judiciary Committee approved S. 1145 by a vote of 13-5. While I would have liked to see S. 1145 pass the full Senate, I believe the process already provided

makes passage of the Patent Reform Act of 2009 even more likely this Congress.

S. 515 represents a bipartisan and bicameral commitment to streamline our nation’s patent system that will improve patent quality and limit unnecessary and counterproductive litigation costs.

House Judiciary chairman JOHN CONYERS and ranking minority member LAMAR SMITH are true partners in this important legislation. For those who might say nothing has changed, I can attest that it has. Just look at the bill. We have listened to many of the concerns raised by stakeholders and have changed the legislative text accordingly.

Let me highlight some of the significant changes we have made to the bill.

For example, S. 515 does not contain an applicant quality submissions provision due to near uniform opposition we heard from the patent community about the burdens this would place on applicants.

Additionally, the Patent Reform Act of 2007 would have eliminated the current opt-out provision for publication of patent applications. Current law permits applicants to request upon filing that their application not be published at 18 months if a certification is made that the invention disclosed in the application has not and will not be the subject of an application filed in another country. Because of serious concerns raised by independent inventors and small entities, we have removed this provision from S. 515.

Patents may be challenged either in court or at the U.S. Patent and Trademark Office, USPTO. The current administrative review process at the USPTO is widely viewed as ineffective and inefficient. Accordingly, last year’s bills proposed a process more like a court proceeding than the current reexamination process. Both bills had a 1-year window for challenges during which patents would not be presumed valid, and a patent could be invalidated by a “preponderance of evidence” against it. However, the Senate bill, S. 1145, added a second window during the life of the patent where only “clear and convincing” evidence could invalidate the patent. Most in the patent community prefer the post-grant review language as passed in the House because, instead of creating a “second window,” it improved upon the existing inter partes reexamination. As such, S. 515 adopts the House approach to expanding inter partes, but includes “public use or sale in the United States” as a basis for challenging a patent. Further, our bill ensures that ex parte reexamination proceedings are maintained, which is an important tool for challenging patents that should not have issued.

With patent litigation costs escalating, the threat of enhanced damages can be quite substantial. For this reason, the Senate and House bills introduced in the 110th Congress narrowed

the circumstances under which treble damages could be awarded for willful infringement of a patent. After introduction of the Patent Reform Act of 2007, the Federal Circuit issued an in banc decision, *In re Seagate*, which instituted an objective recklessness standard to prove willfulness. After considerable discussion with stakeholders in the patent community, we believe the *Seagate* decision is a positive improvement to the law and, therefore, have sought to incorporate correlating language into S. 515.

There are other changes we made to the Patent Reform Act of 2009, but I want to focus my remaining remarks on two key issues: how damages are awarded in infringement lawsuits and inequitable conduct reform.

I am aware of the concerns that some have raised about the damages provision contained in S. 1145. I have heard from some who are concerned that courts have allowed damages for infringement to be based on the market for an entire product, when all that was infringed is a minor component of the product. I have also heard from some who argue that the current language will severely limit the amount of damages an infringer has to pay, thereby encouraging infringing behavior.

The sponsors of the Patent Reform Act of 2009 all agree that we need to improve the damages provision. In crafting a fair damages provision, we can rely upon well-reasoned and persuasive case law, scholarship, and other texts. I am confident that we will achieve consensus language in this area, but make no mistake: it will take willing partners to craft a compromise that will not have deleterious effects on any one sector of our economy.

For years I have been arguing if we are serious about enacting comprehensive patent law reform then we must take steps to ensure that the inequitable conduct doctrine is applied in a manner consistent with its original purpose: to sanction true misconduct and to do so in a proportional and fair manner. Inequitable conduct reform is core to this bill, as it dictates how patents are prosecuted years before litigation. The inequitable conduct defense is frequently pled, rarely proven, and always drives up the cost of litigation tremendously.

Under current law, any perceived transgression of the patent owner is being painted as “fraud.” If an inequitable conduct claim wins, a valid patent will be held entirely void, and the infringer walks away without any liability. There is virtually no downside for the infringer to raise this type of attack. This is why inequitable conduct challenges are raised in nearly every patent case. It has become, in the words of the Federal Circuit, a “plague” on the patent system.

The development of a more objective and clearer inequitable conduct standard will remove the uncertainty and confusion that defines current patent litigation. We cannot settle for mere

codification of current practices. Chairman LEAHY and Chairman CONYERS both know of my strong interest in this area and have agreed to incorporate changes to the law. There is no doubt that inequitable conduct reform has the potential to single-handedly revolutionize the manner in which patent applications are prosecuted. Arguably, reform in this area will have the most favorable impact on patent quality and the ability for the USPTO to reduce its pendency—thereby fostering a strong and vibrant environment for all innovation and entrepreneurship.

Now more than ever, our industries need reassurance and predictability in order to move forward in these challenging times. I believe the Patent Reform Act of 2009 has the potential to complement all of the stimulatory efforts currently under way. Now is the time to act.

By Mr. DODD:

S. 517. A bill for the relief of Alejandro Gomez and Juan Sebastian Gomez; to the Committee on the Judiciary.

Mr. DODD. Mr. President, today I send to the desk a private relief bill to provide permanent resident status to Juan and Alejandro Gomez, and ask that it be appropriately referred.

