their home or their place of residence. It also protects newborns who are still in the maternity ward.

Grace Preston, who is the international sales manager for Secure Care, told us that the company has significantly expanded its growth by selling overseas. Grace also told us that Secure Care could not have done that without Federal and State export programs working together. In New Hampshire, we are very fortunate because our State and Federal export services work seamlessly, and that has been important in helping our businesses grow their exports.

In 2010 New Hampshire's exports grew about 40 percent. That was almost twice the national average and the most of any State in the country. So it has been very critical to our small businesses.

But we also heard that State and Federal agencies don't always have that same collaborative relationship in other places across the country. According to our former New Hampshire trade director, Dawn Wivell, these services sometimes, in some places, can overlap or, even worse, sometimes there are agencies that refuse to work together. Our bill attempts to require better coordination to make more successes like Secure Care a reality across the country.

Our bill also encourages the Federal Government to do more to promote the opportunity of exporting and to get the word out about Federal export programs.

Foreign markets can be daunting for small businesses, but that should not stop our innovators from trying to compete. Our small businesses must be assured that the Federal Government will help them when considering exporting. Part of our responsibility is to try to do everything we can to put into place policies that help small businesses when they want to try to export.

I thank Senator AYOTTE for her cooperation and for the work we have done together. I thank both Senator AYOTTE and her staff, along with mine, for working on this issue. I look forward to advancing this legislation in the Senate and to continue to recognize the important role that small business plays in our economy.

Ms. AYOTTE. Mr. President, I am pleased today to join my colleague from New Hampshire, Senator SHAHEEN, in introducing the Small Business Export Growth Act, which would help small businesses better navigate the complex process of promoting and selling their goods abroad.

Senator SHAHEEN and I serve together on the Small Business Committee, and as she mentioned, we held a field hearing in Manchester, New Hampshire, last August to examine the role of exports in small business growth and job creation. We heard testimony from key national and New Hampshire-based stakeholders about ways to improve coordination among regulatory agencies, and how to ease the burdens faced by small business owners seeking to grow and export their products to foreign markets. The Small Business Export Growth Act represents a commonsense, bipartisan response to the issues identified at that hearing.

This legislation makes improvements to the operational efficiency of the Trade Promotion Coordinating Committee, TPCC, and improves Congressional oversight of the TPCC's activities. The bill also gives the Small Business Administration a larger voice in developing export policy and facilitates more networking opportunities for small businesses.

New Hampshire companies export to 160 countries and our exports are increasing at the fourth highest rate of any State. In fact, New Hampshire is leading the ten northeastern states in exports. Since 2003, New Hampshire exports have risen three times faster than the State's economy. Small businesses comprise over 96 percent of all New Hampshire firms, and it is imperative that we empower them with the tools they need to grow and hire. Opening markets around the world for our small businesses is an area in which we can find bipartisan agreement.

During the Manchester Small Business Week Forum I attended yesterday, I heard first-hand about the challenges small business owners are facing as they try to grow and create jobs in this tough economic climate. Exporting represents an enormous opportunity, not only for New Hampshire small businesses, but for small businesses across the country. The Small Business Export Growth Act will help smaller firms to compete in the global marketplace.

AMENDMENTS SUBMITTED AND PROPOSED

SA 2127. Mr. DURBIN (for himself and Mr. BLUMENTHAL) submitted an amendment intended to be proposed by him to the bill S. 3187, to amend the Federal Food, Drug, and Cosmetic Act to revise and extend the user-fee programs for prescription drugs and medical devices, to establish user-fee programs for generic drugs and biosimilars, and for other purposes; which was ordered to lie on the table.

SA 2128. Mrs. GILLIBRAND (for herself and Mr. BLUMENTHAL) submitted an amendment intended to be proposed by her to the bill S. 3187, supra; which was ordered to lie on the table.

SA 2129. Mr. GRASSLEY submitted an amendment intended to be proposed by him to the bill S. 3187, supra; which was ordered to lie on the table.

SA 2130. Mr. BURR (for himself and Mr. COBURN) submitted an amendment intended to be proposed by him to the bill S. 3187, supra; which was ordered to lie on the table.

SA 2131. Mr. COBURN (for himself and Mr. BURR) submitted an amendment intended to be proposed by him to the bill S. 3187, supra; which was ordered to lie on the table.

SA 2132. Mr. COBURN (for himself and Mr. BURR) submitted an amendment intended to be proposed by him to the bill S. 3187, supra; which was ordered to lie on the table.

SA 2133. Mr. DEMINT (for himself and Mr. VITTER) submitted an amendment intended to be proposed by him to the bill S. 3187, supra; which was ordered to lie on the table.

SA 2134. Mr. BLUMENTHAL submitted an amendment intended to be proposed by him to the bill S. 3187, supra; which was ordered to lie on the table.

SA 2135. Mr. BLUMENTHAL submitted an amendment intended to be proposed by him to the bill S. 3187, supra; which was ordered to lie on the table.

SA 2136. Mr. BLUMENTHAL (for himself, Mr. FRANKEN, Mr. SCHUMER, Mr. CARDIN, and Ms. KLOBUCHAR) submitted an amendment intended to be proposed by him to the bill S. 3187, supra; which was ordered to lie on the table.

SA 2137. Mr. ROCKEFELLER submitted an amendment intended to be proposed by him to the bill S. 3187, supra; which was ordered to lie on the table.

SA 2138. Mr. VITTER submitted an amendment intended to be proposed by him to the bill S. 3187, supra; which was ordered to lie on the table.

SA 2139. Mr. SCHUMER submitted an amendment intended to be proposed by him to the bill S. 3187, supra; which was ordered to lie on the table.

SA 2140. Mr. SCHUMER (for himself, Mr. MERKLEY, and Mr. BLUMENTHAL) submitted an amendment intended to be proposed by him to the bill S. 3187, supra; which was ordered to lie on the table.

SA 2141. Mr. CARDIN (for himself and Ms. LANDRIEU) submitted an amendment intended to be proposed by him to the bill S. 3187, supra; which was ordered to lie on the table.

SA 2142. Mr. LEAHY submitted an amendment intended to be proposed by him to the bill S. 3187, supra; which was ordered to lie on the table.

SA 2143. Mr. PAUL submitted an amendment intended to be proposed by him to the bill S. 3187, supra; which was ordered to lie on the table.

SA 2144. Mr. HATCH (for himself, Mr. BURR, Mr. ALEXANDER, and Mr. ROBERTS) submitted an amendment intended to be proposed by him to the bill S. 3187, supra; which was ordered to lie on the table.

SA 2145. Mr. PORTMAN submitted an amendment intended to be proposed by him to the bill S. 3187, supra; which was ordered to lie on the table.

SA 2146. Mr. PORTMAN submitted an amendment intended to be proposed by him to the bill S. 3187, supra; which was ordered to lie on the table.

SA 2147. Mr. HATCH (for himself, Mr. BROWN of Massachusetts, Mr. BURR, Mr. COBURN, Mr. CORNYN, Mr. LUGAR, Mr. ROBERTS, Mr. HOEVEN, Mrs. HUTCHISON, Mr. LEE, Mr. WICKER, Mr. COATS, Mr. BARRASSO, Mr. TOOMEY, Mr. MORAN, Ms. COLLINS, Mr. INHOFE, Mr. BLUNT, Mr. PORTMAN, Mr. ALEXANDER, Ms. AYOTTE, and Mr. CRAPO) submitted an amendment intended to be proposed by him to the bill S. 3187, supra; which was ordered to lie on the table.

SA 2148. Mr. KOHL (for himself, Mr. GRASSLEY, Ms. KLOBUCHAR, Mr. FRANKEN, Mr. JOHNSON of South Dakota, Mr. BROWN of Ohio, Mr. BINGAMAN, and Mr. SANDERS) submitted an amendment intended to be proposed by him to the bill S. 3187, supra; which was ordered to lie on the table.

SA 2149. Mr. KOHL (for himself, Mr. GRASSLEY, and Mr. BLUMENTHAL) submitted an amendment intended to be proposed by him to the bill S. 3187, supra; which was ordered to lie on the table.

TEXT OF AMENDMENTS

SA 2127. Mr. DURBIN (for himself and Mr. BLUMENTHAL) submitted an

amendment intended to be proposed by him to the bill S. 3187, to amend the Federal Food, Drug, and Cosmetic Act to revise and extend the user-fee programs for prescription drugs and medical devices, to establish user-fee programs for generic drugs and biosimilars, and for other purposes; which was ordered to lie on the table; as follows:

At the end of title XI, add the following:

SEC. 11___. REGISTRATION OF FACILITIES WITH RESPECT TO DIETARY SUPPLEMENTS.

(a) IN GENERAL.—Section 415(a) (21 U.S.C. 350d(a)) is amended by adding at the end the following:

''(6) REQUIREMENTS WITH RESPECT TO DIETARY SUPPLEMENTS.—

''(A) IN GENERAL.—A facility engaged in the manufacturing processing, packing, or holding of dietary supplements that is required to register under this section shall comply with the requirements of this paragraph, in addition to the other requirements of this section.

''(B) ADDITIONAL INFORMATION.—A facility described in subparagraph (A) shall submit a registration under paragraph (1) that includes, in addition to the information required under paragraph (2)—

''(i) a description of each dietary supplement product manufactured by such facility;

''(ii) a list of all ingredients in each such dietary supplement product; and

''(iii) a copy of the label and labeling for each such product.

''(C) REGISTRATION WITH RESPECT TO NEW, REFORMULATED, AND DISCONTINUED DIETARY SUPPLEMENT PRODUCTS.—

''(i) IN GENERAL.—Not later than the date described in clause (ii), if a facility described in subparagraph (A)—

''(I) manufactures a dietary supplement product that the facility previously did not manufacture and for which the facility did not submit the information required under clauses (i) through (iii) of subparagraph (B);

''(II) reformulates a dietary supplement product for which the facility previously submitted the information required under clauses (i) through (iii) of subparagraph (B); or

''(III) no longer manufactures a dietary supplement for which the facility previously submitted the information required under clauses (i) through (iii) of subparagraph (B), such facility shall submit to the Secretary an updated registration describing the change described in subclause (I), (II), or (III) and, in the case of a facility described in subclause (I) or (II), containing the information required under clauses (i) through (iii) of subparagraph (B).

''(ii) DATE DESCRIBED.—The date described in this clause is—

''(I) in the case of a facility described in subclause (I) of clause (i), 30 days after the date on which such facility first markets the dietary supplement product described in such subclause;

''(II) in the case of a facility described in subclause (II) of clause (i), 30 days after the date on which such facility first markets the reformulated dietary supplement product described in such subclause; or

''(III) in the case of a facility described in subclause (III) of clause (i), 30 days after the date on which such facility removes the dietary supplement product described in such subclause from the market.''.

(b) ENFORCEMENT.—Section 403 (21 U.S.C. 343) is amended by adding at the end the following:

''(z) If it is a dietary supplement for which a facility is required to submit the registration information required under section 415(a)(6) and such facility has not complied with the requirements of such section 415(a)(6) with respect to such dietary supplement.''.

SA 2128. Mrs. GILLIBRAND (for herself and Mr. BLUMENTHAL) submitted an amendment intended to be proposed by her to the bill S. 3187, to amend the Federal Food, Drug, and Cosmetic Act to revise and extend the user-fee programs for prescription drugs and medical devices, to establish user-fee programs for generic drugs and biosimilars, and for other purposes; which was ordered to lie on the table; as follows:

At the end of title IX, add the following:

SEC. 9___. PATIENT MEDICATION INFORMATION FOR PRESCRIPTION DRUGS.

(a) SHORT TITLE.—This section may be cited as the ''Cody Miller Initiative for Safer Prescriptions Act''.

(b) PATIENT MEDICATION INFORMATION FOR PRESCRIPTION DRUGS.—Chapter V (21 U.S.C. 351 et seq.) is amended by inserting after section 505E, as added by this Act, the following:

''SEC. 505F. PATIENT MEDICATION INFORMATION FOR PRESCRIPTION DRUGS.

''(a) IN GENERAL.—Not later than 2 years after the date of enactment of this section, the Secretary shall issue regulations regarding the authorship, content, format, and dissemination requirements for patient medication information (referred to in this section as 'PMI') for drugs subject to section 503(b)(1).

''(b) CONTENT.—The regulations promulgated under subsection (a) shall require that the PMI with respect to a drug—

''(1) be scientifically accurate and based on the professional labeling approved by the Secretary and authoritative, peer-reviewed literature; and

''(2) includes nontechnical, understandable, plain language that is not promotional in tone or content, and contains at least—

''(A) the established name of drug, including the established name of such drug as a listed drug (as described in section 505(j)(2)(A)) and as a drug that is the subject of an approved abbreviated new drug application under section 505(j) or of an approved license for a biological product submitted under section 351(k) of the Public Health Service Act, if applicable;

''(B) drug uses and clinical benefits;

''(C) general directions for proper use;

''(D) contraindications, common side effects, and most serious risks of the drug, especially with respect to certain groups such as children, pregnant women, and the elderly;

''(E) measures patients may be able to take, if any, to reduce the side effects and risks of the drug;

''(F) when a patient should contact his or her health care professional;

''(G) instructions not to share medications, and, if any exist, key storage requirements, and recommendations relating to proper disposal of any unused portion of the drug; and

''(H) known clinically important interactions with other drugs and substances.

''(c) TIMELINESS, CONSISTENCY, AND ACCURACY.—The regulations promulgated under subsection (a) shall include standards related to—

''(1) performing timely updates of drug information as new drugs and new information becomes available;

''(2) ensuring that common information is applied consistently and simultaneously across similar drug products and for drugs within classes of medications in order to avoid patient confusion and harm; and

''(3) developing a process, including consumer testing, to assess the quality and effectiveness of PMI in ensuring that PMI promotes patient understanding and safe and effective medication use.

''(d) ELECTRONIC REPOSITORY.—The regulations promulgated under subsection (a) shall provide for the development of a publicly accessible electronic repository for all PMI documents and content to facilitate the availability of PMI.''.

(c) PUBLICATION ON INTERNET WEBSITE.—The Secretary of Health and Human Services shall publish on the Internet website of the Food and Drug Administration a link to the Daily Med website (http://dailymed.nlm.nih.gov/dailymed) (or any successor website).

SA 2129. Mr. GRASSLEY submitted an amendment intended to be proposed by him to the bill S. 3187, to amend the Federal Food, Drug, and Cosmetic Act to revise and extend the user-fee programs for prescription drugs and medical devices, to establish user-fee programs for generic drugs and biosimilars, and for other purposes; which was ordered to lie on the table; as follows:

At the end of title XI, add the following:

SEC. 11___. REGULATIONS ON CLINICAL TRIAL REGISTRATION; GAO STUDY OF CLINICAL TRIAL REGISTRATION AND REPORTING REQUIREMENTS.

(a) DEFINITIONS.—In this section—

(1) the term ''applicable clinical trial'' has the meaning given such term under section 402(j) of the Public Health Service Act (42 U.S.C. 282(j));

(2) the term ''Director'' means the Director of the National Institutes of Health;

(3) the term ''responsible party'' has the meaning given such term under such section 402(j); and

(4) the term ''Secretary'' means the Secretary of Health and Human Services.

(b) REQUIRED REGULATIONS.—

(1) PROPOSED RULEMAKING.—Not later than 180 days after the date of enactment of this Act, the Secretary, acting through the Director, shall issue a notice of proposed rulemaking for a proposed rule on the registration of applicable clinical trials by responsible parties under section 402(j) of the Public Health Service Act (42 U.S.C. 282(j)) (as amended by section 801 of the Food and Drug Administration Amendments Act of 2007).

(2) FINAL RULE.—Not later than 180 days after the issuance of the notice of proposed rulemaking under paragraph (1), the Secretary, acting through the Director, shall issue the final rule on the registration of applicable clinical trials by responsible parties under such section 402(j).

(3) LETTER TO CONGRESS.—If the final rule described in paragraph (2) is not issued by the date required under such paragraph, the Secretary shall submit to Congress a letter that describes the reasons why such final rule has not been issued.

(c) REPORT BY GAO.—

(1) IN GENERAL.—Not later than 2 years after the issuance of the final rule under subsection (b), the Comptroller General of the United States shall submit to the Committee on Health, Education, Labor, and Pensions of the Senate and the Committee on Energy and Commerce of the House of Representatives a report on the implementation of the registration and reporting requirements for applicable drug and device clinical trials

under section 402(j) the Public Health Service Act (42 U.S.C. 282(j)) (as amended by section 801 of the Food and Drug Administration Amendments Act of 2007).

(2) CONTENT.—The report under paragraph (1) shall include—

(A) information on the rate of compliance and non-compliance (by category of sponsor, category of trial (phase II, III, or IV), whether the applicable clinical trial is conducted domestically, in foreign sites, or a combination of sites, and such other categories as the Comptroller General determines useful) with the requirements of—

(i) registering applicable clinical trials under such section 402(j);

(ii) reporting the results of such trials under such section; and

(iii) the completeness of the reporting of the required data under such section; and

(B) information on the promulgation of regulations for the registration of applicable clinical trials by the responsible parties under such section 402(j).

(3) RECOMMENDATIONS.—If the Comptroller General finds problems with timely compliance or completeness of the data being reported under such section 402(j), or finds that the implementation of registration and reporting requirements under such section 402(j) for applicable drug and device clinical trials could be improved, the Comptroller General shall, after consulting with the Commissioner of Food and Drugs, applicable stakeholders, and experts in the conduct of clinical trials, make recommendations for administrative or legislative actions to increase the compliance with the requirements of such section 402(j).

SA 2130. Mr. BURR (for himself and Mr. COBURN) submitted an amendment intended to be proposed by him to the bill S. 3187, to amend the Federal Food, Drug, and Cosmetic Act to revise and extend the user-fee programs for prescription drugs and medical devices, to establish user-fee programs for generic drugs and biosimilars, and for other purposes; which was ordered to lie on the table; as follows:

At the end of title XI, add the following:

SEC. 11___. TRANSPARENCY IN FDA USER FEE AGREEMENT NEGOTIATIONS.

(a) PDUFA.—Section 736B(d) (21 U.S.C. 379h–2(d)), as amended by section 104, is further amended by adding at the end the following:

''(7) INCLUSION OF CONGRESSIONAL REPRESENTATIVES.—Notwithstanding any other provision of this section, Members of Congress or their designated staff may be present at any negotiation meeting conducted under this subsection between the Food and Drug Administration and the regulated industry, if a Member of Congress decides to attend, or have his or her designated staff attend on his or her behalf. Any staff designated under the preceding sentence may be required to comply with applicable confidentiality agreements.''.

(b) MDUFA.—Section 738A(b) (21 U.S.C. 379j–1(b)), as amended by section 204, is further amended by adding at the end the following:

''(7) INCLUSION OF CONGRESSIONAL REPRESENTATIVES.—Notwithstanding any other provision of this section, Members of Congress or their designated staff may be present at any negotiation meeting conducted under this subsection between the Food and Drug Administration and the regulated industry, if a Member of Congress decides to attend, or have his or her designated staff attend on his or her behalf. Any staff designated under the preceding sentence may be required to comply with applicable confidentiality agreements.''.

(c) GDUFA.—Section 744C(d), as added by section 303 of this Act, is amended by adding at the end the following:

''(7) INCLUSION OF CONGRESSIONAL REPRESENTATIVES.—Notwithstanding any other provision of this section, Members of Congress or their designated staff may be present at any negotiation meeting conducted under this subsection between the Food and Drug Administration and the regulated industry, if a Member of Congress decides to attend, or have his or her designated staff attend on his or her behalf. Any staff designated under the preceding sentence may be required to comply with applicable confidentiality agreements.''.

(d) BSUFA.—Section 744I(e), as added by section 403 of this Act, is amended by adding at the end the following:

''(4) INCLUSION OF CONGRESSIONAL REPRESENTATIVES.—Notwithstanding any other provision of this section, Members of Congress or their designated staff may be present at any negotiation meeting conducted under this subsection between the Food and Drug Administration and the regulated industry, if a Member of Congress decides to attend, or have his or her designated staff attend on his or her behalf. Any staff designated under the preceding sentence may be required to comply with applicable confidentiality agreements.''.

SA 2131. Mr. COBURN (for himself and Mr. BURR) submitted an amendment intended to be proposed by him to the bill S. 3187, to amend the Federal Food, Drug, and Cosmetic Act to revise and extend the user-fee programs for prescription drugs and medical devices, to establish user-fee programs for generic drugs and biosimilars, and for other purposes; which was ordered to lie on the table; as follows:

At the end of title VII, add the following:

SEC. 7___. INDEPENDENT ASSESSMENT.

(a) IN GENERAL.—The Secretary shall contract with a private, independent consulting firm capable of performing the technical analysis, management assessment, and program evaluation tasks required to conduct a comprehensive assessment of the process for the review of drug applications under subsections (b) and (j) of section 505 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 355(b), (j)) and subsections (a) and (k) of section 351 of the Public Health Service Act (42 U.S.C. 262(a), (k)). The assessment shall address the premarket review process of drugs by the Food and Drug Administration, using an assessment framework that draws from appropriate quality system standards, including management responsibility, documents controls and records management, and corrective and preventive action.

(b) PARTICIPATION.—Representatives of the Food and Drug Administration and manufacturers of drugs subject to user fees under part 2 of subchapter C of chapter VII of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 379g et seq.) shall participate in a comprehensive assessment of the process for the review of drug applications under section 505 of the Federal Food, Drug, and Cosmetic Act and section 351 of the Public Health Service Act. The assessment shall be conducted in phases.

(c) FIRST CONTRACT.—The Secretary shall award the contract for the first assessment under this section not later than March 31, 2013. Such contractor shall evaluate the implementation of recommendations and publish a written assessment not later than February 1, 2016.

(d) FINDINGS AND RECOMMENDATIONS.—

(1) IN GENERAL.—The Secretary shall publish the findings and recommendations under this section that are likely to have a significant impact on review times not later than 6 months after the contract is awarded. Final comprehensive findings and recommendations shall be published not later than 1 year after the contract is awarded.

(2) IMPLEMENTATION PLAN.—The Food and Drug Administration shall publish an implementation plan not later than 6 months after the date of receipt of each set of recommendation.

(e) SCOPE OF ASSESSMENT.—The assessment under this section shall include the following:

(1) Identification of process improvements and best practices for conducting predictable, efficient, and consistent premarket reviews that meet regulatory review standards.

(2) Analysis of elements of the review process that consume or save time to facilitate a more efficient process. Such analysis shall include—

(A) consideration of root causes for inefficiencies that may affect review performance and total time to decision;

(B) recommended actions to correct any failures to meet user fee program goals; and

(C) consideration of the impact of combination products on the review process.

(3) Assessment of methods and controls of the Food and Drug Administration for collecting and reporting information on premarket review process resource use and performance.

(4) Assessment of effectiveness of the reviewer training program of the Food and Drug Administration.

(5) Recommendations for ongoing periodic assessments and any additional, more detailed or focused assessments.

(f) REQUIREMENTS.—The Secretary shall—

(1) analyze the recommendations for improvement opportunities identified in the assessment, develop and implement a corrective action plan, and ensure its effectiveness;

(2) incorporate the findings and recommendations of the contractors, as appropriate, into the management of the premarket review program of the Food and Drug Administration; and

(3) incorporate the results of the assessment in a Good Review Management Practices guidance document, which shall include initial and ongoing training of Food and Drug Administration staff, and periodic audits of compliance with the guidance.

SA 2132. Mr. COBURN (for himself and Mr. BURR) submitted an amendment intended to be proposed by him to the bill S. 3187, to amend the Federal Food, Drug, and Cosmetic Act to revise and extend the user-fee programs for prescription drugs and medical devices, to establish user-fee programs for generic drugs and biosimilars, and for other purposes; which was ordered to lie on the table; as follows:

At the end of title XI, add the following:

SEC. 11___. PERFORMANCE AWARDS.

(a) IN GENERAL.—Not later than 1 year after the date of enactment of this Act, the Secretary of Health and Human Services (referred to in this section as the ''Secretary'') shall establish a system by which a portion of the performance awards of each employee described in subsection (b) shall be connected to the evaluation of the employee's contribution, in the discretion of the Secretary, to the goals under the user fee agreements described in section 101(b), 201(b), 301(b), or 401(b), as appropriate.

(b) EMPLOYEES DESCRIBED.—

(1) IN GENERAL.—Subsection (a) shall apply only to employees who—

(A) are employed by the Center for Drug Evaluation and Research, the Center for Devices and Radiological Health, or the Center for Biologics Evaluation and Research; and

(B) are involved in the review of drugs, devices, or biological products.

(2) COMMISSIONED CORPS.—For purposes of this section, the term ''employee'' includes members of the Public Health Service Commissioned Corps.

(c) EFFECT ON AWARD.—The degree to which the performance award of an employee is affected by the evaluation of the employee's contribution to the goals under the user fee agreements, as described in subsection (a), shall be proportional to the extent to which the employee is involved in the review of drugs, devices, or biological products.

(d) REPORT.—The Secretary shall issue an annual report detailing how many employees were involved in meeting the goals under the user fee agreements described in section 101(b), 201(b), 301(b), and 401(b), and the manner of the involvement of such employees.

SA 2133. Mr. DEMINT (for himself and Mr. VITTER) submitted an amendment intended to be proposed by him to the bill S. 3187, to amend the Federal Food, Drug, and Cosmetic Act to revise and extend the user-fee programs for prescription drugs and medical devices, to establish user-fee programs for generic drugs and biosimilars, and for other purposes; which was ordered to lie on the table; as follows:

At the appropriate place, insert the following:

SEC. 11___. DOCUMENT DISCLOSURE RELATING TO THE PATIENT PROTECTION AND AFFORDABLE CARE ACT.

(a) IN GENERAL.—Not later than 60 days after the date of the enactment of this Act, a representative of the Executive Office of the President shall provide to Congress all documents and correspondences exchanged between employees of the Executive Office of the President and the Pharmaceutical Research and Manufacturers of America since January 20, 2009.

(b) PUBLICATION OF DOCUMENTS AND CORRESPONDENCES.—The Secretary of Health and Human Services shall publish all documents and correspondences described in subsection (a) on the Internet website of the Department of Health and Human Services.

SA 2134. Mr. BLUMENTHAL submitted an amendment intended to be proposed by him to the bill S. 3187, to amend the Federal Food, Drug, and Cosmetic Act to revise and extend the user-fee programs for prescription drugs and medical devices, to establish user-fee programs for generic drugs and biosimilars, and for other purposes; which was ordered to lie on the table; as follows:

At the end of title X, insert the following:

SEC. 10___. MARKET MANIPULATION WITH RESPECT TO DRUGS IN SHORTAGE.

(a) DEFINITIONS.—In this section:

(1) DRUG.—The term ''drug'' has the meaning given such term in section 201(g)(1) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 321(g)(1)) and is intended for human use.

(2) DRUG SHORTAGE.—The term ''drug shortage'' or ''shortage'', with respect to a drug defined in section 506C(a) of the Federal Food Drug and Cosmetic Act (21 U.S.C. 356c(a)), means a period of time when the demand or projected demand for the drug within the United States exceeds the supply of the drug (as defined in section 506(c) of the Federal Food Drug and Cosmetic Act (21 U.S.C. 356(c)).

(b) PROHIBITION ON MARKET MANIPULATION.—It shall be unlawful for any person to directly or indirectly use any manipulative or deceptive device or contrivance, in connection with the purchase or sale of a drug in shortage, in contravention of rules or regulations the Federal Trade Commission may prescribe as necessary or appropriate in the public interest or for the protection of United States citizens.

(c) PROHIBITION ON FALSE INFORMATION.—It shall be unlawful for any person to report or distribute information related to the purchase or sale of a prescription drug in shortage if the person knew the information to be false or misleading, in order to support activities described in subsection (b).

(d) ENFORCEMENT BY FEDERAL TRADE COMMISSION.—

(1) UNFAIR OR DECEPTIVE ACTS OR PRACTICES.—A violation of subsection (b) shall be treated as an unfair and deceptive act or practice in violation of a regulation under section 18(a)(1)(B) of the Federal Trade Commission Act (15 U.S.C. 57a(a)(1)(B)) regarding unfair or deceptive acts or practices.

(2) POWERS OF COMMISSION.—

(A) IN GENERAL.—The Federal Trade Commission shall enforce this section in the same manner, by the same means, and with the same jurisdiction, powers, and duties as though all applicable terms and provisions of the Federal Trade Commission Act (15 U.S.C. 41 et seq.) were incorporated into and made a part of this section.

(B) PRIVILEGES AND IMMUNITIES.—Any person who violates this section shall be subject to the penalties and entitled to the privileges and immunities provided in the Federal Trade Commission Act (15 U.S.C. 41 et seq.).

(e) ENFORCEMENT BY STATES.—

(1) IN GENERAL.—In any case in which the attorney general of a State has reason to believe that an interest of the residents of the State has been or is threatened or adversely affected by the engagement of any person in an act that violates subsection (b), the attorney general of the State may, as parens patriae, bring a civil action on behalf of the residents of the State in an appropriate district court of the United States—

(A) to enjoin further violation of such subsection by such person;

(B) to compel compliance with such subsection;

(C) to obtain damages, restitution, or other compensation on behalf of such residents;

(D) to obtain such other relief as the court considers appropriate; or

(E) to obtain civil penalties in the amount determined under paragraph (2).

(2) CIVIL PENALTIES.—

(A) IN GENERAL.—In addition to any penalty applicable under the Federal Trade Commission Act (15 U.S.C. 41 et seq.), any person that violates subsection (b) or (c) shall be subject to a civil penalty of not more than $1,000,000.

(B) METHOD.—The civil penalty provided under subparagraph (A) shall be obtained in the same manner as civil penalties imposed under section 5 of the Federal Trade Commission Act (15 U.S.C. 45).

(C) MULTIPLE OFFENSES; OTHER CONSIDERATIONS.—In assessing the civil penalty under this paragraph—

(i) each day of a continuing violation shall be considered a separate violation; and

(ii) the seriousness of the violation, and the efforts of the person committing the violation to remedy the harm caused by the violation shall be considered.

(D) ADJUSTMENT FOR INFLATION.—Beginning on the date on which the Bureau of Labor Statistics first publishes the Consumer Price Index after the date that is 1 year after the date of the enactment of this Act, and annually thereafter, the maximum amount specified in subparagraph (A) shall be increased by the percentage increase in the Consumer Price Index published on that date from the Consumer Price Index published the previous year.

(3) RIGHTS OF FEDERAL TRADE COMMISSION.—

(A) NOTICE TO FEDERAL TRADE COMMISSION.—

(i) IN GENERAL.—Except as provided in clause (iii), the attorney general of a State shall notify the Federal Trade Commission in writing that the attorney general intends to bring a civil action under paragraph (1) before initiating the civil action.

(ii) CONTENTS.—The notification required by clause (i) with respect to a civil action shall include a copy of the complaint to be filed to initiate the civil action.

(iii) EXCEPTION.—If it is not feasible for the attorney general of a State to provide the notification required by clause (i) before initiating a civil action under paragraph (1), the attorney general shall notify the Federal Trade Commission immediately upon instituting the civil action.

(B) INTERVENTION BY FEDERAL TRADE COMMISSION.—The Federal Trade Commission may—

(i) intervene in any civil action brought by the attorney general of a State under paragraph (1); and

(ii) upon intervening—

(I) be heard on all matters arising in the civil action; and

(II) file petitions for appeal of a decision in the civil action.

(4) INVESTIGATORY POWERS.—Nothing in this subsection may be construed to prevent the attorney general of a State from exercising the powers conferred on the attorney general by the laws of the State to conduct investigations, to administer oaths or affirmations, or to compel the attendance of witnesses or the production of documentary or other evidence.

(5) PREEMPTIVE ACTION BY FEDERAL TRADE COMMISSION.—If the Federal Trade Commission institutes a civil action or an administrative action with respect to a violation of subsection (b), the attorney general of a State may not, during the pendency of such action, bring a civil action under paragraph (1) against any defendant named in the complaint of the Commission for the violation with respect to which the Commission instituted such action.

(6) VENUE; SERVICE OF PROCESS.—

(A) VENUE.—Any action brought under paragraph (1) may be brought in—

(i) the district court of the United States that meets applicable requirements relating to venue under section 1391 of title 28, United States Code; or

(ii) another court of competent jurisdiction.

(B) SERVICE OF PROCESS.—In an action brought under paragraph (1), process may be served in any district in which the defendant—

(i) is an inhabitant; or

(ii) may be found.

(7) ACTIONS BY OTHER STATE OFFICIALS.—

(A) IN GENERAL.—In addition to civil actions brought by attorneys general under paragraph (1), any other officer of a State who is authorized by the State to do so may bring a civil action under paragraph (1), subject to the same requirements and limitations that apply under this subsection to civil actions brought by attorneys general.

(B) SAVINGS PROVISION.—Nothing in this subsection may be construed to prohibit an authorized official of a State from initiating or continuing any proceeding in a court of the State for a violation of any civil or criminal law of the State.

(f) REPORTING OF MARKET MANIPULATION WITH RESPECT TO DRUGS IN SHORTAGE, REFERRALS, AND EDUCATION AND OUTREACH.—

(1) LOGGING AND ACKNOWLEDGING COMPLAINTS OF MARKET MANIPULATION.—Not later than 1 year after the date of the enactment of this Act, the Federal Trade Commission shall establish a process by which the Commission shall log and acknowledge the receipt by the Commission of each complaint submitted to the Commission by a person in which the person—

(A) complains of a violation of subsection (b) about which the person certifies a reasonable belief or knowledge of such violation; or

(B) claims to be a victim of a violation of such section.

(2) REFERRALS.—To the degree practicable, the Commission shall refer each person from whom the Commission receives a complaint under paragraph (1) to an appropriate entity for—

(A) in the case of a victim of a violation of subsection (b), assistance in mitigating any damages caused by such violation; or

(B) enforcement of such subsection.

(3) PROGRAM OF EDUCATION AND OUTREACH.—The Commission shall carry out a program of education and outreach whereby the Commission informs consumers of the following:

(A) The prohibition set forth in subsection (b).

(B) Common ways in which such subsection is violated and how consumers can protect themselves from violations of such subsection.

(C) The process established under paragraph (1).

(g) AUTHORIZATION OF APPROPRIATIONS.—There are authorized to be appropriated such sums as may be necessary to carry out this section.

SA 2135. Mr. BLUMENTHAL submitted an amendment intended to be proposed by him to the bill S. 3187, to amend the Federal Food, Drug, and Cosmetic Act to revise and extend the user-fee programs for prescription drugs and medical devices, to establish user-fee programs for generic drugs and biosimilars, and for other purposes; which was ordered to lie on the table; as follows:

At the end of title X, add the following:

SEC. 10___. CRITICAL DRUG SUPPLY REINFORCEMENT PROGRAM.

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

"Subchapter G—Drug Shortages

"SEC. 575. DEFINITIONS.

''For purposes of this subchapter—

''(1) the term 'critical reinforcement drug' means a drug that—

''(A) is the subject of a permanent discontinuance or an interruption in the manufacture of the drug that could lead to a meaningful disruption in the supply of that drug in the United States, as defined in section 506C(f)(3); and

''(B) is identified as vulnerable to a drug shortage based on the criteria established under section 575A;

''(2) the term 'drug'—

''(A) means a drug (as defined in section 201(g)) that is intended for human use and is the subject of an approved application under section 505(j); and

''(B) does not include biological products (as defined in section 351 of the Public Health Service Act); and

''(3) the term 'drug shortage' or 'shortage', with respect to a drug, means a period of time when the demand or projected demand for the drug within the United States exceeds the supply of the drug.

"SEC. 575A. CRITICAL DRUG SUPPLY EVALUATION AND REINFORCEMENT.

''(a) DEVELOPMENT OF CRITERIA FOR EVALUATION OF CRITICAL REINFORCEMENT NEED.—

''(1) EVALUATION.—Not later than 180 days after the date of enactment of this section, the Secretary, in consultation with Office of Drug Shortages, shall conduct an evaluation to establish evidence-based criteria for identifying drugs that are vulnerable to a drug shortage.

''(2) CONTENT.—The evaluation under paragraph (1) shall include a comprehensive trend analysis to forecast drug shortages and target drugs that are vulnerable to a shortage. The Secretary is authorized to contract with a third party to conduct or participate in such evaluation. In conducting such evaluation, the Secretary or any authorized third party shall not use any confidential, trade secret, or proprietary information of any other entity without such entity's consent.

''(3) CONSULTATION WITH STAKEHOLDERS.—The Secretary, as part of the evaluation under paragraph (1), shall convene a discussion with stakeholders to assess methodology and findings applicable to such evaluation.

''(4) REPORT TO CONGRESS.—Not later than 2 years after the date of enactment of this section, the Secretary shall submit a report to Congress that describes the methods and processes used to conduct the evaluation under this subsection.

''(b) CRITICAL REINFORCEMENT.—To carry out this section, the Secretary may award the incentives under subsection (d) to qualified manufacturers to secure an agreement—

''(1) for the rapid production of a critical reinforcement drug;

''(2) that the qualified manufacturer will maintain production of a critical reinforcement drug; or

''(3) that would allow the Secretary to purchase supply of a critical reinforcement drug from the qualified manufacturer under certain market conditions and on terms and conditions mutually agreed upon.

''(c) QUALIFIED MANUFACTURERS.—To be a qualified manufacturer for purposes of this section—

''(1) an entity shall be a drug manufacturer; and

''(2) the Secretary shall ensure that the manufacturer—

''(A) is in compliance with good manufacturing practice regulations of the Food and Drug Administration to produce a critical reinforcement drug or a similar product; and

''(B)(i) currently produces a critical reinforcement drug or a similar product and can increase production immediately to address the shortage with no regulatory approvals required;

''(ii) does not currently produce a critical reinforcement drug but has the capability, capacity and regulatory authority to do so and could commence supply in time to address need; or

''(iii) has capability and capacity to produce a critical reinforcement drug but not the regulatory authority and could commence supply upon regulatory filing and approval.

''(d) INCENTIVES.—

''(1) IN GENERAL.—If the Secretary ensures a manufacturer is a qualified manufacturer, the Secretary shall negotiate a manufacturing contingency plan with the manufacturer to meet an identified critical reinforcement in subsection (c). The Secretary may—

''(A) expedite the review of any abbreviated new drug application submitted under section 505 by the qualified manufacturer for a drug that is vulnerable to shortage as identified pursuant to the criteria established under subsection (a); and

''(B) waive any application fees related to such an abbreviated new drug application.

''(2) LIMITATION.—If the qualified manufacturer fails to meet benchmarks specified by the Secretary in the agreement between the Secretary and the manufacturer, or otherwise violates such agreement, the Secretary may retroactively assess the application fees waived under paragraph (1)(B).

''(e) TRADEMARK PROTECTION.—Nothing in this section shall be construed to alter or modify in any way, any applicable patent, copyright, trademark, or other intellectual property rights of any holder of a new drug application, an abbreviated new drug application, or a biologics license application, including any applicable regulatory exclusivity periods or periods during which the Secretary may not accept for filing or approve any new drug application, an abbreviated new drug application, or a biologics license application, and procedures associated therewith, under this Act or the Public Health Service Act.''.

SA 2136. Mr. BLUMENTHAL (for himself, Mr. FRANKEN, Mr. SCHUMER, Mr. CARDIN, and Ms. KLOBUCHAR) submitted an amendment intended to be proposed by him to the bill S. 3187, to amend the Federal Food, Drug, and Cosmetic Act to revise and extend the user-fee programs for prescription drugs and medical devices, to establish user-fee programs for generic drugs and biosimilars, and for other purposes; which was ordered to lie on the table; as follows:

At the end of title X, add the following:

SEC. 10___. CIVIL PENALTIES FOR FAILURE TO SUBMIT NOTIFICATION.

Section 303 (21 U.S.C. 333) is amended—

(1) in subsection (f)(5), by inserting ''or subsection (h)'' after ''or (9)'' each place such term appears; and

(2) by adding at the end the following:

''(h)(1) Any manufacturer that knowingly fails to submit a notification in violation of section 506C(a) shall be subject to a civil money penalty not to exceed $10,000 for each day on which the violation continues, and not to exceed $1,800,000 for all such violations adjudicated in a single proceeding.

''(2) Not later than 180 days after the date of enactment of the Food and Drug Administration Safety and Innovation Act, the Secretary shall, subject to paragraph (1), promulgate final regulations establishing a schedule of civil monetary penalties for violations of section 506C(a).''.

SA 2137. Mr. ROCKEFELLER submitted an amendment intended to be proposed by him to the bill S. 3187, to amend the Federal Food, Drug, and Cosmetic Act to revise and extend the user-fee programs for prescription drugs and medical devices, to establish user-fee programs for generic drugs and biosimilars, and for other purposes; which was ordered to lie on the table; as follows:

At the end of title VII, add the following:

SEC. 7___. PROHIBITION OF AUTHORIZED GENERICS.

(a) IN GENERAL.—Section 505 (21 U.S.C. 355), as amended by section 510(a), is further amended by adding at the end the following:

''(x) PROHIBITION OF AUTHORIZED GENERIC DRUGS.—

''(1) IN GENERAL.—Notwithstanding any other provision of this Act, no holder of a new drug application approved under subsection (c) shall manufacture, market, sell, or distribute an authorized generic drug, directly or indirectly, or authorize any other person to manufacture, market, sell, or distribute an authorized generic drug.

''(2) AUTHORIZED GENERIC DRUG.—For purposes of this subsection, the term 'authorized generic drug'—

''(A) means any version of a listed drug (as such term is used in subsection (j)) that the holder of the new drug application approved under subsection (c) for that listed drug seeks to commence marketing, selling, or distributing, directly or indirectly, after receipt of a notice sent pursuant to subsection (j)(2)(B) with respect to that listed drug; and

''(B) does not include any drug to be marketed, sold, or distributed—

''(i) by an entity eligible for 180-day exclusivity with respect to such drug under subsection (j)(5)(B)(iv); or

''(ii) after expiration or forfeiture of any 180-day exclusivity with respect to such drug under such subsection (j)(5)(B)(iv).''.

(b) CONFORMING AMENDMENT.—Section 505(t)(3) (21 U.S.C. 355(t)(3)) is amended by striking ''In this section'' and inserting ''In this subsection''.

SA 2138. Mr. VITTER submitted an amendment intended to be proposed by him to the bill S. 3187, to amend the Federal Food, Drug, and Cosmetic Act to revise and extend the user-fee programs for prescription drugs and medical devices, to establish user-fee programs for generic drugs and biosimilars, and for other purposes; which was ordered to lie on the table; as follows:

At the end, add the following:

DIVISION B—FLOOD INSURANCE

SEC. 100. REFERENCES.

Except as expressly provided otherwise, any reference to ''this Act'' contained in any division of this Act shall be treated as referring only to the provisions of that division.

TITLE I—FLOOD INSURANCE REFORM AND MODERNIZATION

SEC. 101. SHORT TITLE.

This title may be cited as the ''Flood Insurance Reform and Modernization Act of 2012''.

SEC. 102. FINDINGS.

Congress finds that—

(1) the flood insurance claims resulting from the hurricane season of 2005 exceeded all previous claims paid by the National Flood Insurance Program;

(2) in order to pay the legitimate claims of policyholders from the hurricane season of 2005, the Federal Emergency Management Agency has borrowed $19,000,000,000 from the Treasury;

(3) the interest alone on this debt has been as high as $800,000,000 annually, and that the Federal Emergency Management Agency has indicated that it will be unable to pay back this debt;

(4) the flood insurance program must be strengthened to ensure it can pay future claims;

(5) while flood insurance is mandatory in the 100-year floodplain, substantial flooding occurs outside of existing special flood hazard areas;

(6) events throughout the country involving areas behind flood control structures, known as ''residual risk'' areas, have produced catastrophic losses;

(7) although such flood control structures produce an added element of safety and therefore lessen the probability that a disaster will occur, they are nevertheless susceptible to catastrophic loss, even though such areas at one time were not included within the 100-year floodplain; and

(8) voluntary participation in the National Flood Insurance Program has been minimal and many families residing outside the 100-year floodplain remain unaware of the potential risk to their lives and property.

SEC. 103. DEFINITIONS.

(a) IN GENERAL.—In this title, the following definitions shall apply:

(1) 100-YEAR FLOODPLAIN.—The term ''100-year floodplain'' means that area which is subject to inundation from a flood having a 1-percent chance of being equaled or exceeded in any given year.

(2) 500-YEAR FLOODPLAIN.—The term ''500-year floodplain'' means that area which is subject to inundation from a flood having a 0.2-percent chance of being equaled or exceeded in any given year.

(3) ADMINISTRATOR.—The term ''Administrator'' means the Administrator of the Federal Emergency Management Agency.

(4) NATIONAL FLOOD INSURANCE PROGRAM.—The term ''National Flood Insurance Program'' means the program established under the National Flood Insurance Act of 1968 (42 U.S.C. 4011 et seq.).

(5) WRITE YOUR OWN.—The term ''Write Your Own'' means the cooperative undertaking between the insurance industry and the Federal Insurance Administration which allows participating property and casualty insurance companies to write and service standard flood insurance policies.

(b) COMMON TERMINOLOGY.—Except as otherwise provided in this title, any terms used in this title shall have the meaning given to such terms under section 1370 of the National Flood Insurance Act of 1968 (42 U.S.C. 4121).

SEC. 104. EXTENSION OF NATIONAL FLOOD INSURANCE PROGRAM.

(a) FINANCING.—Section 1309(a) of the National Flood Insurance Act of 1968 (42 U.S.C. 4016(a)) is amended by striking ''the earlier of the date of the enactment into law of an Act that specifically amends the date specified in this section or May 31, 2012'' and inserting ''September 30, 2016''.

(b) PROGRAM EXPIRATION.—Section 1319 of the National Flood Insurance Act of 1968 (42 U.S.C. 4026) is amended by striking ''the earlier of the date of the enactment into law of an Act that specifically amends the date specified in this section or May 31, 2012'' and inserting ''September 30, 2016''.

SEC. 105. AVAILABILITY OF INSURANCE FOR MULTIFAMILY PROPERTIES.

Section 1305 of the National Flood Insurance Act of 1968 (42 U.S.C. 4012) is amended—

(1) in subsection (b)(2)(A), by inserting ''not described in subsection (a) or (d)'' after ''properties''; and

(2) by adding at the end the following:

''(d) AVAILABILITY OF INSURANCE FOR MULTIFAMILY PROPERTIES.—

''(1) IN GENERAL.—The Administrator shall make flood insurance available to cover residential properties of more than 4 units. Notwithstanding any other provision of law, the maximum coverage amount that the Administrator may make available under this subsection to such residential properties shall be equal to the coverage amount made available to commercial properties.

''(2) RULE OF CONSTRUCTION.—Nothing in this subsection shall be construed to limit the ability of individuals residing in residential properties of more than 4 units to obtain insurance for the contents and personal articles located in such residences.''.

SEC. 106. REFORM OF PREMIUM RATE STRUCTURE.

(a) TO EXCLUDE CERTAIN PROPERTIES FROM RECEIVING SUBSIDIZED PREMIUM RATES.—

(1) IN GENERAL.—Section 1307 of the National Flood Insurance Act of 1968 (42 U.S.C. 4014) is amended—

(A) in subsection (a)(2), by striking ''; and'' and inserting the following: '', except that the Administrator shall not estimate rates under this paragraph for—

''(A) any property which is not the primary residence of an individual;

''(B) any severe repetitive loss property;

''(C) any property that has incurred flood-related damage in which the cumulative amounts of payments under this title equaled or exceeded the fair market value of such property;

''(D) any business property; or

''(E) any property which on or after the date of the enactment of the Flood Insurance Reform and Modernization Act of 2012 has experienced or sustained—

''(i) substantial damage exceeding 50 percent of the fair market value of such property; or

''(ii) substantial improvement exceeding 30 percent of the fair market value of such property; and''; and

(B) by adding at the end the following:

''(g) NO EXTENSION OF SUBSIDY TO NEW POLICIES OR LAPSED POLICIES.—The Administrator shall not provide flood insurance to prospective insureds at rates less than those estimated under subsection (a)(1), as required by paragraph (2) of that subsection, for—

''(1) any property not insured by the flood insurance program as of the date of the enactment of the Flood Insurance Reform and Modernization Act of 2012;

''(2) any policy under the flood insurance program that has lapsed in coverage, as a result of the deliberate choice of the holder of such policy; or

''(3) any prospective insured who refuses to accept any offer for mitigation assistance by the Administrator (including an offer to relocate), including an offer of mitigation assistance—

''(A) following a major disaster, as defined in section 102 of the Robert T. Stafford Disaster Relief and Emergency Assistance Act (42 U.S.C. 5122); or

''(B) in connection with—

''(i) a repetitive loss property; or

''(ii) a severe repetitive loss property.

''(h) DEFINITION.—In this section, the term 'severe repetitive loss property' has the following meaning:

''(1) SINGLE-FAMILY PROPERTIES.—In the case of a property consisting of 1 to 4 residences, such term means a property that—

''(A) is covered under a contract for flood insurance made available under this title; and

''(B) has incurred flood-related damage—

''(i) for which 4 or more separate claims payments have been made under flood insurance coverage under this chapter, with the amount of each such claim exceeding $5,000, and with the cumulative amount of such claims payments exceeding $20,000; or

''(ii) for which at least 2 separate claims payments have been made under such coverage, with the cumulative amount of such claims exceeding the value of the property.

''(2) MULTIFAMILY PROPERTIES.—In the case of a property consisting of more than 4 units, such term shall have such meaning as the Director shall by regulation provide.''.

(2) EFFECTIVE DATE.—The amendments made by paragraph (1) shall become effective 90 days after the date of the enactment of this Act.

(b) ESTIMATES OF PREMIUM RATES.—Section 1307(a)(1)(B) of the National Flood Insurance Act of 1968 (42 U.S.C. 4014(a)(1)(B)) is amended—

(1) in clause (ii), by striking ''and'' at the end;

(2) in clause (iii), by adding ''and'' at the end; and

(3) by inserting after clause (iii) the following:

''(iv) all costs, as prescribed by principles and standards of practice in ratemaking adopted by the American Academy of Actuaries and the Casualty Actuarial Society, including—

''(I) an estimate of the expected value of future costs,

''(II) all costs associated with the transfer of risk, and

''(III) the costs associated with an individual risk transfer with respect to risk classes, as defined by the Administrator,''.

(c) INCREASE IN ANNUAL LIMITATION ON PREMIUM INCREASES.—Section 1308(e) of the National Flood Insurance Act of 1968 (42 U.S.C. 4015(e)) is amended—

(1) by striking ''under this title for any properties within any single'' and inserting the following: ''under this title for any properties—

''(1) within any single'';

(2) by striking ''10 percent'' and inserting ''15 percent''; and

(3) by striking the period at the end and inserting the following: ''; and

''(2) described in subparagraphs (A) through (E) of section 1307(a)(2) shall be increased by 25 percent each year, until the average risk premium rate for such properties is equal to the average of the risk premium rates for properties described under paragraph (1).''.

(d) PREMIUM PAYMENT FLEXIBILITY FOR NEW AND EXISTING POLICYHOLDERS.—Section 1308 of the National Flood Insurance Act of 1968 (42 U.S.C. 4015) is amended by adding at the end the following:

''(g) FREQUENCY OF PREMIUM COLLECTION.—With respect to any chargeable premium rate prescribed under this section, the Administrator shall provide policyholders that are not required to escrow their premiums and fees for flood insurance as set forth under section 102 of the Flood Disaster Protection Act of 1973 (42 U.S.C. 4012a) with the option of paying their premiums either annually or in more frequent installments.''.

SEC. 107. MANDATORY COVERAGE AREAS.

(a) SPECIAL FLOOD HAZARD AREAS.—Not later than 90 days after the date of the enactment of this Act, the Administrator shall issue final regulations establishing a revised definition of areas of special flood hazards for purposes of the National Flood Insurance Program.

(b) RESIDUAL RISK AREAS.—The regulations required by subsection (a) shall require the expansion of areas of special flood hazards to include areas of residual risk that are located behind levees or near dams or other flood control structures, as determined by the Administrator.

(c) MANDATORY PARTICIPATION IN NATIONAL FLOOD INSURANCE PROGRAM.—

(1) IN GENERAL.—Any area described in subsection (b) shall be subject to the mandatory purchase requirements of sections 102 and 202 of the Flood Disaster Protection Act of 1973 (42 U.S.C. 4012a, 4106).

(2) LIMITATION.—The mandatory purchase requirement under paragraph (1) shall have no force or effect until the mapping of all residual risk areas in the United States that the Administrator determines essential in order to administer the National Flood Insurance Program, as required under section 118, are in the maintenance phase.

(3) ACCURATE PRICING.—In carrying out the mandatory purchase requirement under paragraph (1), the Administrator shall ensure that the price of flood insurance policies in areas of residual risk accurately reflects the level of flood protection provided by any levee, dam, or other flood control structure in such area, regardless of the certification status of the flood control structure.

(d) DECERTIFICATION.—Upon decertification of any levee, dam, or flood control structure under the jurisdiction of the Army Corps of Engineers, the Corps shall immediately provide notice to the Administrator of the National Flood Insurance Program.

SEC. 108. PREMIUM ADJUSTMENT.

Section 1308 of the National Flood Insurance Act of 1968 (42 U.S.C. 4015), as amended by section 106(c), is further amended by adding at the end the following:

''(h) PREMIUM ADJUSTMENT TO REFLECT CURRENT RISK OF FLOOD.—Notwithstanding subsection (f), upon the effective date of any revised or updated flood insurance rate map under this Act, the Flood Disaster Protection Act of 1973, or the Flood Insurance Reform and Modernization Act of 2012, any property located in an area that is participating in the national flood insurance program shall have the risk premium rate charged for flood insurance on such property adjusted to accurately reflect the current risk of flood to such property, subject to any other provision of this Act. Any increase in the risk premium rate charged for flood insurance on any property that is covered by a flood insurance policy on the effective date of such an update that is a result of such updating shall be phased in over a 4-year period, at the rate of 40 percent for the first year following such effective date and 20 percent for each of the second, third, and fourth years following such effective date. In the case of any area that was not previously designated as an area having special flood hazards and that, pursuant to any issuance, revision, updating, or other change in a flood insurance map, becomes designated as such an area, the chargeable risk premium rate for flood insurance under this title that is purchased on or after the date of enactment of this subsection with respect to any property that is located within such area shall be phased in over a 4-year period, at the rate of 40 percent for the first year following the effective date of such issuance, revision, updating, or change and 20 percent for each of the second, third, and fourth years following such effective date.''.

SEC. 109. STATE CHARTERED FINANCIAL INSTITUTIONS.

Section 1305(c) of the National Flood Insurance Act of 1968 (42 U.S.C. 4012(c)) is amended—

(1) in paragraph (1), by striking '', and'' and inserting a semicolon;

(2) in paragraph (2), by striking the period at the end and inserting ''; and''; and

(3) by adding at the end the following:

''(3) given satisfactory assurance that by the date that is 6 months after the date of enactment of the Flood Insurance Reform and Modernization Act of 2012, lending institutions chartered by a State, and not insured by the Federal Deposit Insurance Corporation or the National Credit Union Administration, shall be subject to regulations by that State that are consistent with the requirements of section 102 of the Flood Disaster Protection Act of 1973 (42 U.S.C. 4012a).''.

SEC. 110. ENFORCEMENT.

Section 102(f)(5) of the Flood Disaster Protection Act of 1973 (42 U.S.C. 4012a(f)(5)) is amended—

(1) in the first sentence, by striking ''$350'' and inserting ''$2,000''; and

(2) by striking the second sentence.

SEC. 111. ESCROW OF FLOOD INSURANCE PAYMENTS.

(a) IN GENERAL.—

(1) DEFINITIONS.—Section 3 of the Flood Disaster Protection Act of 1973 (42 U.S.C. 4003) is amended—

(A) in paragraph (10), by striking ''and'' at the end;

(B) in paragraph (11), by striking the period at the end and inserting a semicolon; and

(C) by adding at the end the following:

''(12) 'State entity for lending regulation' means the State entity or agency with primary responsibility for the supervision or regulation of State lending institutions in a State; and

''(13) 'State lending institution' means any bank, savings and loan association, credit union, farm credit bank, production credit association, or similar lending institution subject to the supervision or regulation of a State entity for lending regulation.''.

(2) ESCROW REQUIREMENTS.—Paragraph (1) of section 102(d) of the Flood Disaster Protection Act of 1973 (42 U.S.C. 4012a(d)) is amended to read as follows:

''(1) REGULATED LENDING INSTITUTIONS AND STATE LENDING INSTITUTIONS.—

''(A) FEDERAL ENTITIES RESPONSIBLE FOR LENDING REGULATIONS.—Each Federal entity for lending regulation (after consultation and coordination with the Federal Financial Institutions Examination Council) shall, by regulation, direct that all premiums and fees for flood insurance under the National Flood Insurance Act of 1968, for improved real estate or a mobile home, shall be paid to the regulated lending institution or servicer for any loan secured by the improved real estate or mobile home, with the same frequency as payments on the loan are made, for the duration of the loan. Except as provided in subparagraph (C), upon receipt of any premiums or fees, the regulated lending institution or servicer shall deposit such premiums and fees in an escrow account on behalf of the borrower. Upon receipt of a notice from the Administrator or the provider of the flood insurance that insurance premiums are due, the premiums deposited in the escrow account shall be paid to the provider of the flood insurance.

''(B) STATE ENTITIES RESPONSIBLE FOR LENDING REGULATIONS.—In order to continue to participate in the flood insurance program, each State shall direct that its State entity for lending regulation require that premiums and fees for flood insurance under the National Flood Insurance Act of 1968, for improved real estate or a mobile home shall be paid to the State lending institution or servicer for any loan secured by the improved real estate or mobile home, with the same frequency as payments on the loan are made, for the duration of the loan. Except as provided in subparagraph (C), upon receipt of any premiums or fees, the State lending institution or servicer shall deposit such premiums and fees in an escrow account on behalf of the borrower. Upon receipt of a notice from the Administrator or the provider of the flood insurance that insurance premiums are due, the premiums deposited in the escrow account shall be paid to the provider of the flood insurance.

''(C) LIMITATION.—Except as may be required under applicable State law, neither a Federal entity for lending regulation nor a State entity for lending regulation may direct or require a regulated lending institution or State lending institution to deposit premiums or fees for flood insurance under the National Flood Insurance Act of 1968 in an escrow account on behalf of a borrower under subparagraph (A) or (B), if—

''(i) the regulated lending institution or State lending institution has total assets of less than $1,000,000,000; and

''(ii) on or before the date of enactment of the Flood Insurance Reform and Modernization Act of 2012 the regulated lending institution or State lending institution—

''(I) was not required under Federal or State law to deposit taxes, insurance premiums, fees, or any other charges in an escrow account for a loan secured by residential improved real estate or a mobile home; and

''(II) did not have a policy of consistently and uniformly requiring the deposit of taxes, insurance premiums, fees, or any other charges in an escrow account for loans secured by residential improved real estate or a mobile home.''.