Juan, 20, and Alejandro, 21, are natives of Colombia who came to the U.S. with their parents in August 1990 on B-2 visitors visas and reside in Miami, FL. Their parents were deported on October 30, 2007. Their initial departure date was September 14, 2007, but because of legislation introduced last Congress that date was extended. However, now they have been ordered to report for deportation on March 15, 2009. Juan and Alejandro have lived continuously in the U.S. for the last 18 years. They have both graduated from Miami Killian High School. Juan is a student at Georgetown University in Washington, D.C. Alejandro is a student at Miami Dade Community College and works at the Biltmore Hotel in Miami. They have the strong support of their community. It would be an extreme hardship to uproot Juan and Alejandro from their community, which has wholeheartedly embraced them, to send them back to Colombia where there lives could be in serious danger.

We all know that the circumstances of Juan and Alejandro are not unique. Just like many other children here illegally, they had no control over their parents' decision to overstay their visas a number of years ago. Most of these young people work hard to complete school and contribute to their communities. Cases like Juan's and Alejandro's are the reason why the so called DREAM Act was attached to the comprehensive immigration reform legislation that the Senate attempted to pass last Congress, only to face a filibuster from opponents of any comprehensive immigration reform proposal.

The DREAM Act has broad partisan support and is not the reason that the

immigration bill stalled in the Senate. I would hope that consideration could be given to delinking the DREAM Act from the larger bill so that we can put in place a legal framework for dealing with young people similar in circumstances to Juan and Alejandro who are caught in this unfortunate immigration status. But that is not likely to happen soon enough to address the problems confronting Juan and Alejandro.

That is why I have decided to re-introduce a private bill on their behalf. I will also be writing to Senator CHARLES SCHUMER, Chairman of the Subcommittee on Immigration to request, pursuant to the Subcommittee's Rules of Procedure, that the Subcommittee formally request an expedited departmental report from the Bureau of Citizenship and Immigration Services regarding the Gomez brothers so that the Subcommittee can then move forward to give consideration to this bill as soon as possible.

I have had the opportunity to meet Juan and Alejandro. They believe that America is their home. They love our country and want to have an opportunity to fulfill their dreams of becoming full participants in this country. Passage of the private bill would give them that opportunity. I look forward to working with the Subcommittee to facilitate its passage.

By Mr. DURBIN:

S. 520. A bill to designate the United States Courthouse under construction at 327 South Church Street, Rockford, Illinois, as the "Stanley J. Roszkowski United States Courthouse"; considered and passed.

Mr. DURBIN. Mr. President, I ask unanimous consent that the text of the bill be printed in the RECORD.

There being no objection, the text of the bill was ordered to be placed in the RECORD, as follows:

S. 520

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

**SECTION 1. STANLEY J. ROSZKOWSKI UNITED STATES COURTHOUSE.**

(a) DESIGNATION.—The United States courthouse under construction, as of the date of enactment of this Act, at 327 South Church Street, Rockford, Illinois, shall be known and designated as the "Stanley J. Roszkowski United States Courthouse".

(b) REFERENCES.—Any reference in a law, map, regulation, document, paper, or other record of the United States to the United States courthouse referred to in subsection (a) shall be deemed to be a reference to the "Stanley J. Roszkowski United States Courthouse".

SUBMITTED RESOLUTIONS

SENATE RESOLUTION 62—A BILL ESTABLISHING A SELECT COMMITTEE OF THE SENATE TO MAKE A THOROUGH AND COMPLETE STUDY AND INVESTIGATION OF THE FACTS AND CIRCUMSTANCES GIVING RISE TO THE ECONOMIC CRISIS FACING THE UNITED STATES AND TO MAKE RECOMMENDATIONS TO PREVENT A FUTURE RECURRENCE OF SUCH A CRISIS

Mr. DORGAN (for himself and Mr. MCCAIN) submitted the following resolution; which was referred to the Committee on Rules and Administration:

S. RES. 62

Whereas the United States is currently facing an unprecedented economic crisis, with massive losses of jobs in the United States and an alarming contraction of economic activity in the United States;

Whereas the United States Government has pledged, committed, or loaned more than \$9,000,000,000,000 as of February 2009 in an attempt to mitigate and resolve the economic crisis and trillions of dollars more may well be necessary before the crisis is over;

Whereas the economic crisis reaches into, and has impacted, almost every aspect of the United States economy and significant parts of the international economy;

Whereas any thorough and complete study and investigation of this complex and far-reaching economic crisis will require sustained and singular focus for many months;

Whereas a study and investigation of this size and scope implicates the jurisdiction of several Standing Committees of the Senate and, if it is to be done correctly and timely, will require a degree of undivided attention and resources beyond the capacity of the Standing Committees of the Senate, which are already over-burdened;

Whereas adding such a significant study and investigation to the duties of the existing Standing Committees of the Senate would make it difficult for such committees to get their regular required work accomplished, particularly when so much attention and so many resources are appropriately devoted to responding to the ongoing economic crisis;

Whereas dozens of important investigations have been conducted with the creation of a select committee of the Senate for a specific purpose and a set time; and

Whereas the American public has a right to get straight answers on how this economic crisis developed and what steps should be taken to make sure that nothing like it happens again: Now therefore be it

*Resolved,*

**SECTION 1. SELECT COMMITTEE ON INVESTIGATION OF THE ECONOMIC CRISIS.**

There is established a select committee of the Senate to be known as the Select Committee on Investigation of the Economic Crisis (hereafter in this resolution referred to as the "Select Committee").

**SEC. 2. PURPOSE AND DUTIES.**

(a) PURPOSE.—The purpose of the Select Committee is to study and investigate the facts and circumstances giving rise to the current economic crisis facing the United States and to recommend actions to be taken to prevent a future recurrence of such a crisis.

(b) DUTIES.—The Select Committee is authorized and directed to do everything necessary or appropriate to conduct the study