(b) APPLICABILITY.—The amendment made by subsection (a)(2) shall apply to any mortgage outstanding or entered into on or after the expiration of the 2-year period beginning on the date of the enactment of this Act.

SEC. 112. MINIMUM DEDUCTIBLES FOR CLAIMS UNDER THE NATIONAL FLOOD INSURANCE PROGRAM.

Section 1312 of the National Flood Insurance Act of 1968 (42 U.S.C. 4019) is amended—

(1) by striking ''The Director is'' and inserting the following:

''(a) IN GENERAL.—The Administrator is''; and

(2) by adding at the end the following:

''(b) MINIMUM ANNUAL DEDUCTIBLE.—

''(1) PRE-FIRM PROPERTIES.—For any structure which is covered by flood insurance under this title, and on which construction or substantial improvement occurred on or before December 31, 1974, or before the effective date of an initial flood insurance rate map published by the Administrator under section 1360 for the area in which such structure is located, the minimum annual deductible for damage to such structure shall be—

''(A) $1,500, if the flood insurance coverage for such structure covers loss of, or physical damage to, such structure in an amount equal to or less than $100,000; and

''(B) $2,000, if the flood insurance coverage for such structure covers loss of, or physical damage to, such structure in an amount greater than $100,000.

''(2) POST-FIRM PROPERTIES.—For any structure which is covered by flood insurance under this title, and on which construction or substantial improvement occurred after December 31, 1974, or after the effective date of an initial flood insurance rate map published by the Administrator under section 1360 for the area in which such structure is located, the minimum annual deductible for damage to such structure shall be—

''(A) $1,000, if the flood insurance coverage for such structure covers loss of, or physical damage to, such structure in an amount equal to or less than $100,000; and

''(B) $1,250, if the flood insurance coverage for such structure covers loss of, or physical damage to, such structure in an amount greater than $100,000.''.

SEC. 113. CONSIDERATIONS IN DETERMINING CHARGEABLE PREMIUM RATES.

Section 1308 of the National Flood Insurance Act of 1968 (42 U.S.C. 4015), as amended by this Act, is amended—

(1) in subsection (a), by striking '', after consultation with'' and all that follows through ''by regulation'' and inserting ''prescribe, after providing notice'';

(2) in subsection (b)—

(A) in paragraph (1), by striking the period at the end and inserting a semicolon;

(B) in paragraph (2), by striking the comma at the end and inserting a semicolon;

(C) in paragraph (3), by striking '', and'' and inserting a semicolon;

(D) in paragraph (4), by striking the period and inserting ''; and''; and

(E) by adding at the end the following:

''(5) adequate, on the basis of accepted actuarial principles, to cover the average historical loss year obligations incurred by the National Flood Insurance Fund.''; and

(3) by adding at the end the following:

''(i) RULE OF CONSTRUCTION.—For purposes of this section, the calculation of an 'average historical loss year'—

''(1) includes catastrophic loss years; and

''(2) shall be computed in accordance with generally accepted actuarial principles.''.

SEC. 114. RESERVE FUND.

Chapter I of the National Flood Insurance Act of 1968 (42 U.S.C. 4011 et seq.) is amended by inserting after section 1310 (42 U.S.C. 4017) the following:

''SEC. 1310A. RESERVE FUND.

''(a) ESTABLISHMENT OF RESERVE FUND.—In carrying out the flood insurance program authorized by this chapter, the Administrator shall establish in the Treasury of the United States a National Flood Insurance Reserve Fund (in this section referred to as the 'Reserve Fund') which shall—

''(1) be an account separate from any other accounts or funds available to the Administrator; and

''(2) be available for meeting the expected future obligations of the flood insurance program.

''(b) RESERVE RATIO.—Subject to the phase-in requirements under subsection (d), the Reserve Fund shall maintain a balance equal to—

''(1) 1 percent of the sum of the total potential loss exposure of all outstanding flood insurance policies in force in the prior fiscal year; or

''(2) such higher percentage as the Administrator determines to be appropriate, taking into consideration any circumstance that may raise a significant risk of substantial future losses to the Reserve Fund.

''(c) MAINTENANCE OF RESERVE RATIO.—

''(1) IN GENERAL.—The Administrator shall have the authority to establish, increase, or decrease the amount of aggregate annual insurance premiums to be collected for any fiscal year necessary—

''(A) to maintain the reserve ratio required under subsection (b); and

''(B) to achieve such reserve ratio, if the actual balance of such reserve is below the amount required under subsection (b).

''(2) CONSIDERATIONS.—In exercising the authority granted under paragraph (1), the Administrator shall consider—

''(A) the expected operating expenses of the Reserve Fund;

''(B) the insurance loss expenditures under the flood insurance program;

''(C) any investment income generated under the flood insurance program; and

''(D) any other factor that the Administrator determines appropriate.

''(3) LIMITATIONS.—In exercising the authority granted under paragraph (1), the Administrator shall be subject to all other provisions of this Act, including any provisions relating to chargeable premium rates or annual increases of such rates.

''(d) PHASE-IN REQUIREMENTS.—The phase-in requirements under this subsection are as follows:

''(1) IN GENERAL.—Beginning in fiscal year 2012 and not ending until the fiscal year in which the ratio required under subsection (b) is achieved, in each such fiscal year the Administrator shall place in the Reserve Fund an amount equal to not less than 7.5 percent of the reserve ratio required under subsection (b).

''(2) AMOUNT SATISFIED.—As soon as the ratio required under subsection (b) is achieved, and except as provided in paragraph (3), the Administrator shall not be required to set aside any amounts for the Reserve Fund.

''(3) EXCEPTION.—If at any time after the ratio required under subsection (b) is achieved, the Reserve Fund falls below the required ratio under subsection (b), the Administrator shall place in the Reserve Fund for that fiscal year an amount equal to not less than 7.5 percent of the reserve ratio required under subsection (b).

''(e) LIMITATION ON RESERVE RATIO.—In any given fiscal year, if the Administrator determines that the reserve ratio required under subsection (b) cannot be achieved, the Administrator shall submit a report to Congress that—

''(1) describes and details the specific concerns of the Administrator regarding the consequences of the reserve ratio not being achieved;

''(2) demonstrates how such consequences would harm the long-term financial soundness of the flood insurance program; and

''(3) indicates the maximum attainable reserve ratio for that particular fiscal year.''.

SEC. 115. REPAYMENT PLAN FOR BORROWING AUTHORITY.

Section 1309 of the National Flood Insurance Act of 1968 (42 U.S.C. 4016) is amended by adding at the end the following:

''(c) Upon the exercise of the authority established under subsection (a), the Administrator shall transmit a schedule for repayment of such amounts to—

''(1) the Secretary of the Treasury;

''(2) the Committee on Banking, Housing, and Urban Affairs of the Senate; and

''(3) the Committee on Financial Services of the House of Representatives.

''(d) In connection with any funds borrowed by the Administrator under the authority established in subsection (a), the Administrator, beginning 6 months after the date on which such funds are borrowed, and continuing every 6 months thereafter until such borrowed funds are fully repaid, shall submit a report on the progress of such repayment to—

''(1) the Secretary of the Treasury;

''(2) the Committee on Banking, Housing, and Urban Affairs of the Senate; and

''(3) the Committee on Financial Services of the House of Representatives.''.

SEC. 116. PAYMENT OF CONDOMINIUM CLAIMS.

Section 1312 of the National Flood Insurance Act of 1968 (42 U.S.C. 4019), as amended by section 112, is amended by adding at the end the following:

''(c) PAYMENT OF CLAIMS TO CONDOMINIUM OWNERS.—The Administrator may not deny payment for any damage to or loss of property which is covered by flood insurance to condominium owners who purchased such flood insurance separate and apart from the flood insurance purchased by the condominium association in which such owner is a member, based solely, or in any part, on the flood insurance coverage of the condominium association or others on the overall property owned by the condominium association.''.

SEC. 117. TECHNICAL MAPPING ADVISORY COUNCIL.

(a) ESTABLISHMENT.—There is established a council to be known as the Technical Mapping Advisory Council (in this section referred to as the ''Council'').

(b) MEMBERSHIP.—

(1) IN GENERAL.—The Council shall consist of the Administrator, or the designee thereof, and 17 additional members to be appointed by the Administrator or the designee of the Administrator, who shall be—

(A) the Under Secretary of Commerce for Oceans and Atmosphere (or the designee thereof);

(B) a member of a recognized professional surveying association or organization;
(C) a member of a recognized professional mapping association or organization;
(D) a member of a recognized professional engineering association or organization;
(E) a member of a recognized professional association or organization representing flood hazard determination firms;
(F) a representative of the United States Geological Survey;
(G) a representative of a recognized professional association or organization representing State geographic information;
(H) a representative of State national flood insurance coordination offices;
(I) a representative of the Corps of Engineers;
(J) the Secretary of the Interior (or the designee thereof);
(K) the Secretary of Agriculture (or the designee thereof);
(L) a member of a recognized regional flood and storm water management organization;
(M) a representative of a State agency that has entered into a cooperating technical partnership with the Administrator and has demonstrated the capability to produce flood insurance rate maps;
(N) a representative of a local government agency that has entered into a cooperating technical partnership with the Administrator and has demonstrated the capability to produce flood insurance rate maps;
(O) a member of a recognized floodplain management association or organization;
(P) a member of a recognized risk management association or organization; and
(Q) a State mitigation officer.

(2) QUALIFICATIONS.—Members of the Council shall be appointed based on their demonstrated knowledge and competence regarding surveying, cartography, remote sensing, geographic information systems, or the technical aspects of preparing and using flood insurance rate maps.

(c) DUTIES.—The Council shall—
(1) recommend to the Administrator how to improve in a cost-effective manner the—
(A) accuracy, general quality, ease of use, and distribution and dissemination of flood insurance rate maps and risk data; and
(B) performance metrics and milestones required to effectively and efficiently map flood risk areas in the United States;
(2) recommend to the Administrator mapping standards and guidelines for—
(A) flood insurance rate maps; and
(B) data accuracy, data quality, data currency, and data eligibility;
(3) recommend to the Administrator how to maintain, on an ongoing basis, flood insurance rate maps and flood risk identification;
(4) recommend procedures for delegating mapping activities to State and local mapping partners;
(5) recommend to the Administrator and other Federal agencies participating in the Council—
(A) methods for improving interagency and intergovernmental coordination on flood mapping and flood risk determination; and
(B) a funding strategy to leverage and coordinate budgets and expenditures across Federal agencies; and
(6) submit an annual report to the Administrator that contains—
(A) a description of the activities of the Council;
(B) an evaluation of the status and performance of flood insurance rate maps and mapping activities to revise and update flood insurance rate maps, as required under section 118; and
(C) a summary of recommendations made by the Council to the Administrator.

(d) FUTURE CONDITIONS RISK ASSESSMENT AND MODELING REPORT.—
(1) IN GENERAL.—The Council shall consult with scientists and technical experts, other Federal agencies, States, and local communities to—
(A) develop recommendations on how to—
(i) ensure that flood insurance rate maps incorporate the best available climate science to assess flood risks; and
(ii) ensure that the Federal Emergency Management Agency uses the best available methodology to consider the impact of—
(I) the rise in the sea level; and
(II) future development on flood risk; and
(B) not later than 1 year after the date of the enactment of this Act, prepare written recommendations in a future conditions risk assessment and modeling report and to submit such recommendations to the Administrator.

(2) RESPONSIBILITY OF THE ADMINISTRATOR.—The Administrator, as part of the ongoing program to review and update National Flood Insurance Program rate maps under section 118, shall incorporate any future risk assessment submitted under paragraph (1)(B) in any such revision or update.

(e) CHAIRPERSON.—The members of the Council shall elect 1 member to serve as the chairperson of the Council (in this section referred to as the ''Chairperson'').

(f) COORDINATION.—To ensure that the Council's recommendations are consistent, to the maximum extent practicable, with national digital spatial data collection and management standards, the Chairperson shall consult with the Chairperson of the Federal Geographic Data Committee (established pursuant to Office of Management and Budget Circular A–16).

(g) COMPENSATION.—Members of the Council shall receive no additional compensation by reason of their service on the Council.

(h) MEETINGS AND ACTIONS.—
(1) IN GENERAL.—The Council shall meet not less frequently than twice each year at the request of the Chairperson or a majority of its members, and may take action by a vote of the majority of the members.
(2) INITIAL MEETING.—The Administrator, or a person designated by the Administrator, shall request and coordinate the initial meeting of the Council.

(i) OFFICERS.—The Chairperson may appoint officers to assist in carrying out the duties of the Council under subsection (c).

(j) STAFF.—
(1) STAFF OF FEMA.—Upon the request of the Chairperson, the Administrator may detail, on a nonreimbursable basis, personnel of the Federal Emergency Management Agency to assist the Council in carrying out its duties.
(2) STAFF OF OTHER FEDERAL AGENCIES.—Upon request of the Chairperson, any other Federal agency that is a member of the Council may detail, on a nonreimbursable basis, personnel to assist the Council in carrying out its duties.

(k) POWERS.—In carrying out this section, the Council may hold hearings, receive evidence and assistance, provide information, and conduct research, as it considers appropriate.

(l) REPORT TO CONGRESS.—The Administrator, on an annual basis, shall report to the Committee on Banking, Housing, and Urban Affairs of the Senate, the Committee on Financial Services of the House of Representatives, and the Office of Management and Budget on the—
(1) recommendations made by the Council;
(2) actions taken by the Federal Emergency Management Agency to address such recommendations to improve flood insurance rate maps and flood risk data; and
(3) any recommendations made by the Council that have been deferred or not acted upon, together with an explanatory statement.

SEC. 118. NATIONAL FLOOD MAPPING PROGRAM.

(a) REVIEWING, UPDATING, AND MAINTAINING MAPS.—The Administrator, in coordination with the Technical Mapping Advisory Council established under section 117, shall establish an ongoing program under which the Administrator shall review, update, and maintain National Flood Insurance Program rate maps in accordance with this section.

(b) MAPPING.—
(1) IN GENERAL.—In carrying out the program established under subsection (a), the Administrator shall—
(A) identify, review, update, maintain, and publish National Flood Insurance Program rate maps with respect to—
(i) all populated areas and areas of possible population growth located within the 100-year floodplain;
(ii) all populated areas and areas of possible population growth located within the 500-year floodplain;
(iii) areas of residual risk, including areas that are protected by levees, dams, and other flood control structures;
(iv) areas that could be inundated as a result of the failure of a levee, dam, or other flood control structure; and
(v) the level of protection provided by flood control structures;
(B) establish or update flood-risk zone data in all such areas, and make estimates with respect to the rates of probable flood caused loss for the various flood risk zones for each such area; and
(C) use, in identifying, reviewing, updating, maintaining, or publishing any National Flood Insurance Program rate map required under this section or under the National Flood Insurance Act of 1968 (42 U.S.C. 4011 et seq.), the most accurate topography and elevation data available.

(2) MAPPING ELEMENTS.—Each map updated under this section shall—
(A) assess the accuracy of current ground elevation data used for hydrologic and hydraulic modeling of flooding sources and mapping of the flood hazard and wherever necessary acquire new ground elevation data utilizing the most up-to-date geospatial technologies in accordance with guidelines and specifications of the Federal Emergency Management Agency; and
(B) develop National Flood Insurance Program flood data on a watershed basis—
(i) to provide the most technically effective and efficient studies and hydrologic and hydraulic modeling; and
(ii) to eliminate, to the maximum extent possible, discrepancies in base flood elevations between adjacent political subdivisions.

(3) OTHER INCLUSIONS.—In updating maps under this section, the Administrator shall include—
(A) any relevant information on coastal inundation from—
(i) an applicable inundation map of the Corps of Engineers; and
(ii) data of the National Oceanic and Atmospheric Administration relating to storm surge modeling;
(B) any relevant information of the United States Geological Survey on stream flows, watershed characteristics, and topography that is useful in the identification of flood hazard areas, as determined by the Administrator;
(C) any relevant information on land subsidence, coastal erosion areas, and other floor-related hazards;
(D) any relevant information or data of the National Oceanic and Atmospheric Administration and the United States Geological Survey relating to the best available climate

science and the potential for future inundation from sea level rise, increased precipitation, and increased intensity of hurricanes due to global warming; and

(E) any other relevant information as may be recommended by the Technical Mapping Advisory Committee.

(c) STANDARDS.—In updating and maintaining maps under this section, the Administrator shall—

(1) establish standards to—

(A) ensure that maps are adequate for—

(i) flood risk determinations; and

(ii) use by State and local governments in managing development to reduce the risk of flooding; and

(B) facilitate identification and use of consistent methods of data collection and analysis by the Administrator, in conjunction with State and local governments, in developing maps for communities with similar flood risks, as determined by the Administrator; and

(2) publish maps in a format that is—

(A) digital geospatial data compliant;

(B) compliant with the open publishing and data exchange standards established by the Open Geospatial Consortium; and

(C) aligned with official data defined by the National Geodetic Survey.

(d) COMMUNICATION AND OUTREACH.—

(1) IN GENERAL.—The Administrator shall—

(A) work to enhance communication and outreach to States, local communities, and property owners about the effects—

(i) of any potential changes to National Flood Insurance Program rate maps that may result from the mapping program required under this section; and

(ii) that any such changes may have on flood insurance purchase requirements; and

(B) engage with local communities to enhance communication and outreach to the residents of such communities on the matters described under subparagraph (A).

(2) REQUIRED ACTIVITIES.—The communication and outreach activities required under paragraph (1) shall include—

(A) notifying property owners when their properties become included in, or when they are excluded from, an area covered by the mandatory flood insurance purchase requirement under section 102 of the Flood Disaster Protection Act of 1973 (42 U.S.C. 4012a);

(B) educating property owners regarding the flood risk and reduction of this risk in their community, including the continued flood risks to areas that are no longer subject to the flood insurance mandatory purchase requirement;

(C) educating property owners regarding the benefits and costs of maintaining or acquiring flood insurance, including, where applicable, lower-cost preferred risk policies under the National Flood Insurance Act of 1968 (42 U.S.C. 4011 et seq.) for such properties and the contents of such properties;

(D) educating property owners about flood map revisions and the process available to such owners to appeal proposed changes in flood elevations through their community; and

(E) encouraging property owners to maintain or acquire flood insurance coverage.

(e) AUTHORIZATION OF APPROPRIATIONS.—There is authorized to be appropriated to the Administrator to carry out this section $400,000,000 for each of fiscal years 2012 through 2016.

SEC. 119. SCOPE OF APPEALS.

Section 1363 of the National Flood Insurance Act of 1968 (42 U.S.C. 4104) is amended—

(1) in subsection (a)—

(A) in the heading, by inserting ''AND DESIGNATIONS OF SPECIAL FLOOD HAZARD AREAS'' after ''ELEVATION DETERMINATIONS'';

(B) by inserting ''and designating special flood hazard areas'' after ''flood elevations''; and

(C) by striking ''such determinations'' and inserting ''such determinations and designations''; and

(2) in subsection (b)—

(A) in the heading, by inserting ''AND DESIGNATIONS OF SPECIAL FLOOD HAZARD AREAS'' after ''ELEVATION DETERMINATIONS'';

(B) in the first sentence, by inserting ''and designation of special flood hazard areas'' after ''flood elevation determinations''; and

(C) by amending the third sentence to read as follows: ''The sole grounds for appeal shall be the possession of knowledge or information indicating that (1) the elevations being proposed by the Administrator with respect to an identified area having special flood hazards are scientifically or technically incorrect, or (2) the designation of an identified special flood hazard area is scientifically or technically incorrect.''

SEC. 120. SCIENTIFIC RESOLUTION PANEL.

(a) ESTABLISHMENT.—The National Flood Insurance Act of 1968 (42 U.S.C. 4011 et seq.) is amended by inserting after section 1363 (42 U.S.C. 4104) the following:

''SEC. 1363A. SCIENTIFIC RESOLUTION PANEL.

''(a) AVAILABILITY.—

''(1) IN GENERAL.—Pursuant to the authority provided under section 1363(e), the Administrator shall make available an independent review panel, to be known as the Scientific Resolution Panel, to any community—

''(A) that has—

''(i) filed a timely map appeal in accordance with section 1363;

''(ii) completed 60 days of consultation with the Federal Emergency Management Agency on the appeal; and

''(iii) not allowed more than 120 days, or such longer period as may be provided by the Administrator by waiver, to pass since the end of the appeal period; or

''(B) that has received an unsatisfactory ruling under the map revision process established pursuant to section 1360(f).

''(2) APPEALS BY OWNERS AND LESSEES.—If a community and an owner or lessee of real property within the community appeal a proposed determination of a flood elevation under section 1363(b), upon the request of the community—

''(A) the owner or lessee shall submit scientific and technical data relating to the appeals to the Scientific Resolution Panel; and

''(B) the Scientific Resolution Panel shall make a determination with respect to the appeals in accordance with subsection (c).

''(3) DEFINITION.—For purposes of paragraph (1)(B), an 'unsatisfactory ruling' means that a community—

''(A) received a revised Flood Insurance Rate Map from the Federal Emergency Management Agency, via a Letter of Final Determination, after September 30, 2008 and prior to the date of enactment of this section;

''(B) has subsequently applied for a Letter of Map Revision or Physical Map Revision with the Federal Emergency Management Agency; and

''(C) has received an unfavorable ruling on their request for a map revision.

''(b) MEMBERSHIP.—The Scientific Resolution Panel made available under subsection (a) shall consist of 5 members with expertise that relate to the creation and study of flood hazard maps and flood insurance. The Scientific Resolution Panel may include representatives from Federal agencies not involved in the mapping study in question and from other impartial experts. Employees of the Federal Emergency Management Agency may not serve on the Scientific Resolution Panel.

''(c) DETERMINATION.—

''(1) IN GENERAL.—Following deliberations, and not later than 90 days after its formation, the Scientific Resolution Panel shall issue a determination of resolution of the dispute. Such determination shall set forth recommendations for the base flood elevation determination or the determination of an area having special flood hazards that shall be reflected in the Flood Insurance Rate Maps.

''(2) BASIS.—The determination of the Scientific Resolution Panel shall be based on—

''(A) data previously provided to the Administrator by the community, and, in the case of a dispute submitted under subsection (a)(2), an owner or lessee of real property in the community; and

''(B) data provided by the Administrator.

''(3) NO ALTERNATIVE DETERMINATIONS PERMISSIBLE.—The Scientific Resolution Panel—

''(A) shall provide a determination of resolution of a dispute that—

''(i) is either in favor of the Administrator or in favor of the community on each distinct element of the dispute; or

''(ii) in the case of a dispute submitted under subsection (a)(2), is in favor of the Administrator, in favor of the community, or in favor of the owner or lessee of real property in the community on each distinct element of the dispute; and

''(B) may not offer as a resolution any other alternative determination.

''(4) EFFECT OF DETERMINATION.—

''(A) BINDING.—The recommendations of the Scientific Resolution Panel shall be binding on all appellants and not subject to further judicial review unless the Administrator determines that implementing the determination of the panel would—

''(i) pose a significant threat due to failure to identify a substantial risk of special flood hazards; or

''(ii) violate applicable law.

''(B) WRITTEN JUSTIFICATION NOT TO ENFORCE.—If the Administrator elects not to implement the determination of the Scientific Resolution Panel pursuant to subparagraph (A), then not later than 60 days after the issuance of the determination, the Administrator shall issue a written justification explaining such election.

''(C) APPEAL OF DETERMINATION NOT TO ENFORCE.—If the Administrator elects not to implement the determination of the Scientific Resolution Panel pursuant to subparagraph (A), the community may appeal the determination of the Administrator as provided for under section 1363(g).

''(d) MAPS USED FOR INSURANCE AND MANDATORY PURCHASE REQUIREMENTS.—With respect to any community that has a dispute that is being considered by the Scientific Resolution Panel formed pursuant to this subsection, the Federal Emergency Management Agency shall ensure that for each such community that—

''(1) the Flood Insurance Rate Map described in the most recently issued Letter of Final Determination shall be in force and effect with respect to such community; and

''(2) flood insurance shall continue to be made available to the property owners and residents of the participating community.''.

(b) CONFORMING AMENDMENTS.—

(1) ADMINISTRATIVE REVIEW.—Section 1363(e) of the National Flood Insurance Act of 1968 (42 U.S.C. 4104(e)) is amended by striking ''an independent scientific body or appropriate Federal agency for advice'' and inserting ''the Scientific Resolution Panel provided for in section 1363A''.

(2) JUDICIAL REVIEW.—The first sentence of section 1363(g) of the National Flood Insurance Act of 1968 (42 U.S.C. 4104(g)) is amended by striking ''Any appellant'' and inserting

''Except as provided in section 1363A, any appellant''.

SEC. 121. REMOVAL OF LIMITATION ON STATE CONTRIBUTIONS FOR UPDATING FLOOD MAPS.

Section 1360(f)(2) of the National Flood Insurance Act of 1968 (42 U.S.C. 4101(f)(2)) is amended by striking '', but which may not exceed 50 percent of the cost of carrying out the requested revision or update''.

SEC. 122. COORDINATION.

(a) INTERAGENCY BUDGET CROSSCUT AND COORDINATION REPORT.—

(1) IN GENERAL.—The Secretary of Homeland Security, the Administrator, the Director of the Office of Management and Budget, and the heads of each Federal department or agency carrying out activities under sections 118 and 119 shall work together to ensure that flood risk determination data and geospatial data are shared among Federal agencies in order to coordinate the efforts of the Nation to reduce its vulnerability to flooding hazards.

(2) REPORT.—Not later than 30 days after the submission of the budget of the United States Government by the President to Congress, the Director of the Office of Management and Budget, in coordination with the Federal Emergency Management Agency, the United States Geological Survey, the National Oceanic and Atmospheric Administration, the Army Corps of Engineers, and other Federal agencies, as appropriate, shall submit to the appropriate authorizing and appropriating committees of the Senate and the House of Representatives an interagency budget crosscut and coordination report, certified by the Secretary or head of each such agency, that—

(A) contains an interagency budget crosscut report that displays relevant sections of the budget proposed for each of the Federal agencies working on flood risk determination data and digital elevation models, including any planned interagency or intra-agency transfers; and

(B) describes how the efforts aligned with such sections complement one another.

(b) DUTIES OF THE ADMINISTRATOR.—In carrying out sections 118 and 119, the Administrator shall—

(1) participate, pursuant to section 216 of the E–Government Act of 2002 (44 U.S.C. 3501 note), in the establishment of such standards and common protocols as are necessary to assure the interoperability of geospatial data for all users of such information;

(2) coordinate with, seek assistance and cooperation of, and provide a liaison to the Federal Geographic Data Committee pursuant to the Office of Management and Budget Circular A–16 and Executive Order 12906 (43 U.S.C. 1457 note; relating to the National Spatial Data Infrastructure) for the implementation of and compliance with such standards;

(3) integrate with, leverage, and coordinate funding of, to the maximum extent practicable, the current flood mapping activities of each unit of State and local government;

(4) integrate with, leverage, and coordinate, to the maximum extent practicable, the current geospatial activities of other Federal agencies and units of State and local government; and

(5) develop a funding strategy to leverage and coordinate budgets and expenditures, and to maintain or establish joint funding and other agreement mechanisms with other Federal agencies and units of State and local government to share in the collection and utilization of geospatial data among all governmental users.

SEC. 123. INTERAGENCY COORDINATION STUDY.

(a) IN GENERAL.—The Administrator shall enter into a contract with the National Academy of Public Administration to conduct a study on how the Federal Emergency Management Agency—

(1) should improve interagency and intergovernmental coordination on flood mapping, including a funding strategy to leverage and coordinate budgets and expenditures; and

(2) can establish joint funding mechanisms with other Federal agencies and units of State and local government to share the collection and utilization of data among all governmental users.

(b) TIMING.—Not later than 180 days after the date of the enactment of this title, the National Academy of Public Administration shall report the findings of the study required under subsection (a) to—

(1) the Committee on Banking, Housing, and Urban Affairs of the Senate;

(2) the Committee on Financial Services of the House of Representatives;

(3) the Committee on Appropriations of the Senate; and

(4) the Committee on Appropriations of the House of Representatives.

SEC. 124. NONMANDATORY PARTICIPATION.

(a) NONMANDATORY PARTICIPATION IN NATIONAL FLOOD INSURANCE PROGRAM FOR 500-YEAR FLOODPLAIN.—Any area located within the 500-year floodplain shall not be subject to the mandatory purchase requirements of sections 102 or 202 of the Flood Disaster Protection Act of 1973 (42 U.S.C. 4012a and 4106).

(b) NOTICE.—

(1) BY ADMINISTRATOR.—In carrying out the National Flood Insurance Program, the Administrator shall provide notice to any community located in an area within the 500-year floodplain.

(2) TIMING OF NOTICE.—The notice required under paragraph (1) shall be made not later than 6 months after the date of completion of the initial mapping of the 500-year floodplain, as required under section 118.

(3) LENDER REQUIRED NOTICE.—

(A) REGULATED LENDING INSTITUTIONS.—Each Federal or State entity for lending regulation (after consultation and coordination with the Federal Financial Institutions Examination Council) shall, by regulation, require regulated lending institutions, as a condition of making, increasing, extending, or renewing any loan secured by property located in an area within the 500-year floodplain, to notify the purchaser or lessee (or obtain satisfactory assurances that the seller or lessor has notified the purchaser or lessee) and the servicer of the loan that such property is located in an area within the 500-year floodplain, in a manner that is consistent with, and substantially identical to, the notice required under section 1364(a)(1) of the National Flood Insurance Act of 1968 (42 U.S.C. 4104a(a)(1)).

(B) FEDERAL OR STATE AGENCY LENDERS.—Each Federal or State agency lender shall, by regulation, require notification in the same manner as provided under subparagraph (A) with respect to any loan that is made by a Federal or State agency lender and secured by property located in an area within the 500-year floodplain.

(C) PENALTY FOR NONCOMPLIANCE.—Any regulated lending institution or Federal or State agency lender that fails to comply with the notice requirements established by this paragraph shall be subject to the penalties prescribed under section 102(f)(5) of the Flood Disaster Protection Act of 1973 (42 U.S.C. 4012a(f)(5)).

SEC. 125. NOTICE OF FLOOD INSURANCE AVAILABILITY UNDER RESPA.

Section 5(b) of the Real Estate Settlement Procedures Act of 1974 (12 U.S.C. 2604(b)), as amended by section 1450 of the Dodd-Frank Wall Street Reform and Consumer Protection Act (Public Law 111–203; 124 Stat. 2174), is amended by adding at the end the following:

''(14) An explanation of flood insurance and the availability of flood insurance under the National Flood Insurance Program, whether or not the real estate is located in an area having special flood hazards.''.

SEC. 126. PARTICIPATION IN STATE DISASTER CLAIMS MEDIATION PROGRAMS.

Chapter I of the National Flood Insurance Act of 1968 (42 U.S.C. 4011 et seq.) is amended by inserting after section 1313 (42 U.S.C. 4020) the following:

''SEC. 1314. PARTICIPATION IN STATE DISASTER CLAIMS MEDIATION PROGRAMS.

''(a) REQUIREMENT TO PARTICIPATE.—In the case of the occurrence of a major disaster, as defined in section 102 of the Robert T. Stafford Disaster Relief and Emergency Assistance Act (42 U.S.C. 5122), that may have resulted in flood damage covered under the flood insurance program established under this chapter and other personal lines residential property insurance coverage offered by a State regulated insurer, upon a request made by the insurance commissioner of a State (or such other official responsible for regulating the business of insurance in the State) for the participation of representatives of the Administrator in a program sponsored by such State for nonbinding mediation of insurance claims resulting from a major disaster, the Administrator shall cause representatives of the flood insurance program to participate in such a State program where claims under the flood insurance program are involved to expedite settlement of flood damage claims resulting from such disaster.

''(b) EXTENT OF PARTICIPATION.—In satisfying the requirements of subsection (a), the Administrator shall require that each representative of the Administrator—

''(1) be certified for purposes of the flood insurance program to settle claims against such program resulting from such disaster in amounts up to the limits of policies under such program;

''(2) attend State-sponsored mediation meetings regarding flood insurance claims resulting from such disaster at such times and places as may be arranged by the State;

''(3) participate in good faith negotiations toward the settlement of such claims with policyholders of coverage made available under the flood insurance program; and

''(4) finalize the settlement of such claims on behalf of the flood insurance program with such policyholders.

''(c) COORDINATION.—Representatives of the Administrator shall at all times coordinate their activities with insurance officials of the State and representatives of insurers for the purposes of consolidating and expediting settlement of claims under the national flood insurance program resulting from such disaster.

''(d) QUALIFICATIONS OF MEDIATORS.—Each State mediator participating in State-sponsored mediation under this section shall be—

''(1)(A) a member in good standing of the State bar in the State in which the mediation is to occur with at least 2 years of practical experience; and

''(B) an active member of such bar for at least 1 year prior to the year in which such mediator's participation is sought; or

''(2) a retired trial judge from any United States jurisdiction who was a member in good standing of the bar in the State in which the judge presided for at least 5 years prior to the year in which such mediator's participation is sought.

''(e) MEDIATION PROCEEDINGS AND DOCUMENTS PRIVILEGED.—As a condition of participation, all statements made and documents produced pursuant to State-sponsored

mediation involving representatives of the Administrator shall be deemed privileged and confidential settlement negotiations made in anticipation of litigation.

''(f) LIABILITY, RIGHTS, OR OBLIGATIONS NOT AFFECTED.—Participation in State-sponsored mediation, as described in this section does not—

''(1) affect or expand the liability of any party in contract or in tort; or

''(2) affect the rights or obligations of the parties, as established—

''(A) in any regulation issued by the Administrator, including any regulation relating to a standard flood insurance policy;

''(B) under this Act; and

''(C) under any other provision of Federal law.

''(g) EXCLUSIVE FEDERAL JURISDICTION.—Participation in State-sponsored mediation shall not alter, change, or modify the original exclusive jurisdiction of United States courts, as set forth in this Act.

''(h) COST LIMITATION.—Nothing in this section shall be construed to require the Administrator or a representative of the Administrator to pay additional mediation fees relating to flood insurance claims associated with a State-sponsored mediation program in which such representative of the Administrator participates.

''(i) EXCEPTION.—In the case of the occurrence of a major disaster that results in flood damage claims under the national flood insurance program and that does not result in any loss covered by a personal lines residential property insurance policy—

''(1) this section shall not apply; and

''(2) the provisions of the standard flood insurance policy under the national flood insurance program and the appeals process established under section 205 of the Bunning-Bereuter-Blumenauer Flood Insurance Reform Act of 2004 (42 U.S.C. 4011 note) and the regulations issued pursuant to such section shall apply exclusively.

''(j) REPRESENTATIVES OF THE ADMINISTRATOR.—For purposes of this section, the term 'representatives of the Administrator' means representatives of the national flood insurance program who participate in the appeals process established under section 205 of the Bunning-Bereuter-Blumenauer Flood Insurance Reform Act of 2004 (42 U.S.C. 4011 note).''.

SEC. 127. ADDITIONAL AUTHORITY OF FEMA TO COLLECT INFORMATION ON CLAIMS PAYMENTS.

(a) IN GENERAL.—The Administrator shall collect, from property and casualty insurance companies that are authorized by the Administrator to participate in the Write Your Own program any information and data needed to determine the accuracy of the resolution of flood claims filed on any property insured with a standard flood insurance policy obtained under the program that was subject to a flood.

(b) TYPE OF INFORMATION TO BE COLLECTED.—The information and data to be collected under subsection (a) may include—

(1) any adjuster estimates made as a result of flood damage, and if the insurance company also insures the property for wind damage—

(A) any adjuster estimates for both wind and flood damage;

(B) the amount paid to the property owner for wind and flood claims;

(C) the total amount paid to the policyholder for damages as a result of the event that caused the flooding and other losses;

(2) any amounts paid to the policyholder by the insurance company for damages to the insured property other than flood damages; and

(3) the total amount paid to the policyholder by the insurance company for all damages incurred to the insured property as a result of the flood.

SEC. 128. OVERSIGHT AND EXPENSE REIMBURSEMENTS OF INSURANCE COMPANIES.

(a) SUBMISSION OF BIENNIAL REPORTS.—

(1) TO THE ADMINISTRATOR.—Not later than 20 days after the date of the enactment of this Act, each property and casualty insurance company that is authorized by the Administrator to participate in the Write Your Own program shall submit to the Administrator any biennial report required by the Federal Emergency Management Agency to be prepared in the prior 5 years by such company.

(2) TO GAO.—Not later than 10 days after the submission of the biennial reports under paragraph (1), the Administrator shall submit all such reports to the Comptroller General of the United States.

(3) NOTICE TO CONGRESS OF FAILURE TO COMPLY.—The Administrator shall notify and report to the Committee on Banking, Housing, and Urban Affairs of the Senate and the Committee on Financial Services of the House of Representatives on any property and casualty insurance company participating in the Write Your Own program that failed to submit its biennial reports as required under paragraph (1).

(4) FAILURE TO COMPLY.—A property and casualty insurance company that is authorized by the Administrator to participate in the Write Your Own program which fails to comply with the reporting requirement under this subsection or the requirement under section 62.23(j)(1) of title 44, Code of Federal Regulations (relating to biennial audit of the flood insurance financial statements) shall be subject to a civil penalty in an amount equal to $1,000 per day for each day that the company remains in noncompliance with either such requirement.

(b) METHODOLOGY TO DETERMINE REIMBURSED EXPENSES.—Not later than 180 days after the date of the enactment of this Act, the Administrator shall develop a methodology for determining the appropriate amounts that participating property and casualty insurance companies should be reimbursed for selling, writing, and servicing flood insurance policies and adjusting flood insurance claims on behalf of the National Flood Insurance Program. The methodology shall be developed using actual expense data for the flood insurance line and can be derived from—

(1) flood insurance expense data produced by participating property and casualty insurance companies;

(2) flood insurance expense data collected by the National Association of Insurance Commissioners; or

(3) a combination of the methodologies described in paragraphs (1) and (2).

(c) SUBMISSION OF EXPENSE REPORTS.—To develop the methodology established under subsection (b), the Administrator may require each property and casualty insurance company participating in the Write Your Own program to submit a report to the Administrator, in a format determined by the Administrator and within 60 days of the request, that details the expense levels of each such company for selling, writing, and servicing standard flood insurance policies and adjusting and servicing claims.

(d) FEMA RULEMAKING ON REIMBURSEMENT OF EXPENSES UNDER THE WYO PROGRAM.—Not later than 12 months after the date of the enactment of this Act, the Administrator shall conduct a rulemaking proceeding to formulate revised expense reimbursements to property and casualty insurance companies participating in the Write Your Own program for their expenses (including their operating and administrative expenses for adjustment of claims) in selling, writing, and servicing standard flood insurance policies, including how such companies shall be reimbursed in both catastrophic and noncatastrophic years. Such reimbursements shall be structured to ensure reimbursements track the actual expenses, including standard business costs and operating expenses, of such companies as close as practicably possible.

(e) REPORT OF THE ADMINISTRATOR.—Not later than 60 days after the effective date of any final rule established pursuant to subsection (d), the Administrator shall submit to the Committee on Banking, Housing, and Urban Affairs of the Senate and the Committee on Financial Services of the House of Representatives a report containing—

(1) the specific rationale and purposes of such rule;

(2) the reasons for the adoption of the policies contained in such rule; and

(3) the degree to which such rule accurately represents the true operating costs and expenses of property and casualty insurance companies participating in the Write Your Own program.

(f) GAO STUDY AND REPORT ON EXPENSES OF WYO PROGRAM.—

(1) STUDY.—Not later than 180 days after the effective date of the final rule established pursuant to subsection (d), the Comptroller General of the United States shall—

(A) conduct a study on the efficacy, adequacy, and sufficiency of the final rules established pursuant to subsection (d); and

(B) report to the Committee on Banking, Housing, and Urban Affairs of the Senate and the Committee on Financial Services of the House of Representatives on the findings of the study conducted under subparagraph (A).

(2) GAO AUTHORITY.—In conducting the study and report required under paragraph (1), the Comptroller General—

(A) may use any previous findings, studies, or reports that the Comptroller General previously completed on the Write Your Own program;

(B) shall determine if—

(i) the final rules established pursuant to subsection (d) allow the Federal Emergency Management Agency to access adequate information regarding the actual expenses of property and casualty insurance companies participating in the Write Your Own program; and

(ii) the actual reimbursements paid out under the final rule established in subsection (d) accurately reflect the expenses reported by property and casualty insurance companies participating in the Write Your Own program, including the standard business costs and operating expenses of such companies; and

(C) shall analyze the effect of such rules on the level of participation of property and casualty insurers in the Write Your Own program.

SEC. 129. MITIGATION.

(a) MITIGATION ASSISTANCE GRANTS.—Section 1366 of the National Flood Insurance Act of 1968 (42 U.S.C. 4104c) is amended—

(1) by striking subsections (b), (d), (f), (g), (h), (k), and (m);

(2) by redesignating subsections (c), (e), (i), and (j) as subsections (b), (c), (e), and (f), respectively;

(3) in subsection (a), by striking the last sentence and inserting the following: ''Such financial assistance shall be made available—

''(1) to States and communities in the form of grants under this section for carrying out mitigation activities;

''(2) to States and communities in the form of grants under this section for carrying out mitigation activities that reduce flood damage to severe repetitive loss structures; and

''(3) to property owners in the form of direct grants under this section for carrying out mitigation activities that reduce flood damage to individual structures for which 2 or more claim payments for losses have been made under flood insurance coverage under this title if the Administrator, after consultation with the State and community, determines that neither the State nor community in which such a structure is located has the capacity to manage such grants.'';

(4) in subsection (b), as so redesignated, in the first sentence—

(A) by striking ''and provides protection against'' and inserting ''provides for reduction of''; and

(B) by inserting before the period at the end the following: '', and may be included in a multi-hazard mitigation plan'';

(5) in subsection (c), as so redesignated—

(A) in paragraph (1), by striking ''(1) USE OF AMOUNTS.—'' and all that follows through the end of the first sentence and inserting the following:

''(1) REQUIREMENT OF CONSISTENCY WITH APPROVED MITIGATION PLAN.—Amounts provided under this section may be used only for mitigation activities that are consistent with mitigation plans that are approved by the Administrator and identified under paragraph (4).'';

(B) by striking paragraphs (2), (3), and (4) and inserting the following new paragraphs:

''(2) REQUIREMENTS OF TECHNICAL FEASIBILITY, COST EFFECTIVENESS, AND INTEREST OF NFIF.—The Administrator may approve only mitigation activities that the Administrator determines are technically feasible and cost-effective and in the interest of, and represent savings to, the National Flood Insurance Fund. In making such determinations, the Administrator shall take into consideration recognized ancillary benefits.

''(3) PRIORITY FOR MITIGATION ASSISTANCE.—In providing grants under this section for mitigation activities, the Administrator shall give priority for funding to activities that the Administrator determines will result in the greatest savings to the National Flood Insurance Fund, including activities for—

''(A) severe repetitive loss structures;

''(B) repetitive loss structures; and

''(C) other subsets of structures as the Administrator may establish.'';

(C) by redesignating paragraph (5) as paragraph (4);

(D) in paragraph (4), as so redesignated—

(i) in the matter preceding subparagraph (A), by striking ''The Director'' and all that follows through ''Such activities may'' and inserting ''Eligible activities under a mitigation plan may'';

(ii) by striking subparagraphs (E) and (H);

(iii) by redesignating subparagraphs (D), (F), and (G) as subparagraphs (E), (G), and (H), respectively;

(iv) by inserting after subparagraph (C) the following new subparagraph:

''(D) elevation, relocation, or floodproofing of utilities (including equipment that serve structures);'';

(v) by inserting after subparagraph (E), as so redesignated, the following new subparagraph:

''(F) the development or update of mitigation plans by a State or community which meet the planning criteria established by the Administrator, except that the amount from grants under this section that may be used under this subparagraph may not exceed $50,000 for any mitigation plan of a State or $25,000 for any mitigation plan of a community;'';

(vi) in subparagraph (H); as so redesignated, by striking ''and'' at the end; and

(vii) by adding at the end the following new subparagraphs:

''(I) other mitigation activities not described in subparagraphs (A) through (G) or the regulations issued under subparagraph (H), that are described in the mitigation plan of a State or community; and

''(J) without regard to the requirements under subsections (d)(1) and (d)(2), and if the State applied for and was awarded at least $1,000,000 in grants available under this section in the prior fiscal year, technical assistance to communities to identify eligible activities, to develop grant applications, and to implement grants awarded under this section, not to exceed $50,000 to any one State in any fiscal year.'';

(E) by adding at the end the following new paragraph:

''(5) ELIGIBILITY OF DEMOLITION AND REBUILDING OF PROPERTIES.—The Administrator shall consider as an eligible activity the demolition and rebuilding of properties to at least base flood elevation or greater, if required by the Administrator or if required by any State regulation or local ordinance, and in accordance with criteria established by the Administrator.''; and

(6) by inserting after subsection (c), as so redesignated, the following new subsection:

''(d) MATCHING REQUIREMENT.—The Administrator may provide grants for eligible mitigation activities as follows:

''(1) SEVERE REPETITIVE LOSS STRUCTURES.—In the case of mitigation activities to severe repetitive loss structures, in an amount up to 100 percent of all eligible costs.

''(2) REPETITIVE LOSS STRUCTURES.—In the case of mitigation activities to repetitive loss structures, in an amount up to 90 percent of all eligible costs.

''(3) OTHER MITIGATION ACTIVITIES.—In the case of all other mitigation activities, in an amount up to 75 percent of all eligible costs.'';

(7) in subsection (e)(2), as so redesignated—

(A) by striking ''certified under subsection (g)'' and inserting ''required under subsection (d)''; and

(B) by striking ''3 times the amount'' and inserting ''the amount'';

(8) in subsection (f)(1), as so redesignated, by striking ''Riegle Community Development and Regulatory Improvement Act of 1994'' and inserting ''Flood Insurance Reform and Modernization Act of 2012''; and

(9) by adding at the end the following new subsections:

''(g) FAILURE TO MAKE GRANT AWARD WITHIN 5 YEARS.—For any application for a grant under this section for which the Administrator fails to make a grant award within 5 years of the date of the application, the grant application shall be considered to be denied and any funding amounts allocated for such grant applications shall remain in the National Flood Mitigation Fund under section 1367 of this title and shall be made available for grants under this section.

''(h) DEFINITIONS.—For purposes of this section, the following definitions shall apply:

''(1) COMMUNITY.—The term 'community' means—

''(A) a political subdivision that—

''(i) has zoning and building code jurisdiction over a particular area having special flood hazards; and

''(ii) is participating in the national flood insurance program; or

''(B) a political subdivision of a State, or other authority, that is designated by political subdivisions, all of which meet the requirements of subparagraph (A), to administer grants for mitigation activities for such political subdivisions.

''(2) REPETITIVE LOSS STRUCTURE.—The term 'repetitive loss structure' has the meaning given such term in section 1370.

''(3) SEVERE REPETITIVE LOSS STRUCTURE.—The term 'severe repetitive loss structure' means a structure that—

''(A) is covered under a contract for flood insurance made available under this title; and

''(B) has incurred flood-related damage—

''(i) for which 4 or more separate claims payments have been made under flood insurance coverage under this title, with the amount of each such claim exceeding $5,000, and with the cumulative amount of such claims payments exceeding $20,000; or

''(ii) for which at least 2 separate claims payments have been made under such coverage, with the cumulative amount of such claims exceeding the value of the insured structure.''.

(b) ELIMINATION OF GRANTS PROGRAM FOR REPETITIVE INSURANCE CLAIMS PROPERTIES.—Chapter I of the National Flood Insurance Act of 1968 is amended by striking section 1323 (42 U.S.C. 4030).

(c) ELIMINATION OF PILOT PROGRAM FOR MITIGATION OF SEVERE REPETITIVE LOSS PROPERTIES.—Chapter III of the National Flood Insurance Act of 1968 is amended by striking section 1361A (42 U.S.C. 4102a).

(d) NATIONAL FLOOD INSURANCE FUND.—Section 1310(a) of the National Flood Insurance Act of 1968 (42 U.S.C. 4017(a)) is amended—

(1) in paragraph (6), by inserting ''and'' after the semicolon;

(2) in paragraph (7), by striking the semicolon and inserting a period; and

(3) by striking paragraphs (8) and (9).

(e) NATIONAL FLOOD MITIGATION FUND.—Section 1367 of the National Flood Insurance Act of 1968 (42 U.S.C. 4104d) is amended—

(1) in subsection (b)—

(A) by striking paragraph (1) and inserting the following new paragraph:

''(1) in each fiscal year, amounts from the National Flood Insurance Fund not to exceed $90,000,000 and to remain available until expended, of which—

''(A) not more than $40,000,000 shall be available pursuant to subsection (a) of this section for assistance described in section 1366(a)(1);

''(B) not more than $40,000,000 shall be available pursuant to subsection (a) of this section for assistance described in section 1366(a)(2); and

''(C) not more than $10,000,000 shall be available pursuant to subsection (a) of this section for assistance described in section 1366(a)(3);''; and

(B) in paragraph (3), by striking ''section 1366(i)'' and inserting ''section 1366(e)'';

(2) in subsection (c), by striking ''sections 1366 and 1323'' and inserting ''section 1366'';

(3) by redesignating subsections (d) and (e) as subsections (f) and (g), respectively; and

(4) by inserting after subsection (c) the following new subsections:

''(d) PROHIBITION ON OFFSETTING COLLECTIONS.—Notwithstanding any other provision of this title, amounts made available pursuant to this section shall not be subject to offsetting collections through premium rates for flood insurance coverage under this title.

''(e) CONTINUED AVAILABILITY AND REALLOCATION.—Any amounts made available pursuant to subparagraph (A), (B), or (C) of subsection (b)(1) that are not used in any fiscal year shall continue to be available for the purposes specified in such subparagraph of subsection (b)(1) pursuant to which such amounts were made available, unless the Administrator determines that reallocation of such unused amounts to meet demonstrated need for other mitigation activities under section 1366 is in the best interest of the National Flood Insurance Fund.''.

(f) INCREASED COST OF COMPLIANCE COVERAGE.—Section 1304(b)(4) of the National

Flood Insurance Act of 1968 (42 U.S.C. 4011(b)(4)) is amended—

(1) by striking subparagraph (B); and

(2) by redesignating subparagraphs (C), (D), and (E) as subparagraphs (B), (C), and (D), respectively.

SEC. 130. FLOOD PROTECTION STRUCTURE ACCREDITATION TASK FORCE.

(a) DEFINITIONS.—In this section—

(1) the term ''flood protection structure accreditation requirements'' means the requirements established under section 65.10 of title 44, Code of Federal Regulations, for levee systems to be recognized on maps created for purposes of the National Flood Insurance Program;

(2) the term ''National Committee on Levee Safety'' means the Committee on Levee Safety established under section 9003 of the National Levee Safety Act of 2007 (33 U.S.C. 3302); and

(3) the term ''task force'' means the Flood Protection Structure Accreditation Task Force established under subsection (b).

(b) ESTABLISHMENT.—

(1) IN GENERAL.—The Administrator and the Secretary of the Army, acting through the Chief of Engineers, in cooperation with the National Committee on Levee Safety, shall jointly establish a Flood Protection Structure Accreditation Task Force.

(2) DUTIES.—

(A) DEVELOPING PROCESS.—The task force shall develop a process to better align the information and data collected by or for the United States Army Corps of Engineers under the Inspection of Completed Works Program with the flood protection structure accreditation requirements so that—

(i) information and data collected for either purpose can be used interchangeably; and

(ii) information and data collected by or for the United States Army Corps of Engineers under the Inspection of Completed Works Program is sufficient to satisfy the flood protection structure accreditation requirements.

(B) GATHERING RECOMMENDATIONS.—The task force shall gather, and consider in the process developed under subparagraph (A), recommendations from interested persons in each region relating to the information, data, and accreditation requirements described in subparagraph (A).

(3) CONSIDERATIONS.—In developing the process under paragraph (2), the task force shall consider changes to—

(A) the information and data collected by or for the United States Army Corps of Engineers under the Inspection of Completed Works Program; and

(B) the flood protection structure accreditation requirements.

(4) RULE OF CONSTRUCTION.—Nothing in this section shall be construed to require a reduction in the level of public safety and flood control provided by accredited levees, as determined by the Administrator for purposes of this section.

(c) IMPLEMENTATION.—The Administrator and the Secretary of the Army, acting through the Chief of Engineers, shall implement the process developed by the task force under subsection (b).

(d) REPORTS.—The Administrator and the Secretary of the Army, acting through the Chief of Engineers, in cooperation with the National Committee on Levee Safety, shall jointly submit to the Committee on Banking, Housing, and Urban Affairs and the Committee on Environment and Public Works of the Senate and the Committee on Financial Services, the Committee on Transportation and Infrastructure, and the Committee on Natural Resources of the House of Representatives reports concerning the activities of the task force and the implementation of the process developed by the task force under subsection (b), including—

(1) an interim report, not later than 180 days after the date of enactment of this Act; and

(2) a final report, not later than 1 year after the date of enactment of this Act.

(e) TERMINATION.—The task force shall terminate on the date of submission of the report under subsection (d)(2).

SEC. 131. FLOOD IN PROGRESS DETERMINATIONS.

(a) REPORT.—

(1) REVIEW.—The Administrator shall review—

(A) the processes and procedures for determining that a flood event has commenced or is in progress for purposes of flood insurance coverage made available under the National Flood Insurance Program;

(B) the processes and procedures for providing public notification that such a flood event has commenced or is in progress;

(C) the processes and procedures regarding the timing of public notification of flood insurance requirements and availability; and

(D) the effects and implications that weather conditions, including rainfall, snowfall, projected snowmelt, existing water levels, and other conditions, have on the determination that a flood event has commenced or is in progress.

(2) REPORT.—Not later than 6 months after the date of enactment of this Act, the Administrator shall submit a report to Congress that describes—

(A) the results and conclusions of the review under paragraph (1); and

(B) any actions taken, or proposed actions to be taken, by the Administrator to provide for more precise and technical processes and procedures for determining that a flood event has commenced or is in progress.

(b) EFFECTIVE DATE OF POLICIES COVERING PROPERTIES AFFECTED BY FLOODING OF THE MISSOURI RIVER IN 2011.—

(1) ELIGIBLE COVERAGE.—For purposes of this subsection, the term ''eligible coverage'' means coverage under a new contract for flood insurance coverage under the National Flood Insurance Program, or a modification to coverage under an existing flood insurance contract, for property damaged by the flooding of the Missouri River that commenced on June 1, 2011, that was purchased or made during the period beginning May 1, 2011, and ending June 6, 2011.

(2) EFFECTIVE DATES.—Notwithstanding section 1306(c) of the National Flood Insurance Act of 1968 (42 U.S.C. 4013(c)), or any other provision of law, any eligible coverage shall—

(A) be deemed to take effect on the date that is 30 days after the date on which all obligations for the eligible coverage (including completion of the application and payment of any initial premiums owed) are satisfactorily completed; and

(B) cover damage to property occurring after the effective date described in subparagraph (A) that resulted from the flooding of the Missouri River that commenced on June 1, 2011, if the property did not suffer damage or loss as a result of such flooding before the effective date described in subparagraph (A).

SEC. 132. CLARIFICATION OF RESIDENTIAL AND COMMERCIAL COVERAGE LIMITS.

Section 1306(b) of the National Flood Insurance Act of 1968 (42 U.S.C. 4013(b)) is amended—

(1) in paragraph (2)—

(A) by striking ''in the case of any residential property'' and inserting ''in the case of any residential building designed for the occupancy of from one to four families''; and

(B) by striking ''shall be made available to every insured upon renewal and every applicant for insurance so as to enable such insured or applicant to receive coverage up to a total amount (including such limits specified in paragraph (1)(A)(i)) of $250,000'' and inserting ''shall be made available, with respect to any single such building, up to an aggregate liability (including such limits specified in paragraph (1)(A)(i)) of $250,000''; and

(2) in paragraph (4)—

(A) by striking ''in the case of any nonresidential property, including churches,'' and inserting ''in the case of any nonresidential building, including a church,''; and

(B) by striking ''shall be made available to every insured upon renewal and every applicant for insurance, in respect to any single structure, up to a total amount (including such limit specified in subparagraph (B) or (C) of paragraph (1), as applicable) of $500,000 for each structure and $500,000 for any contents related to each structure'' and inserting ''shall be made available with respect to any single such building, up to an aggregate liability (including such limits specified in subparagraph (B) or (C) of paragraph (1), as applicable) of $500,000, and coverage shall be made available up to a total of $500,000 aggregate liability for contents owned by the building owner and $500,000 aggregate liability for each unit within the building for contents owned by the tenant''.

SEC. 133. LOCAL DATA REQUIREMENT.

(a) IN GENERAL.—Notwithstanding any other provision of this title, an area that is within or includes a community that is identified by the Administrator as Community Identification Number 360467 and impacted by the Jamaica Bay flooding source or identified by the Administrator as Community Identification Number 360495 may not be or become designated as an area having special flood hazards for purposes of the National Flood Insurance Program, unless the designation is made on the basis of—

(1) flood hazard analyses of hydrologic, hydraulic, or coastal flood hazards that have been properly calibrated and validated, and are specific and directly relevant to the geographic area being studied; and

(2) ground elevation information of sufficient accuracy and precision to meet the guidelines of the Administration for accuracy at the 95 percent confidence level.

(b) REMAPPING.—

(1) REMAPPING REQUIRED.—If the Administrator determines that an area described in subsection (a) has been designated as an area of special flood hazard on the basis of information that does not comply with the requirements under subsection (a), the Administrator shall revise and update any National Flood Insurance Program rate map for the area—

(A) using information that complies with the requirements under subsection (a); and

(B) in accordance with the procedures established under section 1363 of the National Flood Insurance Act of 1968 (42 U.S.C. 4104) for flood elevation determinations.

(2) INTERIM PERIOD.—A National Flood Insurance Program rate map in effect on the date of enactment of this Act for an area for which the Administrator has made a determination under paragraph (1) shall continue in effect with respect to the area during the period—

(A) beginning on the date of enactment of this Act; and

(B) ending on the date on which the Administrator determines that the requirements under section 1363 of the National Flood Insurance Act of 1968 (42 U.S.C. 4104) for flood elevation determinations have been met with respect to a revision and update under paragraph (1) of a National Flood Insurance rate map for the area.

(3) DEADLINE.—The Administrator shall issue a preliminary National Flood Insurance Program rate map resulting from a revision and update required under paragraph (1) not later than 1 year after the date of enactment of this Act.

(4) RISK PREMIUM RATE CLARIFICATION.—

(A) IN GENERAL.—If a revision and update required under paragraph (1) results in a reduction in the risk premium rate for a property in an area for which the Administrator has made a determination under paragraph (1), the Administrator shall—

(i) calculate the difference between the reduced risk premium rate and the risk premium rate paid by a policyholder with respect to the property during the period—

(I) beginning on the date on which the National Flood Insurance Program rate map in effect for the area on the date of enactment of this Act took effect; and

(II) ending on the date on which the revised or updated National Flood Insurance Program rate map takes effect; and

(ii) reimburse the policyholder an amount equal to such difference.

(B) FUNDING.—Notwithstanding section 1310 of the National Flood Insurance Act of 1968 (42 U.S.C. 4017), there shall be available to the Administrator from premiums deposited in the National Flood Insurance Fund pursuant to subsection (d) of such section 1310, of amounts not otherwise obligated, the amount necessary to carry out this paragraph.

(c) TERMINATION.—

(1) IN GENERAL.—Except as provided in paragraph (2), this section shall cease to have effect on the effective date of a National Flood Insurance Program rate map revised and updated under subsection (b)(1).

(2) REIMBURSEMENTS.—Subsection (b)(4) shall cease to have effect on the date on which the Administrator has made all reimbursements required under subsection (b)(4).

SEC. 134. ELIGIBILITY FOR FLOOD INSURANCE FOR PERSONS RESIDING IN COMMUNITIES THAT HAVE MADE ADEQUATE PROGRESS ON THE CONSTRUCTION, RECONSTRUCTION, OR IMPROVEMENT OF A FLOOD PROTECTION SYSTEM.

(a) ELIGIBILITY FOR FLOOD INSURANCE COVERAGE.—

(1) IN GENERAL.—Notwithstanding any other provision of law, a person residing in a community that the Administrator determines has made adequate progress on the reconstruction or improvement of a flood protection system that will afford flood protection for a 100-year floodplain (without regard to the level of Federal funding of or participation in the construction, reconstruction, or improvement), shall be eligible for flood insurance coverage under the National Flood Insurance Program—

(A) if the person resides in a community that is a participant in the National Flood Insurance Program; and

(B) at a risk premium rate that does not exceed the risk premium rate that would be chargeable if the flood protection system had been completed.

(2) ADEQUATE PROGRESS.—

(A) RECONSTRUCTION OR IMPROVEMENT.—For purposes of paragraph (1), the Administrator shall determine that a community has made adequate progress on the reconstruction or improvement of a flood protection system if—

(i) 100 percent of the project cost has been authorized;

(ii) not less than 60 percent of the project cost has been secured or appropriated;

(iii) not less than 50 percent of the flood protection system has been assessed as being without deficiencies; and

(iv) the reconstruction or improvement has a project schedule that does not exceed 5 years, beginning on the date on which the reconstruction or construction of the improvement commences.

(B) CONSIDERATIONS.—In determining whether a flood protection system have been assessed as being without deficiencies, the Administrator shall consider the requirements under section 65.10 of chapter 44, Code of Federal Regulations, or any successor thereto.

(b) TERMINATION OF ELIGIBILITY.—

(1) ADEQUATE CONTINUING PROGRESS.—The Administrator shall issue rules to establish a method of determining whether a community has made adequate continuing progress on the reconstruction or improvement of a flood protection system that includes—

(A) a requirement that the Administrator shall—

(i) consult with the owner of the flood protection system—

(I) 6 months after the date of a determination under subsection (a);

(II) 18 months after the date of a determination under subsection (a); and

(III) 36 months after the date of a determination under subsection (a); and

(ii) after each consultation under clause (i), determine whether the reconstruction or improvement is reasonably likely to be completed in accordance with the project schedule described in subsection (a)(2)(A)(iv); and

(B) a requirement that, if the Administrator makes a determination under subparagraph (A)(ii) that reconstruction or improvement is not reasonably likely to be completed in accordance with the project schedule, the Administrator shall—

(i) not later than 30 days after the date of the determination, notify the owner of the flood protection system of the determination and provide the rationale and evidence for the determination; and

(ii) provide the owner of the flood protection system the opportunity to appeal the determination.

(2) TERMINATION.—The Administrator shall terminate the eligibility for flood insurance coverage under the National Flood Insurance Program of persons residing in a community with respect to which the Administrator made a determination under subsection (a) if—

(A) the Administrator determines that the community has not made adequate continuing progress; or

(B) on the date that is 5 years after the date on which the reconstruction or construction of the improvement commences, the project has not been completed.

(3) WAIVER.—A person whose eligibility would otherwise be terminated under paragraph (2)(B) shall continue to be eligible to purchase flood insurance coverage described in subsection (a) if the Administrator determines—

(A) the community has made adequate continuing progress on the reconstruction or improvement of a flood protection system; and

(B) there is a reasonable expectation that the reconstruction or improvement of the flood protection system will be completed not later than 1 year after the date of the determination under this paragraph.

(4) RISK PREMIUM RATE.—If the Administrator terminates the eligibility of persons residing in a community to purchase flood insurance coverage described in subsection (a), the Administrator shall establish an appropriate risk premium rate for flood insurance coverage under the National Flood Insurance Program for persons residing in the community that purchased flood insurance coverage before the date on which the termination of eligibility takes effect, taking into consideration the then-current state of the flood protection system.

SEC. 135. STUDIES AND REPORTS.

(a) REPORT ON EXPANDING THE NATIONAL FLOOD INSURANCE PROGRAM.—Not later than 1 year after the date of the enactment of this Act, the Comptroller General of the United States shall conduct a study and submit a report to the Committee on Banking, Housing, and Urban Affairs of the Senate and the Committee on Financial Services of the House of Representatives, on—

(1) the number of flood insurance policy holders currently insuring—

(A) a residential structure up to the maximum available coverage amount, as established in section 61.6 of title 44, Code of Federal Regulations, of—

(i) $250,000 for the structure; and

(ii) $100,000 for the contents of such structure; or

(B) a commercial structure up to the maximum available coverage amount, as established in section 61.6 of title 44, Code of Federal Regulations, of $500,000;

(2) the increased losses the National Flood Insurance Program would have sustained during the 2004 and 2005 hurricane season if the National Flood Insurance Program had insured all policyholders up to the maximum conforming loan limit for fiscal year 2006 of $417,000, as established under section 302(b)(2) of the Federal National Mortgage Association Charter Act (12 U.S.C. 1717(b)(2));

(3) the availability in the private marketplace of flood insurance coverage in amounts that exceed the current limits of coverage amounts established in section 61.6 of title 44, Code of Federal Regulations; and

(4) what effect, if any—

(A) raising the current limits of coverage amounts established in section 61.6 of title 44, Code of Federal Regulations, would have on the ability of private insurers to continue providing flood insurance coverage; and

(B) reducing the current limits of coverage amounts established in section 61.6 of title 44, Code of Federal Regulations, would have on the ability of private insurers to provide sufficient flood insurance coverage to effectively replace the current level of flood insurance coverage being provided under the National Flood Insurance Program.

(b) REPORT OF THE ADMINISTRATOR ON ACTIVITIES UNDER THE NATIONAL FLOOD INSURANCE PROGRAM.—

(1) IN GENERAL.—The Administrator shall, on an annual basis, submit a full report on the operations, activities, budget, receipts, and expenditures of the National Flood Insurance Program for the preceding 12-month period to the Committee on Banking, Housing, and Urban Affairs of the Senate and the Committee on Financial Services of the House of Representatives.

(2) TIMING.—Each report required under paragraph (1) shall be submitted to the committees described in paragraph (1) not later than 3 months following the end of each fiscal year.

(3) CONTENTS.—Each report required under paragraph (1) shall include—

(A) the current financial condition and income statement of the National Flood Insurance Fund established under section 1310 of the National Flood Insurance Act of 1968 (42 U.S.C. 4017), including—

(i) premiums paid into such Fund;

(ii) policy claims against such Fund; and

(iii) expenses in administering such Fund;

(B) the number and face value of all policies issued under the National Flood Insurance Program that are in force;

(C) a description and summary of the losses attributable to repetitive loss structures;

(D) a description and summary of all losses incurred by the National Flood Insurance Program due to—

(i) hurricane related damage; and

(ii) nonhurricane related damage;

(E) the amounts made available by the Administrator for mitigation assistance under section 1366(c)(4) of the National Flood Insurance Act of 1968 (42 U.S.C. 4104c(c)(4) for the purchase of properties substantially damaged by flood for that fiscal year, and the actual number of flood damaged properties purchased and the total cost expended to purchase such properties;

(F) the estimate of the Administrator as to the average historical loss year, and the basis for that estimate;

(G) the estimate of the Administrator as to the maximum amount of claims that the National Flood Insurance Program would have to expend in the event of a catastrophic year;

(H) the average—

(i) amount of insurance carried per flood insurance policy;

(ii) premium per flood insurance policy; and

(iii) loss per flood insurance policy; and

(I) the number of claims involving damages in excess of the maximum amount of flood insurance available under the National Flood Insurance Program and the sum of the amount of all damages in excess of such amount.

(c) GAO STUDY ON PRE-FIRM STRUCTURES.—Not later than 1 year after the date of the enactment of this Act, the Comptroller General of the United States shall conduct a study and submit a report to the Committee on Banking, Housing, and Urban Affairs of the Senate and the Committee on Financial Services of the House of Representatives, on the—

(1) composition of the remaining pre-FIRM structures that are explicitly receiving discounted premium rates under section 1307 of the National Flood Insurance Act of 1968 (42 U.S.C. 4014), including the historical basis for the receipt of such subsidy and the extent to which pre-FIRM structures are currently owned by the same owners of the property at the time of the original FIRM;

(2) number and fair market value of such structures;

(3) respective income level of the owners of such structures;

(4) number of times each such structure has been sold since 1968, including specific dates, sales price, and any other information the Secretary determines appropriate;

(5) total losses incurred by such structures since the establishment of the National Flood Insurance Program compared to the total losses incurred by all structures that are charged a nondiscounted premium rate;

(6) total cost of foregone premiums since the establishment of the National Flood Insurance Program, as a result of the subsidies provided to such structures;

(7) annual cost as a result of the subsidies provided to such structures;

(8) the premium income collected and the losses incurred by the National Flood Insurance Program as a result of such explicitly subsidized structures compared to the premium income collected and the losses incurred by such Program as a result of structures that are charged a nondiscounted premium rate, on a State-by-State basis; and

(9) the options for eliminating the subsidy to such structures.

(d) GAO REVIEW OF FEMA CONTRACTORS.—The Comptroller General of the United States, in conjunction with the Office of the Inspector General of the Department of Homeland Security, shall—

(1) conduct a review of the 3 largest contractors the Administrator uses in administering the National Flood Insurance Program; and

(2) not later than 18 months after the date of the enactment of this Act, submit a report on the findings of such review to the Administrator, the Committee on Banking, Housing, and Urban Affairs of the Senate, and the Committee on Financial Services of the House of Representatives.

SEC. 136. REINSURANCE.

(a) REINSURANCE ASSESSMENT.—

(1) PRIVATE MARKET PRICING ASSESSMENT.—Not later than 12 months after the date of the enactment of this Act, the Administrator shall submit to Congress a report that—

(A) assesses the capacity of the private reinsurance, capital, and financial markets to assist communities, on a voluntary basis, in managing the full range of financial risks associated with flooding by requesting proposals to assume a portion of the insurance risk of the National Flood Insurance Program;

(B) describes any responses to the request for proposals under subparagraph (A);

(C) assesses whether the rates and terms contained in any proposals received by the Administrator are—

(i) reasonable and appropriate; and

(ii) in an amount sufficient to maintain the ability of the National Flood Insurance Program to pay claims;

(D) describes the extent to which carrying out the proposals received by the Administrator would minimize the likelihood that the Administrator would use the borrowing authority under section 1309 of the National Flood Insurance Act of 1968 (42 U.S.C. 4016);

(E) describes fluctuations in historical reinsurance rates; and

(F) includes an economic cost-benefit analysis of the impact on the National Flood Insurance Program if the Administrator were to exercise the authority under section 1335(a)(2) of the National Flood Insurance Act of 1968 (42 U.S.C. 4055(a)(2)), as added by this section, to secure reinsurance of coverage provided by the National Flood Insurance Program from the private market.

(2) PROTOCOL FOR RELEASE OF DATA.—The Administrator shall develop a protocol, including adequate privacy protections, to provide for the release of data sufficient to conduct the assessment required under paragraph (1).

(b) REINSURANCE.—The National Flood Insurance Act of 1968 (42 U.S.C. 4011 et seq.) is amended—

(1) in section 1331(a)(2) (42 U.S.C. 4051(a)(2)), by inserting ‘‘, including as reinsurance of coverage provided by the flood insurance program’’ before ‘‘, on such terms’’;

(2) in section 1332(c)(2) (42 U.S.C. 4052(c)(2)), by inserting ‘‘or reinsurance’’ after ‘‘flood insurance coverage’’;

(3) in section 1335(a) (42 U.S.C. 4055(a))—

(A) by striking ‘‘The Director’’ and inserting the following:

‘‘(1) IN GENERAL.—The Administrator’’; and

(B) by adding at the end the following:

‘‘(2) PRIVATE REINSURANCE.—The Administrator is authorized to secure reinsurance of coverage provided by the flood insurance program from the private market at rates and on terms determined by the Administrator to be reasonable and appropriate, in an amount sufficient to maintain the ability of the program to pay claims.’’;

(4) in section 1346(a) (12 U.S.C. 4082(a))—

(A) in the matter preceding paragraph (1), by inserting after ‘‘for the purpose of’’ the following: ‘‘securing reinsurance of insurance coverage provided by the program or for the purpose of’’;

(B) in paragraph (1)—

(i) by striking ‘‘estimating’’ and inserting ‘‘Estimating’’; and

(ii) by striking the semicolon at the end and inserting a period;

(C) in paragraph (2)—

(i) by striking ‘‘receiving’’ and inserting ‘‘Receiving’’; and

(ii) by striking the semicolon at the end and inserting a period;

(D) in paragraph (3)—

(i) by striking ‘‘making’’ and inserting ‘‘Making’’; and

(ii) (ii) by striking ‘‘ ‘; and’ ’’ and inserting a period;

(E) by redesignating paragraph (4) as paragraph (5);

(F) in paragraph (5), as so redesignated, by striking ‘‘otherwise’’ and inserting ‘‘Otherwise’’; and

(G) by inserting after paragraph (3) the following new paragraph:

‘‘(4) Placing reinsurance coverage on insurance provided by such program;’’; and

(5) in section 1370(a)(3) (42 U.S.C. 4121(a)(3)), by striking ‘‘include any’’ and all that follows and inserting the following: ‘‘include any organization or person that is authorized to engage in the business of insurance under the laws of any State, subject to the reporting requirements of the Securities Exchange Act of 1934 pursuant to section 13(a) or 15(d) of such Act (15 U.S.C. 78m(a) and 78o(d)), or authorized by the Administrator to assume reinsurance on risks insured by the flood insurance program;’’.

(c) ASSESSMENT OF CLAIMS-PAYING ABILITY.—

(1) ASSESSMENT.—

(A) ASSESSMENT REQUIRED.—

(i) IN GENERAL.—Not later than September 30 of each year, the Administrator shall conduct an assessment of the ability of the National Flood Insurance Program to pay claims.

(ii) PRIVATE MARKET REINSURANCE.—The assessment under this paragraph for any year in which the Administrator exercises the authority under section 1335(a)(2) of the National Flood Insurance Act of 1968 (42 U.S.C. 4055(a)(2)), as added by this section, to secure reinsurance of coverage provided by the National Flood Insurance Program from the private market shall include information relating the use of private sector reinsurance and reinsurance equivalents by the Administrator, whether or not the Administrator used the borrowing authority under section 1309 of the National Flood Insurance Act of 1968 (42 U.S.C. 4016).

(iii) FIRST ASSESSMENT.—The Administrator shall conduct the first assessment required under this paragraph not later than September 30, 2012.

(B) CONSIDERATIONS.—In conducting an assessment under subparagraph (A), the Administrator shall take into consideration regional concentrations of coverage written by the National Flood Insurance Program, peak flood zones, and relevant mitigation measures.

(2) ANNUAL REPORT OF THE ADMINISTRATOR OF ACTIVITIES UNDER THE NATIONAL FLOOD INSURANCE PROGRAM.—The Administrator shall—

(A) include the results of each assessment in the report required under section 135(b); and

(B) not later than 30 days after the date on which the Administrator completes an assessment required under paragraph (1), make the results of the assessment available to the public.

SEC. 137. GAO STUDY ON BUSINESS INTERRUPTION AND ADDITIONAL LIVING EXPENSES COVERAGES.

(a) STUDY.—The Comptroller General of the United States shall conduct a study concerning—

(1) the availability of additional living expenses and business interruption coverage in the private marketplace for flood insurance;

(2) the feasibility of allowing the National Flood Insurance Program to offer such coverage at the option of the consumer;

(3) the estimated cost to consumers if the National Flood Insurance Program priced such optional coverage at true actuarial rates;

(4) the impact such optional coverage would have on consumer participation in the National Flood Insurance Program; and

(5) the fiscal impact such optional coverage would have upon the National Flood Insurance Fund if such optional coverage were included in the National Flood Insurance Program, as described in paragraph (2), at the price described in paragraph (3).

(b) REPORT.—Not later than 1 year after the date of the enactment of this Act, the Comptroller General shall submit to the Committee on Banking, Housing, and Urban Affairs of the Senate and the Committee on Financial Services of the House of Representatives a report containing the results of the study under subsection (a).

SEC. 138. POLICY DISCLOSURES.

(a) IN GENERAL.—Notwithstanding any other provision of law, in addition to any other disclosures that may be required, each policy under the National Flood Insurance Program shall state all conditions, exclusions, and other limitations pertaining to coverage under the subject policy, regardless of the underlying insurance product, in plain English, in boldface type, and in a font size that is twice the size of the text of the body of the policy.

(b) VIOLATIONS.—Any person that violates the requirements of this section shall be subject to a fine of not more than $50,000 at the discretion of the Administrator.

SEC. 139. REPORT ON INCLUSION OF BUILDING CODES IN FLOODPLAIN MANAGEMENT CRITERIA.

Not later than 6 months after the date of the enactment of this Act, the Administrator of the Federal Emergency Management Agency shall conduct a study and submit a report to the Committee on Banking, Housing, and Urban Affairs of the Senate and the Committee on Financial Services of the House of Representatives regarding the impact, effectiveness, and feasibility of amending section 1361 of the National Flood Insurance Act of 1968 (42 U.S.C. 4102) to include widely used and nationally recognized building codes as part of the floodplain management criteria developed under such section, and shall determine—

(1) the regulatory, financial, and economic impacts of such a building code requirement on homeowners, States and local communities, local land use policies, and the Federal Emergency Management Agency;

(2) the resources required of State and local communities to administer and enforce such a building code requirement;

(3) the effectiveness of such a building code requirement in reducing flood-related damage to buildings and contents;

(4) the impact of such a building code requirement on the actuarial soundness of the National Flood Insurance Program;

(5) the effectiveness of nationally recognized codes in allowing innovative materials and systems for flood-resistant construction;

(6) the feasibility and effectiveness of providing an incentive in lower premium rates for flood insurance coverage under such Act for structures meeting whichever of such widely used and nationally recognized building codes or any applicable local building codes provides greater protection from flood damage;

(7) the impact of such a building code requirement on rural communities with different building code challenges than urban communities; and

(8) the impact of a such a building code requirement on Indian reservations.

SEC. 140. STUDY OF PARTICIPATION AND AFFORDABILITY FOR CERTAIN POLICYHOLDERS.

(a) FEMA STUDY.—The Administrator shall conduct a study of—

(1) methods to encourage and maintain participation in the National Flood Insurance Program;

(2) methods to educate consumers about the National Flood Insurance Program and the flood risk associated with their property;

(3) methods for establishing an affordability framework for the National Flood Insurance Program, including methods to aid individuals to afford risk-based premiums under the National Flood Insurance Program through targeted assistance rather than generally subsidized rates, including means-tested vouchers; and

(4) the implications for the National Flood Insurance Program and the Federal budget of using each such method.

(b) NATIONAL ACADEMY OF SCIENCES ECONOMIC ANALYSIS.—To inform the Administrator in the conduct of the study under subsection (a), the National Academy of Sciences, in consultation with the Comptroller General of the United States, shall conduct and submit to the Administrator an economic analysis of the costs and benefits to the Federal Government of a flood insurance program with full risk-based premiums, combined with means-tested Federal assistance to aid individuals who cannot afford coverage, through an insurance voucher program. The analysis shall compare the costs of a program of risk-based rates and means-tested assistance to the current system of subsidized flood insurance rates and federally funded disaster relief for people without coverage.

(c) REPORT.—Not later than 270 days after the date of enactment of this Act, the Administrator shall submit to the Committee on Banking, Housing, and Urban Affairs of the Senate and the Committee on Financial Services of the House of Representatives a report that contains the results of the study and analysis under this section.

(d) FUNDING.—Notwithstanding section 1310 of the National Flood Insurance Act of 1968 (42 U.S.C. 4017), there shall be available to the Administrator from the National Flood Insurance Fund, of amounts not otherwise obligated, not more than $750,000 to carry out this section.

SEC. 141. STUDY AND REPORT CONCERNING THE PARTICIPATION OF INDIAN TRIBES AND MEMBERS OF INDIAN TRIBES IN THE NATIONAL FLOOD INSURANCE PROGRAM.

(a) DEFINITION.—In this section, the term ''Indian tribe'' has the meaning given that term in section 4 of the Indian Self-Determination and Education Assistance Act (25 U.S.C. 450b).

(b) FINDINGS.—Congress finds that participation by Indian tribes in the National Flood Insurance Program is low. Only 45 of 565 Indian tribes participate in the National Flood Insurance Program.

(c) STUDY.—The Comptroller General of the United States, in coordination and consultation with Indian tribes and members of Indian tribes throughout the United States, shall carry out a study that examines—

(1) the factors contributing to the current rates of participation by Indian tribes and members of Indian tribes in the National Flood Insurance Program; and

(2) methods of encouraging participation by Indian tribes and members of Indian tribes in the National Flood Insurance Program.

(d) REPORT.—Not later than 6 months after the date of enactment of this Act, the Comptroller General shall submit to Congress a report that—

(1) contains the results of the study carried out under subsection (c);

(2) describes the steps that the Administrator should take to increase awareness and encourage participation by Indian tribes and members of Indian tribes in the National Flood Insurance Program; and

(3) identifies any legislative changes that would encourage participation by Indian tribes and members of Indian tribes in the National Flood Insurance Program.

SEC. 142. TECHNICAL CORRECTIONS.

(a) FLOOD DISASTER PROTECTION ACT OF 1973.—The Flood Disaster Protection Act of 1973 (42 U.S.C. 4002 et seq.) is amended—

(1) by striking ''Director'' each place that term appears, except in section 102(f)(3) (42 U.S.C. 4012a(f)(3)), and inserting ''Administrator''; and

(2) in section 201(b) (42 U.S.C. 4105(b)), by striking ''Director's'' and inserting ''Administrator's''.

(b) NATIONAL FLOOD INSURANCE ACT OF 1968.—The National Flood Insurance Act of 1968 (42 U.S.C. 4001 et seq.) is amended—

(1) by striking ''Director'' each place that term appears and inserting ''Administrator''; and

(2) in sections 1363 (42 U.S.C. 4104), by striking ''Director's'' each place that term appears and inserting ''Administrator's''.

(c) FEDERAL FLOOD INSURANCE ACT OF 1956.—Section 15(e) of the Federal Flood Insurance Act of 1956 (42 U.S.C. 2414(e)) is amended by striking ''Director'' each place that term appears and inserting ''Administrator''.

SEC. 143. PRIVATE FLOOD INSURANCE POLICIES.

(a) DEFINITIONS.—In this section the following definitions shall apply:

(1) GUIDELINES.—The term ''Guidelines'' means the Mandatory Purchase of Flood Insurance Guidelines issued by the Administrator.

(2) STATE ENTITY FOR LENDING REGULATION.—The term ''State entity for lending regulation'' means, with respect to a State, the entity or agency with primary responsibility for the supervision of lending institutions chartered by the State and not insured by the Federal Deposit Insurance Corporation or the National Credit Union Administration.

(b) AMENDMENTS REQUIRED.—

(1) IN GENERAL.—Not later than 120 days after the date of enactment of this Act, the Administrator shall amend the Guidelines to clarify that a lender or a lending institution chartered by a State and not insured by the Federal Deposit Insurance Corporation or the National Credit Union Administration may accept a private primary flood insurance policy in lieu of a National Flood Insurance Program flood policy to satisfy the mandatory purchase requirements under section 102 of the Flood Disaster Protection Act of 1973 (42 U.S.C. 4012a), if the private primary flood insurance policy—

(A) is available for sale under the laws of the State in which the private primary flood insurance policy is to be written;

(B) meets the minimum requirements for flood insurance coverage under subsections (a) and (b) of such section 102; and

(C) complies with applicable Federal regulations.

(2) STATE LAW CONSIDERATIONS.—Neither the Guidelines nor the amendments to the Guidelines made under paragraph (1) shall be construed to preempt State insurance law, regulation, or guidance.

(c) NOTIFICATION.—

(1) TO FEDERAL AND STATE ENTITIES FOR LENDING REGULATION.—Not later than 30 days after the date on which the Administrator

amends the Guidelines under subsection (b), the Administrator shall notify the Federal entities for lending regulation and the State entities for lending regulation of the amendment, in order to encourage the acceptance of private primary flood insurance in lieu of a National Flood Insurance Program flood policy to satisfy the mandatory purchase requirements under section 102 of the Flood Disaster Protection Act of 1973 (42 U.S.C. 4012a).

(2) TO LENDERS.—The Administrator and each Federal entity for lending regulation shall include the notification required under paragraph (1) in any edition of a publication that the Administrator or Federal entity for lending regulation provides to lenders that is published after the date of enactment of this Act.

(d) TRAINING.—Not later than 60 days after the date on which the Administrator makes the notification under subsection (c), the Federal entities for lending regulation shall train each employee having responsibility for compliance audits to implement the amendments to the Guidelines under subsection (b).

SEC. 144. TREATMENT OF SWIMMING POOL ENCLOSURES OUTSIDE OF HURRICANE SEASON.

Notwithstanding any other provision of law, the adequate land use and control measures developed pursuant to section 1361 of the National Flood Insurance Act of 1968 (42 U.S.C. 4102) and applicable to non-residential structures located within coastal areas as identified by the Administrator may permit, at the discretion of the appropriate State and local authority, the use of non-supporting breakaway walls in V Zones and openings in walls in coastal A Zones in the space below the lowest floor used solely for swimming pools after November 30 and before June 1 of any year. Permitting this use does not alter the terms and conditions of eligibility and insurability of coverage for a building as set out in the Standard Flood Insurance Policy of the Federal Emergency Management Agency.

TITLE II—COMMISSION ON NATURAL CATASTROPHE RISK MANAGEMENT AND INSURANCE

SEC. 201. SHORT TITLE.

This title may be cited as the ''Commission on Natural Catastrophe Risk Management and Insurance Act of 2012''.

SEC. 202. FINDINGS.

Congress finds that—

(1) Hurricanes Katrina, Rita, and Wilma, which struck the United States in 2005, caused, by some estimates, in excess of $200,000,000,000 in total economic losses;

(2) many meteorologists predict that the United States is in a period of increased hurricane activity;

(3) the Federal Government and State governments have provided billions of dollars to pay for losses from natural catastrophes, including hurricanes, earthquakes, volcanic eruptions, tsunamis, tornados, flooding, wildfires, droughts, and other natural catastrophes;

(4) many Americans are finding it increasingly difficult to obtain and afford property and casualty insurance coverage;

(5) some insurers are not renewing insurance policies, are excluding certain risks, such as wind damage, and are increasing rates and deductibles in some markets;

(6) the inability of property and business owners in vulnerable areas to obtain and afford property and casualty insurance coverage endangers the national economy and public health and safety;

(7) almost every State in the United States is at risk of a natural catastrophe, including hurricanes, earthquakes, volcanic eruptions, tsunamis, tornados, flooding, wildfires, droughts, and other natural catastrophes;

(8) building codes and land use regulations play an indispensable role in managing catastrophe risks, by preventing building in high risk areas and ensuring that appropriate mitigation efforts are completed where building has taken place;

(9) several proposals have been introduced in Congress to address the affordability and availability of natural catastrophe insurance across the United States, but there is no consensus on what, if any, role the Federal Government should play; and

(10) an efficient and effective approach to assessing natural catastrophe risk management and insurance is to establish a nonpartisan commission to study the management of natural catastrophe risk, and to require such commission to timely report to Congress on its findings.

SEC. 203. ESTABLISHMENT.

There is established a nonpartisan Commission on Natural Catastrophe Risk Management and Insurance (in this title referred to as the ''Commission'').

SEC. 204. MEMBERSHIP.

(a) APPOINTMENT.—The Commission shall be composed of 16 members, of whom—

(1) 2 members shall be appointed by the majority leader of the Senate;

(2) 2 members shall be appointed by the minority leader of the Senate;

(3) 2 members shall be appointed by the Speaker of the House of Representatives;

(4) 2 members shall be appointed by the minority leader of the House of Representatives;

(5) 2 members shall be appointed by the Chairman of the Committee on Banking, Housing, and Urban Affairs of the Senate;

(6) 2 members shall be appointed by the Ranking Member of the Committee on Banking, Housing, and Urban Affairs of the Senate;

(7) 2 members shall be appointed by the Chairman of the Committee on Financial Services of the House of Representatives; and

(8) 2 members shall be appointed by the Ranking Member of the Committee on Financial Services of the House of Representatives.

(b) QUALIFICATION OF MEMBERS.—

(1) IN GENERAL.—Members of the Commission shall be appointed under subsection (a) from among persons who—

(A) have expertise in insurance, reinsurance, insurance regulation, policyholder concerns, emergency management, risk management, public finance, financial markets, actuarial analysis, flood mapping and planning, structural engineering, building standards, land use planning, natural catastrophes, meteorology, seismology, environmental issues, or other pertinent qualifications or experience; and

(B) are not officers or employees of the United States Government or of any State or local government.

(2) DIVERSITY.—In making appointments to the Commission—

(A) every effort shall be made to ensure that the members are representative of a broad cross section of perspectives within the United States; and

(B) each member of Congress described in subsection (a) shall appoint not more than 1 person from any single primary area of expertise described in paragraph (1)(A) of this subsection.

(c) PERIOD OF APPOINTMENT.—

(1) IN GENERAL.—Each member of the Commission shall be appointed for the duration of the Commission.

(2) VACANCIES.—A vacancy on the Commission shall not affect its powers, but shall be filled in the same manner as the original appointment.

(d) QUORUM.—

(1) MAJORITY.—A majority of the members of the Commission shall constitute a quorum, but a lesser number, as determined by the Commission, may hold hearings.

(2) APPROVAL ACTIONS.—All recommendations and reports of the Commission required by this title shall be approved only by a majority vote of all of the members of the Commission.

(e) CHAIRPERSON.—The Commission shall, by majority vote of all of the members, select 1 member to serve as the Chairperson of the Commission (in this title referred to as the ''Chairperson'').

(f) MEETINGS.—The Commission shall meet at the call of its Chairperson or a majority of the members.

SEC. 205. DUTIES OF THE COMMISSION.

The Commission shall examine the risks posed to the United States by natural catastrophes, and means for mitigating those risks and for paying for losses caused by natural catastrophes, including assessing—

(1) the condition of the property and casualty insurance and reinsurance markets prior to and in the aftermath of Hurricanes Katrina, Rita, and Wilma in 2005, and the 4 major hurricanes that struck the United States in 2004;

(2) the current condition of, as well as the outlook for, the availability and affordability of insurance in all regions of the country;

(3) the current ability of States, communities, and individuals to mitigate their natural catastrophe risks, including the affordability and feasibility of such activities;

(4) the ongoing exposure of the United States to natural catastrophes, including hurricanes, earthquakes, volcanic eruptions, tsunamis, tornados, flooding, wildfires, droughts, and other natural catastrophes;

(5) the catastrophic insurance and reinsurance markets and the relevant practices in providing insurance protection to different sectors of the American population;

(6) implementation of a catastrophic insurance system that can resolve key obstacles currently impeding broader implementation of catastrophic risk management and financing with insurance;

(7) the financial feasibility and sustainability of a national, regional, or other pooling mechanism designed to provide adequate insurance coverage and increased underwriting capacity to insurers and reinsurers, including private-public partnerships to increase insurance capacity in constrained markets;

(8) methods to promote public or private insurance policies to reduce losses caused by natural catastrophes in the uninsured sectors of the American population;

(9) approaches for implementing a public or private insurance scheme for low-income communities, in order to promote risk reduction and insurance coverage in such communities;

(10) the impact of Federal and State laws, regulations, and policies (including rate regulation, market access requirements, reinsurance regulations, accounting and tax policies, State residual markets, and State catastrophe funds) on—

(A) the affordability and availability of catastrophe insurance;

(B) the capacity of the private insurance market to cover losses inflicted by natural catastrophes;

(C) the commercial and residential development of high-risk areas; and

(D) the costs of natural catastrophes to Federal and State taxpayers;

(11) the present and long-term financial condition of State residual markets and catastrophe funds in high-risk regions, including the likelihood of insolvency following a natural catastrophe, the concentration of risks within such funds, the reliance on post-event assessments and State funding, and the adequacy of rates;

(12) the role that innovation in financial services could play in improving the affordability and availability of natural catastrophe insurance, specifically addressing measures that would foster the development of financial products designed to cover natural catastrophe risk, such as risk-linked securities;

(13) the need for strengthened land use regulations and building codes in States at high risk for natural catastrophes, and methods to strengthen the risk assessment and enforcement of structural mitigation and vulnerability reduction measures, such as zoning and building code compliance;

(14) the benefits and costs of proposed Federal natural catastrophe insurance programs (including the Federal Government's provision of reinsurance to State catastrophe funds, private insurers, or other entities), specifically addressing the costs to taxpayers, tax equity considerations, and the record of other government insurance programs (particularly with regard to charging actuarially sound prices);

(15) the ability of the United States private insurance market—

(A) to cover insured losses caused by natural catastrophes, including an estimate of the maximum amount of insured losses that could be sustained during a single year and the probability of natural catastrophes occurring in a single year that would inflict more insured losses than the United States insurance and reinsurance markets could sustain; and

(B) to recover after covering substantial insured losses caused by natural catastrophes;

(16) the impact that demographic trends could have on the amount of insured losses inflicted by future natural catastrophes;

(17) the appropriate role, if any, for the Federal Government in stabilizing the property and casualty insurance and reinsurance markets; and

(18) the role of the Federal, State, and local governments in providing incentives for feasible risk mitigation efforts.

SEC. 206. REPORT.

(a) IN GENERAL.—Not later than 9 months after the date of the enactment of this Act, the Commission shall submit to the Committee on Banking, Housing, and Urban Affairs of the Senate and the Committee on Financial Services of the House of Representatives a final report containing—

(1) a detailed statement of the findings and assessments conducted by the Commission pursuant to section 205; and

(2) any recommendations for legislative, regulatory, administrative, or other actions at the Federal, State, or local levels that the Commission considers appropriate, in accordance with the requirements of section 205.

(b) EXTENSION OF TIME.—The Commission may request Congress to extend the period of time for the submission of the report required under subsection (a) for an additional 3 months.

SEC. 207. POWERS OF THE COMMISSION.

(a) MEETINGS; HEARINGS.—The Commission may hold such hearings, sit and act at such times and places, take such testimony, and receive such evidence as the Commission considers necessary to carry out the purposes of this title. Members may attend meetings of the Commission and vote in person, via telephone conference, or via video conference.

(b) AUTHORITY OF MEMBERS OR AGENTS OF THE COMMISSION.—Any member or agent of the Commission may, if authorized by a vote of the Commission, take any action which the Commission is authorized to take by this title.

(c) OBTAINING OFFICIAL DATA.—

(1) AUTHORITY.—Notwithstanding any provision of section 552a of title 5, United States Code, the Commission may secure directly from any department or agency of the United States any information necessary to enable the Commission to carry out this title.

(2) PROCEDURE.—Upon the request of the Chairperson, the head of such department or agency shall furnish to the Commission the information requested.

(d) POSTAL SERVICES.—The Commission may use the United States mails in the same manner and under the same conditions as other departments and agencies of the Federal Government.

(e) ADMINISTRATIVE SUPPORT SERVICES.—Upon the request of the Commission, the Administrator of General Services shall provide to the Commission, on a reimbursable basis, any administrative support services necessary for the Commission to carry out its responsibilities under this title.

(f) ACCEPTANCE OF GIFTS.—The Commission may accept, hold, administer, and utilize gifts, donations, and bequests of property, both real and personal, for the purposes of aiding or facilitating the work of the Commission. The Commission shall issue internal guidelines governing the receipt of donations of services or property.

(g) VOLUNTEER SERVICES.—Notwithstanding the provisions of section 1342 of title 31, United States Code, the Commission may accept and utilize the services of volunteers serving without compensation. The Commission may reimburse such volunteers for local travel and office supplies, and for other travel expenses, including per diem in lieu of subsistence, as authorized by section 5703 of title 5, United States Code.

(h) FEDERAL PROPERTY AND ADMINISTRATIVE SERVICES ACT OF 1949.—Subject to the Federal Property and Administrative Services Act of 1949, the Commission may enter into contracts with Federal and State agencies, private firms, institutions, and individuals for the conduct of activities necessary to the discharge of its duties and responsibilities.

(i) LIMITATION ON CONTRACTS.—A contract or other legal agreement entered into by the Commission may not extend beyond the date of the termination of the Commission.

SEC. 208. COMMISSION PERSONNEL MATTERS.

(a) TRAVEL EXPENSES.—The members of the Commission shall be allowed travel expenses, including per diem in lieu of subsistence, at rates authorized for employees of agencies under subchapter I of chapter 57 of title 5, United States Code, while away from their homes or regular places of business in the performance of services for the Commission.

(b) SUBCOMMITTEES.—The Commission may establish subcommittees and appoint members of the Commission to such subcommittees as the Commission considers appropriate.

(c) STAFF.—Subject to such policies as the Commission may prescribe, the Chairperson may appoint and fix the pay of such additional personnel as the Chairperson considers appropriate to carry out the duties of the Commission. The Commission shall confirm the appointment of the executive director by majority vote of all of the members of the Commission.

(d) APPLICABILITY OF CERTAIN CIVIL SERVICE LAWS.—Staff of the Commission may be—

(1) appointed without regard to the provisions of title 5, United States Code, governing appointments in the competitive service; and

(2) paid without regard to the provisions of chapter 51 and subchapter III of chapter 53 of that title relating to classification and General Schedule pay rates, except that an individual so appointed may not receive pay in excess of the annual rate of basic pay prescribed for GS–15 of the General Schedule under section 5332 of that title.

(e) EXPERTS AND CONSULTANTS.—In carrying out its objectives, the Commission may procure temporary and intermittent services of consultants and experts under section 3109(b) of title 5, United States Code, at rates for individuals which do not exceed the daily equivalent of the annual rate of basic pay prescribed for GS–15 of the General Schedule under section 5332 of that title.

(f) DETAIL OF GOVERNMENT EMPLOYEES.—Upon request of the Chairperson, any Federal Government employee may be detailed to the Commission to assist in carrying out the duties of the Commission—

(1) on a reimbursable basis; and

(2) such detail shall be without interruption or loss of civil service status or privilege.

SEC. 209. TERMINATION.

The Commission shall terminate 90 days after the date on which the Commission submits its report under section 206.

SEC. 210. AUTHORIZATION OF APPROPRIATIONS.

There are authorized to be appropriated to the Commission, such sums as may be necessary to carry out this title, to remain available until expended.

TITLE III—ALTERNATIVE LOSS ALLOCATION

SEC. 301. SHORT TITLE.

This title may be cited as the ''Consumer Option for an Alternative System to Allocate Losses Act of 2012'' or the ''COASTAL Act of 2012''.

SEC. 302. ASSESSING AND MODELING NAMED STORMS OVER COASTAL STATES.

Subtitle C of title XII of the Omnibus Public Land Management Act of 2009 (33 U.S.C. 3601 et seq.) (also known as the ''Integrated Coastal and Ocean Observation System Act of 2009'') is amended by adding at the end the following:

''SEC. 12312. ASSESSING AND MODELING NAMED STORMS OVER COASTAL STATES.

''(a) DEFINITIONS.—In this section:

''(1) COASTAL FORMULA.—The term 'COASTAL Formula' has the meaning given the term in section 1337(a) of the National Flood Insurance Act of 1968.

''(2) COASTAL STATE.—The term 'coastal State' has the meaning given the term 'coastal state' in section 304 of the Coastal Zone Management Act of 1972 (16 U.S.C. 1453).

''(3) COASTAL WATERS.—The term 'coastal waters' has the meaning given the term in such section.

''(4) COVERED DATA.—The term 'covered data' means, with respect to a named storm identified by the Administrator under subsection (b)(2)(A), empirical data that are—

''(A) collected before, during, or after such storm; and

''(B) necessary to determine magnitude and timing of wind speeds, rainfall, the barometric pressure, river flows, the extent, height, and timing of storm surge, topographic and bathymetric data, and other measures required to accurately model and assess damage from such storm.

''(5) INDETERMINATE LOSS.—The term 'indeterminate loss' has the meaning given the

term in section 1337(a) of the National Flood Insurance Act of 1968.

''(6) NAMED STORM.—The term 'named storm' means any organized weather system with a defined surface circulation and maximum winds of at least 39 miles per hour which the National Hurricane Center of the United States National Weather Service names as a tropical storm or a hurricane.

''(7) NAMED STORM EVENT MODEL.—The term 'Named Storm Event Model' means the official meteorological and oceanographic computerized model, developed by the Administrator under subsection (b)(1)(A), which utilizes covered data to replicate the magnitude, timing, and spatial variations of winds, rainfall, and storm surges associated with named storms that threaten any portion of a coastal State.

''(8) PARTICIPANT.—The term 'participant' means a Federal, State, or private entity that chooses to cooperate with the Administrator in carrying out the provisions of this section by collecting, contributing, and maintaining covered data.

''(9) POST-STORM ASSESSMENT.—The term 'post-storm assessment' means a scientific assessment produced and certified by the Administrator to determine the magnitude, timing, and spatial variations of winds, rainfall, and storm surges associated with a specific named storm to be used in the COASTAL Formula.

''(10) STATE.—The term 'State' means a State of the United States, the District of Columbia, the Commonwealth of Puerto Rico, and any other territory or possession of the United States.

''(b) NAMED STORM EVENT MODEL AND POST-STORM ASSESSMENT.—

''(1) ESTABLISHMENT OF NAMED STORM EVENT MODEL.—

''(A) IN GENERAL.—Not later than 540 days after the date of the enactment of the Consumer Option for an Alternative System to Allocate Losses Act of 2012, the Administrator shall develop by regulation the Named Storm Event Model.

''(B) ACCURACY.—The Named Storm Event Model shall be designed to generate post-storm assessments, as provided in paragraph (2), that have a degree of accuracy of not less than 90 percent for every indeterminate loss for which a post-storm assessment is utilized.

''(2) POST-STORM ASSESSMENT.—

''(A) IDENTIFICATION OF NAMED STORMS THREATENING COASTAL STATES.—After the establishment of the COASTAL Formula, the Administrator shall, in consultation with the Secretary of Homeland Security, identify named storms that may reasonably constitute a threat to any portion of a coastal State.

''(B) POST-STORM ASSESSMENT REQUIRED.—Upon identification of a named storm under subparagraph (A), the Administrator shall develop a post-storm assessment for such named storm using the Named Storm Event Model and covered data collected for such named storm pursuant to the protocol established under subsection (c)(1).

''(C) SUBMITTAL OF POST-STORM ASSESSMENT.—Not later than 90 days after an identification of a named storm is made under subparagraph (A), the Administrator shall submit to the Secretary of Homeland Security the post-storm assessment developed for such storm under subparagraph (B).

''(3) ACCURACY.—The Administrator shall ensure, to the greatest extent practicable, that each post-storm assessment developed under paragraph (2) has a degree of accuracy of not less than 90 percent.

''(4) CERTIFICATION.—For each post-storm assessment carried out under paragraph (2), the Administrator shall—

''(A) certify the degree of accuracy for such assessment, including specific reference to any segments or geographic areas for which the assessment is less than 90 percent accurate; and

''(B) report such certification to the Secretary of Homeland Security for the purposes of use with indeterminate loss claims under section 1337 of the National Flood Insurance Act of 1968.

''(5) FINALITY OF DETERMINATIONS.—A certification of the degree of accuracy of a post-storm assessment under this subsection by the Administrator shall be final and shall not be subject to judicial review.

''(6) AVAILABILITY.—The Administrator shall make available to the public the Named Storm Event Model and any post-storm assessment developed under this subsection.

''(c) ESTABLISHMENT OF A PROTOCOL FOR POST-STORM ASSESSMENT.—

''(1) IN GENERAL.—Not later than 540 days after the date of the enactment of the Consumer Option for an Alternative System to Allocate Losses Act of 2012, the Administrator shall establish a protocol, based on the plan submitted under subsection (d)(3), to collect and assemble all covered data required by the Administrator to produce post-storm assessments required by subsection (b), including assembling data collected by participants and stored in the database established under subsection (f) and from such other sources as the Administrator considers appropriate.

''(2) ACQUISITION OF SENSORS AND STRUCTURES.—If the Administrator is unable to use a public or private asset to obtain covered data as part of the protocol established under paragraph (1), the Administrator may acquire such sensors and structures for the placement of sensors as may be necessary to obtain such data.

''(3) USE OF FEDERAL ASSETS.—If the protocol requires placement of a sensor to develop assessments pursuant to subsection (b), the Administrator shall, to the extent practicable, use Federal assets for the placement of such sensors.

''(4) USE OF ACQUIRED STRUCTURES.—

''(A) IN GENERAL.—If the Administrator acquires a structure for the placement of a sensor for purposes of such protocol, the Administrator shall to the extent practical permit other public and private entities to place sensors on such structure to collect—

''(i) meteorological data;

''(ii) national security-related data;

''(iii) navigation-related data;

''(iv) hydrographic data; or

''(v) such other data as the Administrator considers appropriate.

''(B) RECEIPT OF CONSIDERATION.—The Administrator may receive consideration for the placement of a sensor on a structure under subparagraph (A).

''(C) IN-KIND CONSIDERATION.—Consideration received under subparagraph (B) may be received in-kind.

''(D) USE OF CONSIDERATION.—To the extent practicable, consideration received under subparagraph (B) shall be used for the maintenance of sensors used to collect covered data.

''(5) COORDINATED DEPLOYMENTS AND DATA COLLECTION PRACTICES.—The Administrator shall, in consultation with the Office of the Federal Coordinator for Meteorology, coordinate the deployment of sensors as part of the protocol established under paragraph (1) and related data collection carried out by Federal, State, academic, and private entities who choose to cooperate with the Administrator in carrying out this subsection.

''(6) PRIORITY ACQUISITION AND DEPLOYMENT.—The Administrator shall give priority in the acquisition for and deployment of sensors under the protocol required by paragraph (1) to areas of coastal States that have the highest risk of being harmed by named storms.

''(d) ASSESSMENT OF SYSTEMS AND EFFORTS TO COLLECT COVERED DATA.—

''(1) IDENTIFICATION OF SYSTEMS AND EFFORTS TO COLLECT COVERED DATA.—Not later than 180 days after the date of the enactment of the Consumer Option for an Alternative System to Allocate Losses Act of 2012, the Administrator shall, in consultation with the Office of the Federal Coordinator for Meteorology—

''(A) carry out a survey to identify all Federal and State efforts and systems that are capable of collecting covered data; and

''(B) consult with private and academic sector entities to identify domestic private and academic systems that are capable of collecting covered data.

''(2) IDENTIFICATION OF GAPS.—The Administrator shall, in consultation with the Office of the Federal Coordinator for Meteorology and individuals and entities consulted under subsection (e)(3), assess the systems identified under paragraph (1) and identify which systems meet the needs of the National Oceanic and Atmospheric Administration for the collection of covered data, including with respect to the accuracy requirement for post-storm assessment under subsection (b)(3).

''(3) PLAN.—Not later than 270 days after the date of the enactment of the Consumer Option for an Alternative System to Allocate Losses Act of 2012, the Administrator shall, in consultation with the Office of the Federal Coordinator for Meteorology, submit to Congress a plan for the collection of covered data necessary to develop the Named Storm Event Model and post-storm assessment required by subsection (b) that addresses any gaps identified in paragraph (2).

''(e) COORDINATION OF COVERED DATA COLLECTION AND MAINTENANCE BY PARTICIPANTS.—

''(1) IN GENERAL.—The Administrator shall, in consultation with the Office of the Federal Coordinator for Meteorology, coordinate the collection and maintenance of covered data by participants under this section—

''(A) to streamline the process of collecting covered data in accordance with the protocol established under subsection (c)(1); and

''(B) to maintain transparency of such process and the database established under subsection (f).

''(2) SHARING INFORMATION.—The Administrator shall establish a process for sharing among participants information relevant to collecting and using covered data for—

''(A) academic research;

''(B) private sector use;

''(C) public outreach; and

''(D) such other purposes as the Administrator considers appropriate.

''(3) CONSULTATION.—In carrying out paragraphs (1) and (2), the Administrator shall consult with the following:

''(A) The Commanding General of the United States Army Corps of Engineers.

''(B) The Administrator of the Federal Emergency Management Agency.

''(C) The Commandant of the Coast Guard.

''(D) The Director of the United States Geological Survey.

''(E) The Office of the Federal Coordinator for Meteorology.

''(F) The Director of the National Science Foundation.

''(G) The Administrator of the National Aeronautics and Space Administration.

''(H) Such public, private, and academic sector entities as the Administrator considers appropriate for purposes of carrying out the provisions of this section.

''(f) ESTABLISHMENT OF COASTAL WIND AND WATER EVENT DATABASE.—

''(1) IN GENERAL.—Not later than 1 year after the date of the enactment of the Consumer Option for an Alternative System to Allocate Losses Act of 2012, the Administrator shall establish a database for the collection and compilation of covered data—

''(A) to support the protocol established under subsection (c)(1); and

''(B) for the purposes listed in subsection (e)(2).

''(2) DESIGNATION.—The database established under paragraph (1) shall be known as the 'Coastal Wind and Water Event Database'.

''(g) COMPTROLLER GENERAL STUDY.—Not later than 1 year after the date of the enactment of the Consumer Option for an Alternative System to Allocate Losses Act of 2012, the Comptroller General of the United States shall—

''(1) complete an audit of Federal efforts to collect covered data for purposes of the Consumer Option for an Alternative System to Allocate Losses Act of 2012, which audit shall—

''(A) examine duplicated Federal efforts to collect covered data; and

''(B) determine the cost effectiveness of such efforts; and

''(2) submit to the Committee on Banking, Housing, and Urban Affairs and the Commerce, Science, and Transportation of the Senate and the Committee on Financial Services and the Committee on Science, Space, and Technology of the House of Representatives a report on the findings of the Comptroller General with respect to the audit completed under paragraph (1).''.

SEC. 303. ALTERNATIVE LOSS ALLOCATION SYSTEM FOR INDETERMINATE CLAIMS.

Part A of chapter II of the National Flood Insurance Act of 1968 (42 U.S.C. 4051 et seq.) is amended by adding at the end the following:

''SEC. 1337. ALTERNATIVE LOSS ALLOCATION SYSTEM FOR INDETERMINATE CLAIMS.

''(a) DEFINITIONS.—In this section:

''(1) ADMINISTRATOR.—The term 'Administrator' means the Administrator of the Federal Emergency Management Agency.

''(2) COASTAL FORMULA.—The term 'COASTAL Formula' means the formula established under subsection (b).

''(3) COASTAL STATE.—The term 'coastal State' has the meaning given the term 'coastal state' in section 304 of the Coastal Zone Management Act of 1972 (16 U.S.C. 1453).

''(4) INDETERMINATE LOSS.—

''(A) IN GENERAL.—The term 'indeterminate loss' means, as determined by an insurance claims adjuster certified under the national flood insurance program and in consultation with an engineer as appropriate, a loss resulting from physical damage to, or loss of, property located in any coastal State arising from the combined perils of flood and wind associated with a named storm.

''(B) REQUIREMENTS.—An insurance claims adjuster certified under the national flood insurance program shall only determine that a loss is an indeterminate loss if the claims adjuster determines that—

''(i) no material remnant of physical buildings or man-made structures remain except building foundations for the specific property for which the claim is made; and

''(ii) there is insufficient or no tangible evidence created, yielded, or otherwise left behind of the specific property for which the claim is made as a result of the named storm.

''(5) NAMED STORM.—The term 'named storm' means any organized weather system with a defined surface circulation and maximum winds of not less than 39 miles per hour which the National Hurricane Center of the United States National Weather Service names as a tropical storm or a hurricane.

''(6) POST-STORM ASSESSMENT.—The term 'post-storm assessment' means the post-storm assessment developed under section 12312(b) of the Omnibus Public Land Management Act of 2009.

''(7) STATE.—The term 'State' means a State of the United States, the District of Columbia, the Commonwealth of Puerto Rico, and any other territory or possession of the United States.

''(8) SECRETARY.—The term 'Secretary' means the Secretary of Homeland Security.

''(9) STANDARD INSURANCE POLICY.—The term 'standard insurance policy' means any insurance policy issued under the national flood insurance program that covers loss or damage to property resulting from water peril.

''(10) PROPERTY.—The term 'property' means real or personal property that is insured under a standard insurance policy for loss or damage to structure or contents.

''(11) UNDER SECRETARY.—The term 'Under Secretary' means the Under Secretary of Commerce for Oceans and Atmosphere, in the Under Secretary's capacity as Administrator of the National Oceanic and Atmospheric Administration.

''(b) ESTABLISHMENT OF FLOOD LOSS ALLOCATION FORMULA FOR INDETERMINATE CLAIMS.—

''(1) IN GENERAL.—Not later than 180 days after the date on which the protocol is established under section 12312(c)(1) of the Omnibus Public Land Management Act of 2009, the Secretary, acting through the Administrator and in consultation with the Under Secretary, shall establish by rule a standard formula to determine and allocate wind losses and flood losses for claims involving indeterminate losses.

''(2) CONTENTS.—The standard formula established under paragraph (1) shall—

''(A) incorporate data available from the Coastal Wind and Water Event Database established under section 12312(f) of the Omnibus Public Land Management Act of 2009;

''(B) use relevant data provided on the National Flood Insurance Program Elevation Certificate for each indeterminate loss for which the formula is used;

''(C) consider any sufficient and credible evidence, approved by the Administrator, of the pre-event condition of a specific property, including the findings of any policyholder or insurance claims adjuster in connection with the indeterminate loss to that specific property;

''(D) include other measures, as the Administrator considers appropriate, required to determine and allocate by mathematical formula the property damage caused by flood or storm surge associated with a named storm; and

''(E) subject to paragraph (3), for each indeterminate loss, use the post-storm assessment to allocate water damage (flood or storm surge) associated with a named storm.

''(3) DEGREE OF ACCURACY REQUIRED.—The standard formula established under paragraph (1) shall specify that the Administrator may only use the post-storm assessment for purposes of the formula if the Under Secretary certifies that the post-storm assessment has a degree of accuracy of not less than 90 percent in connection with the specific indeterminate loss for which the assessment and formula are used.

''(c) AUTHORIZED USE OF POST-STORM ASSESSMENT AND COASTAL FORMULA.—

''(1) IN GENERAL.—Subject to paragraph (3), the Administrator may use the post-storm assessment and the COASTAL Formula to—

''(A) review flood loss payments for indeterminate losses, including as part of the quality assurance reinspection program of the Federal Emergency Management Agency for claims under the national flood insurance program and any other process approved by the Administrator to review and validate payments under the national flood insurance program for indeterminate losses following a named storm; and

''(B) assist the national flood insurance program to—

''(i) properly cover qualified flood loss for claims for indeterminate losses; and

''(ii) avoid paying for any loss or damage to property caused by any peril (including wind), other than flood or storm surge, that is not covered under a standard policy under the national flood insurance program.

''(2) FEDERAL DISASTER DECLARATION.—Subject to paragraph (3), in order to expedite claims and reduce costs to the national flood insurance program, following any major disaster declared by the President under section 401 of the Robert T. Stafford Disaster Relief and Emergency Assistance Act (42 U.S.C. 5170) relating to a named storm in a coastal State, the Administrator may use the COASTAL Formula to determine and pay for any flood loss covered under a standard insurance policy under the national flood insurance program, if the loss is an indeterminate loss.

''(3) NATIONAL ACADEMY OF SCIENCES EVALUATION.—

''(A) EVALUATION REQUIRED.—

''(i) EVALUATION.—Upon the issuance of the rule establishing the COASTAL Formula, and each time the Administrator modifies the COASTAL Formula, the National Academy of Sciences shall—

''(I) evaluate the expected financial impact on the national flood insurance program of the use of the COASTAL Formula as so established or modified; and

''(II) evaluate the validity of the scientific assumptions upon which the formula is based and determine whether the COASTAL formula can achieve a degree of accuracy of not less than 90 percent in allocating flood losses for indeterminate losses.

''(ii) REPORT.—The National Academy of Sciences shall submit a report containing the results of each evaluation under clause (i) to the Administrator, the Committee on Banking, Housing, and Urban Affairs of the Senate, and the Committee on Financial Services of the House of Representatives.

''(B) EFFECTIVE DATE AND APPLICABILITY.—

''(i) EFFECTIVE DATE.—Paragraphs (1) and (2) of this subsection shall not take effect unless the report under subparagraph (A) relating to the establishment of the COASTAL Formula concludes that the use of the COASTAL Formula for purposes of paragraph (1) and (2) would not have an adverse financial impact on the national flood insurance program and that the COASTAL Formula is based on valid scientific assumptions that would allow a degree of accuracy of not less than 90 percent to be achieved in allocating flood losses for indeterminate losses.

''(ii) EFFECT OF MODIFICATIONS.—Unless the report under subparagraph (A) relating to a modification of the COASTAL Formula concludes that the use of the COASTAL Formula, as so modified, for purposes of paragraphs (1) and (2) would not have an adverse financial impact on the national flood insurance program and that the COASTAL Formula is based on valid scientific assumptions that would allow a degree of accuracy of not less than 90 percent to be achieved in allocating flood losses for indeterminate losses the Administrator may not use the COASTAL Formula, as so modified, for purposes of paragraphs (1) and (2).

''(C) FUNDING.—Notwithstanding section 1310 of the National Flood Insurance Act of 1968 (42 U.S.C. 4017), there shall be available to the Administrator from the National

Flood Insurance Fund, of amounts not otherwise obligated, not more than $750,000 to carry out this paragraph.

''(d) DISCLOSURE OF COASTAL FORMULA.—Not later than 30 days after the date on which a post-storm assessment is submitted to the Secretary under section 12312(b)(2)(C) of the Omnibus Public Land Management Act of 2009, for each indeterminate loss for which the COASTAL Formula is used pursuant to subsection (c)(2), the Administrator shall disclose to the policyholder that makes a claim relating to the indeterminate loss—

''(1) that the Administrator used the COASTAL Formula with respect to the indeterminate loss; and

''(2) a summary of the results of the use of the COASTAL Formula.

''(e) CONSULTATION.—In carrying out subsections (b) and (c), the Secretary shall consult with—

''(1) the Under Secretary for Oceans and Atmosphere;

''(2) the Director of the National Institute of Standards and Technology;

''(3) the Chief of Engineers of the United States Army Corps of Engineers;

''(4) the Director of the United States Geological Survey;

''(5) the Office of the Federal Coordinator for Meteorology;

''(6) State insurance regulators of coastal States; and

''(7) such public, private, and academic sector entities as the Secretary considers appropriate for purposes of carrying out such subsections.

''(f) RECORDKEEPING.—Each consideration and measure the Administrator determines necessary to carry out subsection (b) may be required, with advanced approval of the Administrator, to be provided for on the National Flood Insurance Program Elevation Certificate, or maintained otherwise on record if approved by the Administrator, for any property that qualifies for the COASTAL Formula under subsection (c).

''(g) CIVIL PENALTY.—

''(1) IN GENERAL.—If an insurance claims adjuster knowingly and willfully makes a false or inaccurate determination relating to an indeterminate loss, the Administrator may, after notice and opportunity for hearing, impose on the insurance claims adjuster a civil penalty of not more than $1,000.

''(2) DEPOSIT.—Notwithstanding section 3302 of title 31, United States Code, or any other law relating to the crediting of money, the Administrator shall deposit in the National Flood Insurance Fund any amounts received under this subsection, which shall remain available until expended and be available to the Administrator for purposes authorized for the National Flood Insurance Fund without further appropriation.

''(h) RULE OF CONSTRUCTION.—Nothing in this subsection shall be construed to require the Administrator to make any payment under the national flood insurance program, or an insurance company to make any payment, for an indeterminate loss based upon post-storm assessment or the COASTAL Formula.

''(i) APPLICABILITY.—Subsection (c) shall apply with respect to an indeterminate loss associated with a named storm that occurs after the date on which the Administrator issues the rule establishing the COASTAL Formula under subsection (b).

''(j) RULE OF CONSTRUCTION.—Nothing in this subsection shall be construed to negate, set aside, or void any policy limit, including any loss limitation, set forth in a standard insurance policy.''.

SA 2139. Mr. SCHUMER submitted an amendment intended to be proposed by him to the bill S. 3187, to amend the Federal Food, Drug, and Cosmetic Act to revise and extend the user-fee programs for prescription drugs and medical devices, to establish user-fee programs for generic drugs and biosimilars, and for other purposes; which was ordered to lie on the table; as follows:

At the end of title XI, add the following:

Subtitle D—Theft of Medical Products

SEC. 1141. SHORT TITLE.

This subtitle may be cited as the ''Safe Doses Act''.

SEC. 1142. THEFT OF MEDICAL PRODUCTS.

(a) PROHIBITED CONDUCT AND PENALTIES.—Chapter 31 of title 18, United States Code, is amended by adding at the end the following:

''§ 670. Theft of medical products

''(a) PROHIBITED CONDUCT.—Whoever, in, or using any means or facility of, interstate or foreign commerce—

''(1) embezzles, steals, or by fraud or deception obtains, or knowingly and unlawfully takes, carries away, or conceals, a pre-retail medical product;

''(2) knowingly and falsely makes, alters, forges, or counterfeits the labeling or documentation (including documentation relating to origination or shipping) of a pre-retail medical product;

''(3) knowingly possesses, transports, or traffics in a pre-retail medical product that was involved in a violation of paragraph (1) or (2);

''(4) with intent to defraud, buys, or otherwise obtains, a pre-retail medical product that has expired or been stolen;

''(5) with intent to defraud, sells, or distributes, a pre-retail medical product that is expired or stolen; or

''(6) attempts or conspires to violate any of paragraphs (1) through (5);

shall be punished as provided in subsection (c) and subject to the other sanctions provided in this section.

''(b) AGGRAVATED OFFENSES.—An offense under this section is an aggravated offense if—

''(1) the defendant is employed by, or is an agent of, an organization in the supply chain for the pre-retail medical product; or

''(2) the violation—

''(A) involves the use of violence, force, or a threat of violence or force;

''(B) involves the use of a deadly weapon;

''(C) results in serious bodily injury or death, including serious bodily injury or death resulting from the use of the medical product involved; or

''(D) is subsequent to a prior conviction for an offense under this section.

''(c) CRIMINAL PENALTIES.—Whoever violates subsection (a)—

''(1) if the offense is an aggravated offense under subsection (b)((2)(C), shall be fined under this title or imprisoned not more than 30 years, or both;

''(2) if the value of the medical products involved in the offense is $5,000 or greater, shall be fined under this title, imprisoned for not more than 15 years, or both, but if the offense is an aggravated offense other than one under subsection (b)(2)(C), the maximum term of imprisonment is 20 years; and

''(3) in any other case, shall be fined under this title, imprisoned for not more than 3 years, or both, but if the offense is an aggravated offense other than one under subsection (b)(2)(C), the maximum term of imprisonment is 5 years.

''(d) CIVIL PENALTIES.—Whoever violates subsection (a) is subject to a civil penalty in an amount not more than the greater of—

''(1) three times the economic loss attributable to the violation; or

''(2) $1,000,000.

''(e) DEFINITIONS.—In this section—

''(1) the term 'pre-retail medical product' means a medical product that has not yet been made available for retail purchase by a consumer;

''(2) the term 'medical product' means a drug, biological product, device, medical food, or infant formula;

''(3) the terms 'device', 'drug', 'infant formula', and 'labeling' have, respectively, the meanings given those terms in section 201 of the Federal Food, Drug, and Cosmetic Act;

''(4) the term 'biological product' has the meaning given the term in section 351 of the Public Health Service Act;

''(5) the term 'medical food' has the meaning given the term in section 5(b) of the Orphan Drug Act; and

''(6) the term 'supply chain' includes manufacturer, wholesaler, repacker, own-labeled distributor, private-label distributor, jobber, broker, drug trader, transportation company, hospital, pharmacy, or security company.''.

(b) CLERICAL AMENDMENT.—The table of sections at the beginning of chapter 31 of title 18, United States Code, is amended by adding after the item relating to section 669 the following:

''670. Theft of medical products.''.

SEC. 1143. CIVIL FORFEITURE.

Section 981(a)(1)(C) of title 18, United States Code, is amended by inserting ''670,'' after ''657,''.

SEC. 1144. PENALTIES FOR THEFT-RELATED OFFENSES.

(a) INTERSTATE OR FOREIGN SHIPMENTS BY CARRIER.—Section 659 of title 18, United States Code, is amended by adding at the end of the fifth undesignated paragraph the following: ''If the offense involves a pre-retail medical product (as defined in section 670), it shall be punished under section 670 unless the penalties provided for under this section are greater.''.

(b) RACKETEERING.—

(1) TRAVEL ACT VIOLATIONS.—Section 1952 of title 18, United States Code, is amended by adding that the end the following:

''(d) If the offense under this section involves an act described in paragraph (1) or (3) of subsection (a) and also involves a pre-retail medical product (as defined in section 670), the punishment for the offense shall be the same as the punishment for an offense under section 670, unless the punishment under subsection (a) is greater.''.

(2) MONEY LAUNDERING.—Section 1957(b)(1) of title 18, United States Code, is amended by adding at the end the following: ''If the offense involves a pre-retail medical product (as defined in section 670) the punishment for the offense shall be the same as the punishment for an offense under section 670 unless the punishment under this subsection is greater.''

(c) BREAKING OR ENTERING CARRIER FACILITIES.—Section 2117 of title 18, United States Code, is amended by adding at the end of the first undesignated paragraph the following: ''If the offense involves a pre-retail medical product (as defined in section 670) the punishment for the offense shall be the same as the punishment for an offense under section 670 unless the punishment under this section is greater.''.

(d) STOLEN PROPERTY.—

(1) TRANSPORTATION OF STOLEN GOODS AND RELATED OFFENSES.—Section 2314 of title 18, United States Code, is amended by adding at the end of the sixth undesignated paragraph the following: ''If the offense involves a pre-retail medical product (as defined in section 670) the punishment for the offense shall be the same as the punishment for an offense under section 670 unless the punishment under this section is greater.''.

(2) SALE OR RECEIPT OF STOLEN GOODS AND RELATED OFFENSES.—Section 2315 of title 18, United States Code, is amended by adding at the end of the fourth undesignated paragraph the following: ''If the offense involves a pre-retail medical product (as defined in section 670) the punishment for the offense shall be the same as the punishment for an offense under section 670 unless the punishment under this section is greater.''.

SEC. 1145. INCLUSION OF NEW OFFENSE AS RICO PREDICATE.

Section 1961(1)(B) of title 18, United States Code, is amended by inserting '', section 670 (relating to theft of medical products)'' before '', sections 891''.

SEC. 1146. AMENDMENT TO EXTEND WIRETAPPING AUTHORITY TO NEW OFFENSE.

Section 2516(1) of title 18, United States Code, is amended—

(1) by redesignating paragraph (s) as paragraph (t);

(2) by striking ''or'' at the end of paragraph (r); and

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

''(s) any violation of section 670 (relating to theft of medical products); or''.

SEC. 1147. REQUIRED RESTITUTION.

Section 3663A(c)(1)(A) of title 18, United States Code, is amended—

(1) in clause (ii), by striking ''or'' at the end;

(2) in clause (iii), by striking ''and'' at the end and inserting ''or''; and

(3) by adding at the end the following:

''(iv) an offense under section 670 (relating to theft of medical products); and''.

SEC. 1148. DIRECTIVE TO THE UNITED STATES SENTENCING COMMISSION.

(a) IN GENERAL.—Pursuant to its authority under section 994 of title 28, United States Code, and in accordance with this section, the United States Sentencing Commission shall review and, if appropriate, amend the Federal sentencing guidelines and policy statements applicable to persons convicted of offenses under section 670 of title 18, United States Code, as added by this Act, section 2118 of title 18, United States Code, or any another section of title 18, United States Code, amended by this Act, to reflect the intent of Congress that penalties for such offenses be sufficient to deter and punish such offenses, and appropriately account for the actual harm to the public from these offenses.

(b) REQUIREMENTS.—In carrying out this section, the United States Sentencing Commission shall—

(1) consider the extent to which the Federal sentencing guidelines and policy statements appropriately reflect—

(A) the serious nature of such offenses;

(B) the incidence of such offenses; and

(C) the need for an effective deterrent and appropriate punishment to prevent such offenses;

(2) consider establishing a minimum offense level under the Federal sentencing guidelines and policy statements for offenses covered by this Act;

(3) account for any additional aggravating or mitigating circumstances that might justify exceptions to the generally applicable sentencing ranges;

(4) ensure reasonable consistency with other relevant directives, Federal sentencing guidelines and policy statements;

(5) make any necessary conforming changes to the Federal sentencing guidelines and policy statements; and

(6) ensure that the Federal sentencing guidelines and policy statements adequately meet the purposes of sentencing set forth in section 3553(a)(2) of title 18, United States Code.

SA 2140. Mr. SCHUMER (for himself, Mr. MERKLEY, and Mr. BLUMENTHAL) submitted an amendment intended to be proposed by him to the bill S. 3187, to amend the Federal Food, Drug, and Cosmetic Act to revise and extend the user-fee programs for prescription drugs and medical devices, to establish user-fee programs for generic drugs and biosimilars, and for other purposes; which was ordered to lie on the table; as follows:

At the end, insert the following:

TITLE ____—PROTECTING PATIENTS AND HOSPITALS FROM PRICE GOUGING ACT

SEC. __01. SHORT TITLE.

This title may be cited as the ''Protecting Patients and Hospitals From Price Gouging Act''.

SEC. __02. FINDINGS AND PURPOSE.

(a) FINDINGS.—Congress finds that—

(1) many pharmaceutical drugs are necessary to maintain the health and welfare of the American people;

(2) currently the Nation is facing a chronic shortage of vital drugs necessary in surgery, to treat cancer, and to fight other life-threatening illnesses; and

(3) in order to prevent any party within the chain of distribution of any vital drugs from taking unfair advantage of consumers during market shortages, the public interest requires that such conduct be prohibited and made subject to criminal penalties.

(b) PURPOSE.—The purpose of this title is to prohibit excessive pricing during market shortages.

SEC. __03. DEFINITIONS.

As used in this title—

(1) the term ''market shortage'' means a situation in which the total supply of all clinically interchangeable versions of an FDA-regulated drug is inadequate to meet the current or projected demand at the user level;

(2) the term ''drug'' means a drug intended for use by human beings, which—

(A) because of its toxicity or other potentiality for harmful effect, or the method of its use, or the collateral measures necessary to its use, is not safe for use except under the supervision of a practitioner licensed by law to administer such drug; or

(B) is limited by an approved application under section 505 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 355) to use under the professional supervision of a practitioner licensed by law to administer such drug;

(3) the term ''biologic'' means a virus, therapeutic serum, toxin, antitoxin, vaccine, blood, blood component or derivative, allergenic product, or analogous product, or arsphenamine or derivative of arsphenamine (or any other trivalent organic arsenic compound), applicable to the prevention, treatment, or cure of a disease or condition of human beings; and

(4) the term ''vital drug'' means any drug or biologic used to prevent or treat a serious or life-threatening disease or medical condition, for which there is no other available source with sufficient supply of that drug or biologic or alternative drug or biologic available.

SEC. __04. UNREASONABLY EXCESSIVE DRUG PRICING.

(a) IN GENERAL.—

(1) AUTHORITY.—The President may issue an Executive Order declaring a market shortage for a period of 6 months with regard to one or more vital drugs due to a market shortage under this title.

(2) UNLAWFUL ACT.—If the President issues an Executive Order under paragraph (1), it shall be unlawful for any person to sell vital drugs at a price that is unreasonably excessive and indicates that the seller is taking unfair advantage of the circumstances related to a market shortage to unreasonably increase prices during such period.

(b) AUTHORITY.—The Attorney General is authorized to enforce penalties under this title.

SEC. __05. ENFORCEMENT.

(a) ENFORCEMENT.—

(1) IN GENERAL.—Whoever sells, or offers to sell, any vital drug during a declared market shortage with the knowledge and intent to charge a price that is unreasonably excessive under the circumstances shall be guilty of an offense under this section and subject to injunction and penalties as provided in paragraphs (2) and (3).

(2) ACTION IN DISTRICT COURT FOR INJUNCTION.—Whenever it shall appear to the Attorney General that any person is engaged in or about to engage in acts or practices constituting a violation of any provision of this section and until such complaint is dismissed by the Attorney General or set aside by a court on review, the Attorney General may in his or her discretion bring an action in the proper district court of the United States, the United States District Court for the District of Columbia, or the United States courts of any territory or other place subject to the jurisdiction of the United States to enjoin such acts or practices, and upon a proper showing a permanent or temporary injunction or restraining order shall be granted without bond in the interest of the public.

(3) CRIMINAL PENALTIES.—Any person acting with the knowledge and intent to charge a price that is unreasonably excessive under the circumstances shall be guilty of an offense under this section and title 18, United States Code, and subject to imprisonment for a term not to exceed 3 years, fined an amount not to exceed $5,000,000, or both.

(b) ENFORCEMENT.—The criminal penalty provided by subsection (a) may be imposed only pursuant to a criminal action brought by the Attorney General or other officer of the Department of Justice.

(c) MULTIPLE OFFENSES.—In assessing the penalty provided by subsection (a) each day of a continuing violation shall be considered a separate violation.

(d) APPLICATION.—

(1) IN GENERAL.—This section shall apply—

(A) in the geographical area where the vital drug market shortage has been declared; and

(B) to all wholesalers and distributors in the chain of distribution.

(2) INAPPLICABLE.—This section shall not apply to a hospital (as defined in section 1861(e) of the Social Security Act (42 U.S.C. 1395x(e)) or a physician (as defined in section 1861(q) of the Social Security Act (42 U.S.C. 1395x(q)).

SEC. __06. DETERMINATION OF UNREASONABLY EXCESSIVE.

(a) IN GENERAL.—The Attorney General, in determining whether an alleged violator's price was unreasonably excessive, shall consider whether—

(1) the price reasonably reflected additional costs, not within the control of that person or company, that were paid, incurred, or reasonably anticipated by that person or company;

(2) the price reasonably reflected additional risks taken by that person or company to produce, distribute, obtain, or sell such product under the circumstances;

(3) there is a gross disparity between the challenged price and the price at which the same or similar goods were readily available in the same region and during the same Presidentially-declared market shortage;

(4) the marginal benefit received by the wholesaler or distributor is significantly changed in comparison with marginal earnings in the year before a market shortage was declared;

(5) the price charged was comparable to the price at which the goods were generally available in the trade area if the wholesaler or distributor did not sell or offer to sell the prescription drug in question prior to the time a market shortage was declared; and

(6) the price was substantially attributable to local, regional, national, or international market conditions.

(b) CONSULTATION.—Not later than 1 year after the date of enactment of this title and annually thereafter, the Attorney General or designee, shall consult with representatives of the National Association of Wholesalers, Group Purchasing Organizations, Pharmaceutical Distributors, Hospitals, Manufacturers, patients, and other interested community organizations to reassess the criteria set forth in subsection (a) in determining unreasonably excessive and prepare and submit to Congress a report on the results of the reassessment.

SEC. __07. DURATION.

(a) IN GENERAL.—Any market shortage declared by the President in accordance with this title shall be in effect for a period of not to exceed 6 months from the date on which the President issues the Executive Order.

(b) TERMINATION.—Any market shortage declared by the President in accordance with this title shall terminate if—

(1) there is enacted a law terminating the market shortage which shall be passed by Congress after a national market shortage is declared; or

(2) the President issues a proclamation terminating the market shortage;

whichever comes first.

(c) DECLARATION RENEWAL.—The President may renew the state of market shortage declared under subsection (a), if the President declares that the severe shortage continues to affect the health and well being of citizens beyond the initial 6-month period.

SA 2141. Mr. CARDIN (for himself and Ms. LANDRIEU) submitted an amendment intended to be proposed by him to the bill S. 3187, to amend the Federal Food, Drug, and Cosmetic Act to revise and extend the user-fee programs for prescription drugs and medical devices, to establish user-fee programs for generic drugs and biosimilars, and for other purposes; which was ordered to lie on the table; as follows:

At the end of title XI, add the following:

SEC. 11___. REPORT ON SMALL BUSINESSES.

Not later than 1 year after the date of enactment of this Act, the Commissioner of Food and Drugs shall submit a report to Congress that includes—

(1) a listing of and staffing levels of all small business offices at the Food and Drug Administration, including the small business liaison program;

(2) the status of partnership efforts between the Food and Drug Administration and the Small Business Administration;

(3) a summary of outreach efforts to small businesses and small business associations, including availability of toll-free telephone help lines;

(4) with respect to the program under the Orphan Drug Act (Public Law 97–414), the number of applications made by small businesses and number of applications approved for research grants, the amount of tax credits issued for clinical research, and the number of companies receiving protocol assistance for the development of drugs for rare diseases and disorders;

(5) with respect to waivers and reductions for small business under the Prescription Drug User Fee Act, the number of small businesses applying for and receiving waivers and reductions from drug user fees under subchapter C of chapter VII of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 379f et seq.);

(6) the number of small businesses submitting applications and receiving approval for unsolicited grant applications from the Food and Drug Administration;

(7) the number of small businesses submitting applications and receiving approval for solicited grant applications from the Food and Drug Administration;

(8) barriers small businesses encounter in the drug and medical device approval process; and

(9) recommendations for changes in the user fee structure to help alleviate generic drug shortages.

SA 2142. Mr. LEAHY submitted an amendment intended to be proposed by him to the bill S. 3187, to amend the Federal Food, Drug, and Cosmetic Act to revise and extend the user-fee programs for prescription drugs and medical devices, to establish user-fee programs for generic drugs and biosimilars, and for other purposes; which was ordered to lie on the table; as follows:

On page 192, strike line 10 through line 21 and insert the following:

(2) by adding at the end the following:

''(b) ABILITY TO RECEIVE AND PROTECT CONFIDENTIAL INFORMATION OBTAINED FROM FOREIGN GOVERNMENT AGENCIES RELATING TO DRUG INSPECTIONS.—

''(1) IN GENERAL.—The Secretary shall not be required to disclose under section 552 of title 5, United States Code (commonly referred to as the Freedom of Information Act), or any other provision of law, any information relating to drug inspections obtained from a foreign government agency, if—

''(A) the information is provided or made available to the United States Government voluntarily and on the condition that the information not be released to the public;

''(B) the foreign government agency, in writing, requests that the information be kept confidential; and

''(C) the Secretary determines that the requirements under subparagraphs (A) and (B) have been satisfied.

''(2) TIME LIMITATIONS.—A foreign government agency may specify in a request described in paragraph (1)(B) that the voluntarily-provided information be withheld from disclosure for a specified time period. Such information may not be withheld under this subsection after the date specified. If no such date is specified, the withholding period shall not exceed 3 years.

''(3) DISCLOSURES NOT AFFECTED.—Nothing in this subsection authorizes any official to withhold, or to authorize the withholding of, information from Congress or information required to be disclosed pursuant to an order of a court of the United States. For purposes of section 552 of title 5, United States Code, this subsection shall be considered a statute described in section 552(b)(3)(B).

SA 2143. Mr. PAUL submitted an amendment intended to be proposed by him to the bill S. 3187, to amend the Federal Food, Drug, and Cosmetic Act to revise and extend the user-fee programs for prescription drugs and medical devices, to establish user-fee programs for generic drugs and biosimilars, and for other purposes; which was ordered to lie on the table; as follows:

At the appropriate place, insert the following:

SEC. 11___. LIMITATION ON SUPPRESSION BY FEDERAL GOVERNMENT OF CLAIMS IN FOOD AND DIETARY SUPPLEMENTS.

(a) IN GENERAL.—The Federal Government may not take any action to prevent use of a claim describing any nutrient in a food or dietary supplement (as such terms are defined in section 201 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 321)) as mitigating, treating, or preventing any disease, disease symptom, or health-related condition, unless a Federal court in a final order following a trial on the merits finds clear and convincing evidence based on qualified expert opinion and published peer-reviewed scientific research that—

(1) the claim is false and misleading in a material respect; and

(2) there is no less speech restrictive alternative to claim suppression, such as use of disclaimers or qualifications, that can render the claim non-misleading.

(b) DEFINITION.—In this section, the term ''material'' means that the Food and Drug Administration has identified a competent consumer survey demonstrating that consumers decided to purchase the food or dietary supplement based on the portion of the claim alleged to be false or misleading.

SEC. 11___. DEFINITION OF DRUG.

(a) IN GENERAL.—Subparagraph (1) of section 201(g) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 321(g)) is amended by striking the second and third sentences and inserting the following: ''A food or dietary supplement for which a claim is made in accordance with section 403(r)(1)(B) is not a drug solely because of such claim.''.

(b) RULES.—All rules of the Food and Drug Administration in existence on the date of the enactment of this Act prohibiting nutrient-disease relationship claims are revoked.

SEC. 11___. MISBRANDED FOOD.

Section 403(r) (21 U.S.C. 343(r)) is amended—

(1) by striking clause (B) of subparagraph (1) and inserting the following:

''(B) describes any nutrient as mitigating, treating, or preventing any disease, disease symptom, or health-related condition if, and only if, the claim has been adjudicated false and misleading in a material respect by final order of a Federal court of competent jurisdiction in accordance with section 1202 of the Health Freedom Act.'';

(2) by striking subparagraph (3);

(3) in the first sentence of subparagraph (4)(A)(i)—

(A) by striking ''or (3)(B)''; and

(B) by striking ''or (1)(B)'';

(4) by striking clause (C) of subparagraph (4);

(5) by striking clause (D) of subparagraph (5); and

(6) in subparagraph (6), in the matter following clause (C), by striking the first sentence.

SEC. 11___. DIETARY SUPPLEMENT LABELING EXEMPTIONS.

Section 403B (21 U.S.C. 343–2) is amended to read as follows:

''FOOD AND DIETARY SUPPLEMENT LABELING

''SEC. 403B. The Federal Government shall take no action to prevent distribution of any publication in connection with the sale of a food or dietary supplement to consumers unless it establishes that a claim contained in the publication—

''(1) names the specific food or dietary supplement sold by the person causing the publication to be distributed;

''(2) represents that the specific food or dietary supplement mitigates, treats, or prevents a disease; and

''(3) proves the claim to be false and misleading in a material respect by final order of a Federal court of competent jurisdiction.''.

SEC. 11___. PROHIBITIONS ON FDA OFFICIALS CARRYING FIREARMS AND MAKING ARRESTS WITHOUT WARRANTS.

Section 702(e) (21 U.S.C. 372(e)) is amended—

(1) by striking paragraph (1);

(2) by redesignating paragraphs (2) and (3) as paragraphs (1) and (2) respectively;

(3) in paragraph (2), as so redesignated, by adding ''and'' after the semicolon at the end;

(4) by striking paragraph (4); and

(5) by redesignating paragraph (5) as paragraph (3).

SEC. 11___. PROHIBITED ACTS.

Section 301 (21 U.S.C. 331) is amended—

(1) in subsection (a), by inserting ''knowing and willful'' before ''introduction or delivery'';

(2) in subsection (b), by inserting ''knowing and willful'' before ''adulteration'';

(3) in subsection (c), by inserting ''knowing and willful'' before ''receipt'';

(4) in subsection (d), by inserting ''knowing and willful'' before ''introduction or delivery'';

(5) in subsection (e), by striking ''The refusal'' and inserting ''The knowing and willful refusal'';

(6) in subsection (f), by inserting ''knowing and willful'' before ''refusal'';

(7) in subsection (g), by inserting ''knowing and willful'' before ''manufacture'';

(8) in subsection (h), by striking ''The giving'' and inserting ''The knowing and willful giving'';

(9) in subsection (i)—

(A) in paragraph (1)—

(i) by striking ''Forging'' and inserting ''Knowingly and willfully forging''; and

(ii) by inserting ''knowingly and willfully'' after ''proper authority'';

(B) in paragraph (2), by striking ''Making'' and inserting ''Knowingly and willfully making''; and

(C) in paragraph (3), by striking ''The doing'' and inserting ''The knowing and willful doing'';

(10) in subsection (j), by striking ''The using'' and inserting ''The knowing and willful using'';

(11) in subsection (k)—

(A) by inserting ''knowing and willful'' before ''alteration''; and

(B) by inserting ''knowing and willful'' before ''doing'';

(12) in subsection (m), by striking ''The sale'' and inserting ''The knowing and willful sale'';

(13) in subsection (n), by striking ''The using'' and inserting ''The knowing and willful using'';

(14) in subsection (o), by inserting ''knowing and willful'' before ''failure'';

(15) in subsection (p), by striking ''The failure'' and inserting ''The knowing and willful failure'';

(16) in subsection (q)—

(A) in paragraph (1), by striking ''The failure'' and inserting ''The knowing and willful failure''; and

(B) in paragraph (2), by inserting ''knowing and willful'' before ''submission'';

(17) in subsection (r), by inserting ''knowing and willful'' before ''movement'';

(18) in subsection (s), by striking ''The failure'' and inserting ''The knowing and willful failure'';

(19) in subsection (t), by striking ''The importation'' and inserting ''The knowing and willful importation'';

(20) in subsection (u), by inserting ''knowing and willful'' before ''failure'';

(21) in subsection (v), by striking ''The introduction'' and inserting ''The knowing and willful introduction'';

(22) in subsection (w), by inserting ''The making'' and inserting ''The knowing and willful making'';

(23) in subsection (x), by inserting ''knowing and willful'' before falsification;

(24) in subsection (y)—

(A) in paragraph (1), by inserting ''knowing and willful'' before ''submission'';

(B) in paragraph (2), by inserting ''knowing and willful'' before ''disclosure''; and

(C) in paragraph (3), by inserting ''knowing and willful'' before ''receipt'';

(25) in subsection (aa), by inserting ''knowing and willful'' before ''importation'';

(26) in subsection (bb), by inserting ''knowing and willful'' before ''transfer'';

(27) in subsection (cc), by inserting ''knowing and willful'' before ''importing'';

(28) in subsection (dd), by inserting ''knowing and willful'' before ''failure'';

(29) in subsection (ee), by inserting ''knowing and willful'' before ''importing'';

(30) in subsection (ff), by inserting ''knowing and willful'' before ''importing'';

(31) in subsection (gg), by inserting ''and willful'' after ''knowing'' each place such term appears;

(32) in subsection (hh), by inserting ''knowing and willful'' before ''failure'';

(33) in subsection (ii), by inserting ''knowing and willful'' before ''falsification of a report'';

(34) in subsection (jj)—

(A) in paragraph (1)—

(i) by inserting ''knowing and willful'' before ''failure''; and

(ii) by inserting ''and willfully'' after ''knowingly'';

(B) in paragraph (2), by inserting ''knowing and willful'' before ''failure''; and

(C) in paragraph (3), by inserting ''knowing and willful'' before ''submission'';

(35) in subsection (kk), by inserting ''knowing and willful'' before ''dissemination'';

(36) in subsection (ll), by striking ''The introduction'' and inserting ''The knowing and willful introduction'';

(37) in subsection (mm), by inserting ''knowing and willful'' before ''failure'';

(38) in subsection (nn), by inserting ''knowing and willful'' before ''falsification'';

(39) in subsection (oo), by inserting ''knowing and willful'' before ''introduction or delivery'';

(40) in subsection (pp), by inserting ''knowing and willful'' before ''introduction or delivery'';

(41) in subsection (qq)—

(A) in paragraph (1), by striking ''Forging'' and inserting ''Knowingly and willfully forging'';

(B) in paragraph (2), by striking ''Making'' and inserting ''Knowingly and willfully making''; and

(C) in paragraph (3), by inserting ''knowingly and willfully'' before ''doing'';

(42) in subsection (rr), by inserting ''knowing and willful'' before ''charitable'';

(43) in subsection (ss), by inserting ''knowing and willful'' before ''failure'';

(44) in subsection (tt), by striking ''Making'' and inserting ''Knowingly and willfully making'';

(45) in subsection (vv), by inserting ''knowing and willful'' before ''failure'';

(46) in subsection (ww), by inserting ''knowing and willful'' before ''failure'';

(47) in subsection (xx), by inserting ''knowing and willful'' before ''refusal'';

(48) in subsection (aaa), as added by section 712, by inserting ''knowing and willful'' before ''failure''; and

(49) in subsection (bbb), as added by section 722, by inserting ''knowing and willful'' before ''violation''.

SA 2144. Mr. HATCH (for himself, Mr. BURR, Mr. ALEXANDER, and Mr. ROBERTS) submitted an amendment intended to be proposed by him to the bill S. 3187, to amend the Federal Food, Drug, and Cosmetic Act to revise and extend the user-fee programs for prescription drugs and medical devices, to establish user-fee programs for generic drugs and biosimilars, and for other purposes; which was ordered to lie on the table; as follows:

On page 150, between lines 2 and 3, insert the following:

''(C)(i) Reclassification by administrative order under subparagraph (A) shall apply only in the case of reclassification of a class III or class II device as a class II or class I device. The Secretary may reclassify a class I or class II device as a class II or class III device by regulation and revoke, because of the change in classification, any regulation or requirement in effect under section 514 or 515 with respect to such device. In the promulgation of such a regulation respecting a device's classification, the Secretary may secure from the panel to which the device was last referred pursuant to subsection (c) a recommendation respecting the proposed change in the device's classification and shall publish in the Federal Register any recommendation submitted to the Secretary by the panel respecting such change. A regulation under this subsection changing the classification of a device from class III to class II may provide that such classification shall not take effect until the effective date of a performance standard established under section 514 for such device.

''(ii) In the case of a device reclassified as described in clause (i), paragraph (2), section 514(a)(1), and section 517(a)(1) shall apply to a regulation promulgated under clause (i) in the same manner such provisions apply to an order issued under subparagraph (A).''.

SA 2145. Mr. PORTMAN submitted an amendment intended to be proposed by him to the bill S. 3187, to amend the Federal Food, Drug, and Cosmetic Act to revise and extend the user-fee programs for prescription drugs and medical devices, to establish user-fee programs for generic drugs and biosimilars, and for other purposes; which was ordered to lie on the table; as follows:

At the end of title XI, add the following:

Subtitle D—Interstate Drug Monitoring Efficiency and Data Sharing

SECTION 1141. SHORT TITLE.

This subtitle may be cited as the ''Interstate Drug Monitoring Efficiency and Data Sharing Act of 2012'' or the ''ID MEDS Act''.

SEC. 1142. NATIONAL INTEROPERABILITY STANDARDS.

(a) IN GENERAL.—Not later than 1 year after the date of enactment of this Act, the Attorney General shall establish national interoperability standards to facilitate the exchange of prescription information across State lines by States receiving grant funds under—

(1) the Harold Rogers Prescription Drug Monitoring Program established under the Departments of Commerce, Justice, and State, the Judiciary, and Related Agencies

Appropriations Act, 2002 (Public Law 107–77; 115 Stat. 748); and

(2) the Controlled Substance Monitoring Program established under section 399O of the Public Health Service Act (42 U.S.C. 280g–3).

(b) REQUIREMENTS.—The Attorney General, in consultation with the Secretary of Health and Human Services, shall ensure that the national interoperability standards established under subsection (a)—

(1) implement open standards that are freely available, without cost and without restriction, in order to promote broad implementation;

(2) provide for the use of exchange intermediaries, or hubs, as necessary to facilitate interstate interoperability by accommodating State-to-hub and direct State-to-State communication;

(3) support transmissions that are fully secured as required, using industry standard methods of encryption, to ensure that Protected Health Information and Personally Identifiable Information (PHI and PII) are not compromised at any point during such transmission; and

(4) employ access control methodologies to share protected information solely in accordance with State laws and regulations.

SEC. 1143. STATE RECIPIENT REQUIREMENTS.

(a) HAROLD ROGERS PRESCRIPTION DRUG MONITORING PROGRAM.—

(1) IN GENERAL.—Not later than 1 year after the date on which the Attorney General establishes national interoperability standards under section 1142(a), a recipient of a grant under the Harold Rogers Prescription Drug Monitoring Program established under the Departments of Commerce, Justice, and State, the Judiciary, and Related Agencies Appropriations Act, 2002 (Public Law 107–77; 115 Stat. 748) shall ensure that the databases of the State comply with such national interoperability standards.

(2) USE OF ENHANCEMENT GRANT FUNDS.—A recipient of an enhancement grant under the Harold Rogers Prescription Drug Monitoring Program established under the Departments of Commerce, Justice, and State, the Judiciary, and Related Agencies Appropriations Act, 2002 (Public Law 107–77; 115 Stat. 748) may use enhancement grant funds to standardize the technology architecture used by the recipient to comply with the national interoperability standards established under section 1142(a).

(b) CONTROLLED SUBSTANCE MONITORING PROGRAM.—Section 399O(e) of the Public Health Service Act (42 U.S.C. 280g–3(e)) is amended by adding at the end the following:

''(5) Not later than 1 year after the date on which the Attorney General establishes national interoperability standards under section 1142(a) of the ID MEDS Act, the State shall ensure that the database complies with such national interoperability standards.''.

SEC. 1144. REPORT.

(a) IN GENERAL.—Not later than 1 year after the date of enactment of this Act, the Attorney General, in consultation with the Secretary of Health and Human Services, shall submit to the Committee on the Judiciary of the Senate and the Committee on the Judiciary of the House of Representatives a report on enhancing the interoperability of State prescription monitoring programs with other technologies and databases used for detecting and reducing fraud, diversion, and abuse of prescription drugs.

(b) CONTENTS.—The report required under subsection (a) shall include—

(1) a discussion of the feasibility of making State prescription monitoring programs interoperable with other relevant technologies and databases, including—

(A) electronic prescribing systems;

(B) databases operated by the Drug Enforcement Agency;

(C) electronic health records; and

(D) pre-payment fraud-detecting analytics technologies;

(2) an assessment of legal, technical, fiscal, privacy, or security challenges that have an impact on interoperability;

(3) a discussion of how State prescription monitoring programs could increase the production and distribution of unsolicited reports to prescribers and dispensers of prescription drugs, law enforcement officials, and health professional licensing agencies, including the enhancement of such reporting through interoperability with other States and relevant technology and databases; and

(4) any recommendations for addressing challenges that impact interoperability of State prescription monitoring programs in order to reduce fraud, diversion, and abuse of prescription drugs.

SA 2146. Mr. PORTMAN submitted an amendment intended to be proposed by him to the bill S. 3187, to amend the Federal Food, Drug, and Cosmetic Act to revise and extend the user-fee programs for prescription drugs and medical devices, to establish user-fee programs for generic drugs and biosimilars, and for other purposes; which was ordered to lie on the table; as follows:

At the end of title XI, insert the following:

Subtitle D—Synthetic Drugs

SECTION 1141. SHORT TITLE.

This subtitle may be cited as the ''Synthetic Drug Abuse Prevention Act of 2012''.

SEC. 1142. ADDITION OF SYNTHETIC DRUGS TO SCHEDULE I OF THE CONTROLLED SUBSTANCES ACT.

(a) CANNABIMIMETIC AGENTS.—Schedule I, as set forth in section 202(c) of the Controlled Substances Act (21 U.S.C. 812(c)) is amended by adding at the end the following:

''(d)(1) Unless specifically exempted or unless listed in another schedule, any material, compound, mixture, or preparation which contains any quantity of cannabimimetic agents, or which contains their salts, isomers, and salts of isomers whenever the existence of such salts, isomers, and salts of isomers is possible within the specific chemical designation.

''(2) In paragraph (1):

''(A) The term 'cannabimimetic agents' means any substance that is a cannabinoid receptor type 1 (CB1 receptor) agonist as demonstrated by binding studies and functional assays within any of the following structural classes:

''(i) 2-(3-hydroxycyclohexyl)phenol with substitution at the 5-position of the phenolic ring by alkyl or alkenyl, whether or not substituted on the cyclohexyl ring to any extent.

''(ii) 3-(1-naphthoyl)indole or 3-(1-naphthylmethane)indole by substitution at the nitrogen atom of the indole ring, whether or not further substituted on the indole ring to any extent, whether or not substituted on the naphthoyl or naphthyl ring to any extent.

''(iii) 3-(1-naphthoyl)pyrrole by substitution at the nitrogen atom of the pyrrole ring, whether or not further substituted in the pyrrole ring to any extent, whether or not substituted on the naphthoyl ring to any extent.

''(iv) 1-(1-naphthylmethylene)indene by substitution of the 3-position of the indene ring, whether or not further substituted in the indene ring to any extent, whether or not substituted on the naphthyl ring to any extent.

''(v) 3-phenylacetylindole or 3-benzoylindole by substitution at the nitrogen atom of the indole ring, whether or not further substituted in the indole ring to any extent, whether or not substituted on the phenyl ring to any extent.

''(B) Such term includes—

''(i) 5-(1,1-dimethylheptyl)-2-[(1R,3S)-3-hydroxycyclohexyl]-phenol (CP–47,497);

''(ii) 5-(1,1-dimethyloctyl)-2-[(1R,3S)-3-hydroxycyclohexyl]-phenol (cannabicyclohexanol or CP–47,497 C8-homolog);

''(iii) 1-pentyl-3-(1-naphthoyl)indole (JWH–018 and AM678);

''(iv) 1-butyl-3-(1-naphthoyl)indole (JWH–073);

''(v) 1-hexyl-3-(1-naphthoyl)indole (JWH–019);

''(vi) 1-[2-(4-morpholinyl)ethyl]-3-(1-naphthoyl)indole (JWH–200);

''(vii) 1-pentyl-3-(2-methoxyphenylacetyl)indole (JWH–250);

''(viii) 1-pentyl-3-[1-(4-methoxynaphthoyl)]indole (JWH–081);

''(ix) 1-pentyl-3-(4-methyl-1-naphthoyl)indole (JWH–122);

''(x) 1-pentyl-3-(4-chloro-1-naphthoyl)indole (JWH–398);

''(xi) 1-(5-fluoropentyl)-3-(1-naphthoyl)indole (AM2201);

''(xii) 1-(5-fluoropentyl)-3-(2-iodobenzoyl)indole (AM694);

''(xiii) 1-pentyl-3-[(4-methoxy)-benzoyl]indole (SR–19 and RCS–4);

''(xiv) 1-cyclohexylethyl-3-(2-methoxyphenylacetyl)indole (SR–18 and RCS–8); and

''(xv) 1-pentyl-3-(2-chlorophenylacetyl)indole (JWH–203).''.

(b) OTHER DRUGS.—Schedule I of section 202(c) of the Controlled Substances Act (21 U.S.C. 812(c)) is amended in subsection (c) by adding at the end the following:

''(18) 4-methylmethcathinone (Mephedrone).

''(19) 3,4-methylenedioxypyrovalerone (MDPV).

''(20) 2-(2,5-Dimethoxy-4-ethylphenyl)ethanamine (2C–E).

''(21) 2-(2,5-Dimethoxy-4-methylphenyl)ethanamine (2C–D).

''(22) 2-(4-Chloro-2,5-dimethoxyphenyl)ethanamine (2C–C).

''(23) 2-(4-Iodo-2,5-dimethoxyphenyl)ethanamine (2C–I).

''(24) 2-[4-(Ethylthio)-2,5-dimethoxyphenyl]ethanamine (2C–T–2).

''(25) 2-[4-(Isopropylthio)-2,5-dimethoxyphenyl]ethanamine (2C–T–4).

''(26) 2-(2,5-Dimethoxyphenyl)ethanamine (2C–H).

''(27) 2-(2,5-Dimethoxy-4-nitrophenyl)ethanamine (2C–N).

''(28) 2-(2,5-Dimethoxy-4-(n)-propylphenyl)ethanamine (2C–P).''.

SEC. 1143. TEMPORARY SCHEDULING TO AVOID IMMINENT HAZARDS TO PUBLIC SAFETY EXPANSION.

Section 201(h)(2) of the Controlled Substances Act (21 U.S.C. 811(h)(2)) is amended—

(1) by striking ''one year'' and inserting ''2 years''; and

(2) by striking ''six months'' and inserting ''1 year''.

SA 2147. Mr. HATCH (for himself, Mr. BROWN of Massachusetts, Mr. BURR, Mr. COBURN, Mr. CORNYN, Mr. LUGAR, Mr. ROBERTS, Mr. HOEVEN, Mrs. HUTCHISON, Mr. LEE, Mr. WICKER, Mr. COATS, Mr. BARRASSO, Mr. TOOMEY, Mr. MORAN, Ms. COLLINS, Mr. INHOFE, Mr. BLUNT, Mr. PORTMAN, Mr. ALEXANDER, Ms. AYOTTE, and Mr. CRAPO) submitted an amendment intended to be proposed by him to the bill S. 3187, to amend the

Federal Food, Drug, and Cosmetic Act to revise and extend the user-fee programs for prescription drugs and medical devices, to establish user-fee programs for generic drugs and biosimilars, and for other purposes; which was ordered to lie on the table; as follows:

At the end of title XI, add the following:

SEC. 11___. REPEAL OF MEDICAL DEVICE EXCISE TAX.

Subsections (a), (b), and (c) of section 1405 of the Health Care and Education Reconciliation Act of 2010, and the amendments made thereby, are hereby repealed; and the Internal Revenue Code of 1986 shall be applied as if such section and amendments had never been enacted.

SA 2148. Mr. KOHL (for himself, Mr. GRASSLEY, Ms. KLOBUCHAR, Mr. FRANKEN, Mr. JOHNSON of South Dakota, Mr. BROWN of Ohio, Mr. BINGAMAN, and Mr. SANDERS) submitted an amendment intended to be proposed by him to the bill S. 3187, to amend the Federal Food, Drug, and Cosmetic Act to revise and extend the user-fee programs for prescription drugs and medical devices, to establish user-fee programs for generic drugs and biosimilars, and for other purposes; which was ordered to lie on the table; as follows:

At the end of the bill, insert the following:

TITLE ___.—PRESERVE ACCESS TO AFFORDABLE GENERICS ACT

SEC. __01. SHORT TITLE.

This title may be cited as the ''Preserve Access to Affordable Generics Act''.

SEC. __02. CONGRESSIONAL FINDINGS AND DECLARATION OF PURPOSES.

(a) FINDINGS.—Congress finds the following:

(1) In 1984, the Drug Price Competition and Patent Term Restoration Act (Public Law 98–417) (referred to in this title as the ''1984 Act''), was enacted with the intent of facilitating the early entry of generic drugs while preserving incentives for innovation.

(2) Prescription drugs make up 10 percent of the national health care spending but for the past decade have been one of the fastest growing segments of health care expenditures.

(3) Until recently, the 1984 Act was successful in facilitating generic competition to the benefit of consumers and health care payers—although 67 percent of all prescriptions dispensed in the United States are generic drugs, they account for only 20 percent of all expenditures.

(4) Generic drugs cost substantially less than brand name drugs, with discounts off the brand price sometimes exceeding 90 percent.

(5) Federal dollars currently account for an estimated 30 percent of the $235,000,000,000 spent on prescription drugs in 2008, and this share is expected to rise to 40 percent by 2018.

(6)(A) In recent years, the intent of the 1984 Act has been subverted by certain settlement agreements between brand companies and their potential generic competitors that make ''reverse payments'' which are payments by the brand company to the generic company.

(B) These settlement agreements have unduly delayed the marketing of low-cost generic drugs contrary to free competition, the interests of consumers, and the principles underlying antitrust law.

(C) Because of the price disparity between brand name and generic drugs, such agreements are more profitable for both the brand and generic manufacturers than competition, and will become increasingly common unless prohibited.

(D) These agreements result in consumers losing the benefits that the 1984 Act was intended to provide.

(b) PURPOSES.—The purposes of this title are—

(1) to enhance competition in the pharmaceutical market by stopping anticompetitive agreements between brand name and generic drug manufacturers that limit, delay, or otherwise prevent competition from generic drugs; and

(2) to support the purpose and intent of antitrust law by prohibiting anticompetitive practices in the pharmaceutical industry that harm consumers.

SEC. __03. UNLAWFUL COMPENSATION FOR DELAY.

(a) IN GENERAL.—The Federal Trade Commission Act (15 U.S.C. 44 et seq.) is amended by—

(1) redesignating section 28 as section 29; and

(2) inserting before section 29, as redesignated, the following:

''SEC. 28. PRESERVING ACCESS TO AFFORDABLE GENERICS.

''(a) IN GENERAL.—

''(1) ENFORCEMENT PROCEEDING.—The Federal Trade Commission may initiate a proceeding to enforce the provisions of this section against the parties to any agreement resolving or settling, on a final or interim basis, a patent infringement claim, in connection with the sale of a drug product.

''(2) PRESUMPTION.—

''(A) IN GENERAL.—Subject to subparagraph (B), in such a proceeding, an agreement shall be presumed to have anticompetitive effects and be unlawful if—

''(i) an ANDA filer receives anything of value; and

''(ii) the ANDA filer agrees to limit or forego research, development, manufacturing, marketing, or sales of the ANDA product for any period of time.

''(B) EXCEPTION.—The presumption in subparagraph (A) shall not apply if the parties to such agreement demonstrate by clear and convincing evidence that the procompetitive benefits of the agreement outweigh the anticompetitive effects of the agreement.

''(b) COMPETITIVE FACTORS.—In determining whether the settling parties have met their burden under subsection (a)(2)(B), the fact finder shall consider—

''(1) the length of time remaining until the end of the life of the relevant patent, compared with the agreed upon entry date for the ANDA product;

''(2) the value to consumers of the competition from the ANDA product allowed under the agreement;

''(3) the form and amount of consideration received by the ANDA filer in the agreement resolving or settling the patent infringement claim;

''(4) the revenue the ANDA filer would have received by winning the patent litigation;

''(5) the reduction in the NDA holder's revenues if it had lost the patent litigation;

''(6) the time period between the date of the agreement conveying value to the ANDA filer and the date of the settlement of the patent infringement claim; and

''(7) any other factor that the fact finder, in its discretion, deems relevant to its determination of competitive effects under this subsection.

''(c) LIMITATIONS.—In determining whether the settling parties have met their burden under subsection (a)(2)(B), the fact finder shall not presume—

''(1) that entry would not have occurred until the expiration of the relevant patent or statutory exclusivity; or

''(2) that the agreement's provision for entry of the ANDA product prior to the expiration of the relevant patent or statutory exclusivity means that the agreement is procompetitive, although such evidence may be relevant to the fact finder's determination under this section.

''(d) EXCLUSIONS.—Nothing in this section shall prohibit a resolution or settlement of a patent infringement claim in which the consideration granted by the NDA holder to the ANDA filer as part of the resolution or settlement includes only one or more of the following:

''(1) The right to market the ANDA product in the United States prior to the expiration of—

''(A) any patent that is the basis for the patent infringement claim; or

''(B) any patent right or other statutory exclusivity that would prevent the marketing of such drug.

''(2) A payment for reasonable litigation expenses not to exceed $7,500,000.

''(3) A covenant not to sue on any claim that the ANDA product infringes a United States patent.

''(e) REGULATIONS AND ENFORCEMENT.—

''(1) REGULATIONS.—The Federal Trade Commission may issue, in accordance with section 553 of title 5, United States Code, regulations implementing and interpreting this section. These regulations may exempt certain types of agreements described in subsection (a) if the Commission determines such agreements will further market competition and benefit consumers. Judicial review of any such regulation shall be in the United States District Court for the District of Columbia pursuant to section 706 of title 5, United States Code.

''(2) ENFORCEMENT.—A violation of this section shall be treated as a violation of section 5.

''(3) JUDICIAL REVIEW.—Any person, partnership or corporation that is subject to a final order of the Commission, issued in an administrative adjudicative proceeding under the authority of subsection (a)(1), may, within 30 days of the issuance of such order, petition for review of such order in the United States Court of Appeals for the District of Columbia Circuit or the United States Court of Appeals for the circuit in which the ultimate parent entity, as defined at 16 CFR 801.1(a)(3), of the NDA holder is incorporated as of the date that the NDA is filed with the Secretary of the Food and Drug Administration, or the United States Court of Appeals for the circuit in which the ultimate parent entity of the ANDA filer is incorporated as of the date that the ANDA is filed with the Secretary of the Food and Drug Administration. In such a review proceeding, the findings of the Commission as to the facts, if supported by evidence, shall be conclusive.

''(f) ANTITRUST LAWS.—Nothing in this section shall be construed to modify, impair or supersede the applicability of the antitrust laws as defined in subsection (a) of the 1st section of the Clayton Act (15 U.S.C. 12(a)) and of section 5 of this Act to the extent that section 5 applies to unfair methods of competition. Nothing in this section shall modify, impair, limit or supersede the right of an ANDA filer to assert claims or counterclaims against any person, under the antitrust laws or other laws relating to unfair competition.

''(g) PENALTIES.—

''(1) FORFEITURE.—Each person, partnership or corporation that violates or assists in the violation of this section shall forfeit and pay to the United States a civil penalty sufficient to deter violations of this section, but

in no event greater than 3 times the value received by the party that is reasonably attributable to a violation of this section. If no such value has been received by the NDA holder, the penalty to the NDA holder shall be shall be sufficient to deter violations, but in no event greater than 3 times the value given to the ANDA filer reasonably attributable to the violation of this section. Such penalty shall accrue to the United States and may be recovered in a civil action brought by the Federal Trade Commission, in its own name by any of its attorneys designated by it for such purpose, in a district court of the United States against any person, partnership or corporation that violates this section. In such actions, the United States district courts are empowered to grant mandatory injunctions and such other and further equitable relief as they deem appropriate.

''(2) CEASE AND DESIST.—

''(A) IN GENERAL.—If the Commission has issued a cease and desist order with respect to a person, partnership or corporation in an administrative adjudicative proceeding under the authority of subsection (a)(1), an action brought pursuant to paragraph (1) may be commenced against such person, partnership or corporation at any time before the expiration of one year after such order becomes final pursuant to section 5(g).

''(B) EXCEPTION.—In an action under subparagraph (A), the findings of the Commission as to the material facts in the administrative adjudicative proceeding with respect to such person's, partnership's or corporation's violation of this section shall be conclusive unless—

''(i) the terms of such cease and desist order expressly provide that the Commission's findings shall not be conclusive; or

''(ii) the order became final by reason of section 5(g)(1), in which case such finding shall be conclusive if supported by evidence.

''(3) CIVIL PENALTY.—In determining the amount of the civil penalty described in this section, the court shall take into account—

''(A) the nature, circumstances, extent, and gravity of the violation;

''(B) with respect to the violator, the degree of culpability, any history of violations, the ability to pay, any effect on the ability to continue doing business, profits earned by the NDA holder, compensation received by the ANDA filer, and the amount of commerce affected; and

''(C) other matters that justice requires.

''(4) REMEDIES IN ADDITION.—Remedies provided in this subsection are in addition to, and not in lieu of, any other remedy provided by Federal law. Nothing in this paragraph shall be construed to affect any authority of the Commission under any other provision of law.

''(h) DEFINITIONS.—In this section:

''(1) AGREEMENT.—The term 'agreement' means anything that would constitute an agreement under section 1 of the Sherman Act (15 U.S.C. 1) or section 5 of this Act.

''(2) AGREEMENT RESOLVING OR SETTLING A PATENT INFRINGEMENT CLAIM.—The term 'agreement resolving or settling a patent infringement claim' includes any agreement that is entered into within 30 days of the resolution or the settlement of the claim, or any other agreement that is contingent upon, provides a contingent condition for, or is otherwise related to the resolution or settlement of the claim.

''(3) ANDA.—The term 'ANDA' means an abbreviated new drug application, as defined under section 505(j) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 355(j)).

''(4) ANDA FILER.—The term 'ANDA filer' means a party who has filed an ANDA with the Food and Drug Administration.

''(5) ANDA PRODUCT.—The term 'ANDA product' means the product to be manufactured under the ANDA that is the subject of the patent infringement claim.

''(6) DRUG PRODUCT.—The term 'drug product' means a finished dosage form (e.g., tablet, capsule, or solution) that contains a drug substance, generally, but not necessarily, in association with 1 or more other ingredients, as defined in section 314.3(b) of title 21, Code of Federal Regulations.

''(7) NDA.—The term 'NDA' means a new drug application, as defined under section 505(b) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 355(b)).

''(8) NDA HOLDER.—The term 'NDA holder' means—

''(A) the party that received FDA approval to market a drug product pursuant to an NDA;

''(B) a party owning or controlling enforcement of the patent listed in the Approved Drug Products With Therapeutic Equivalence Evaluations (commonly known as the 'FDA Orange Book') in connection with the NDA; or

''(C) the predecessors, subsidiaries, divisions, groups, and affiliates controlled by, controlling, or under common control with any of the entities described in subparagraphs (A) and (B) (such control to be presumed by direct or indirect share ownership of 50 percent or greater), as well as the licensees, licensors, successors, and assigns of each of the entities.

''(9) PATENT INFRINGEMENT.—The term 'patent infringement' means infringement of any patent or of any filed patent application, extension, reissue, renewal, division, continuation, continuation in part, reexamination, patent term restoration, patents of addition and extensions thereof.

''(10) PATENT INFRINGEMENT CLAIM.—The term 'patent infringement claim' means any allegation made to an ANDA filer, whether or not included in a complaint filed with a court of law, that its ANDA or ANDA product may infringe any patent held by, or exclusively licensed to, the NDA holder of the drug product.

''(11) STATUTORY EXCLUSIVITY.—The term 'statutory exclusivity' means those prohibitions on the approval of drug applications under clauses (ii) through (iv) of section 505(c)(3)(E) (5- and 3-year data exclusivity), section 527 (orphan drug exclusivity), or section 505A (pediatric exclusivity) of the Federal Food, Drug, and Cosmetic Act.''.

(b) EFFECTIVE DATE.—Section 28 of the Federal Trade Commission Act, as added by this section, shall apply to all agreements described in section 28(a)(1) of that Act entered into after November 15, 2009. Section 28(g) of the Federal Trade Commission Act, as added by this section, shall not apply to agreements entered into before the date of enactment of this Act.

SEC. __04. NOTICE AND CERTIFICATION OF AGREEMENTS.

(a) NOTICE OF ALL AGREEMENTS.—Section 1112(c)(2) of the Medicare Prescription Drug, Improvement, and Modernization Act of 2003 (21 U.S.C. 355 note) is amended by—

(1) striking ''the Commission the'' and inserting the following: ''the Commission—

''(1) the'';

(2) striking the period and inserting ''; and''; and

(3) inserting at the end the following:

''(2) any other agreement the parties enter into within 30 days of entering into an agreement covered by subsection (a) or (b).''.

(b) CERTIFICATION OF AGREEMENTS.—Section 1112 of such Act is amended by adding at the end the following:

''(d) CERTIFICATION.—The Chief Executive Officer or the company official responsible for negotiating any agreement required to be filed under subsection (a), (b), or (c) shall execute and file with the Assistant Attorney General and the Commission a certification as follows: 'I declare that the following is true, correct, and complete to the best of my knowledge: The materials filed with the Federal Trade Commission and the Department of Justice under section 1112 of subtitle B of title XI of the Medicare Prescription Drug, Improvement, and Modernization Act of 2003, with respect to the agreement referenced in this certification: (1) represent the complete, final, and exclusive agreement between the parties; (2) include any ancillary agreements that are contingent upon, provide a contingent condition for, or are otherwise related to, the referenced agreement; and (3) include written descriptions of any oral agreements, representations, commitments, or promises between the parties that are responsive to subsection (a) or (b) of such section 1112 and have not been reduced to writing.'.''.

SEC. __05. FORFEITURE OF 180-DAY EXCLUSIVITY PERIOD.

Section 505(j)(5)(D)(i)(V) of the Federal Food, Drug and Cosmetic Act (21 U.S.C. 355(j)(5)(D)(i)(V)) is amended by inserting ''section 28 of the Federal Trade Commission Act or'' after ''that the agreement has violated''.

SEC. __06. COMMISSION LITIGATION AUTHORITY.

Section 16(a)(2) of the Federal Trade Commission Act (15 U.S.C. 56(a)(2)) is amended—

(1) in subparagraph (D), by striking ''or'' after the semicolon;

(2) in subparagraph (E), by inserting ''or'' after the semicolon; and

(3) inserting after subparagraph (E) the following:

''(F) under section 28;''.

SEC. __07. STATUTE OF LIMITATIONS.

The Commission shall commence any enforcement proceeding described in section 28 of the Federal Trade Commission Act, as added by section 03, except for an action described in section 28(g)(2) of the Federal Trade Commission Act, not later than 3 years after the date on which the parties to the agreement file the Notice of Agreement as provided by sections 1112(c)(2) and (d) of the Medicare Prescription Drug Improvement and Modernization Act of 2003 (21 U.S.C. 355 note).

SEC. __08. SEVERABILITY.

If any provision of this title, an amendment made by this title, or the application of such provision or amendment to any person or circumstance is held to be unconstitutional, the remainder of this title, the amendments made by this title, and the application of the provisions of such title or amendments to any person or circumstance shall not be affected thereby.

SA 2149. Mr. KOHL (for himself, Mr. GRASSLEY, and Mr. BLUMENTHAL) submitted an amendment intended to be proposed by him to the bill S. 3187, to amend the Federal Food, Drug, and Cosmetic Act to revise and extend the user-fee programs for prescription drugs and medical devices, to establish user-fee programs for generic drugs and biosimilars, and for other purposes; which was ordered to lie on the table; as follows:

At the end of title XI, add the following:

SEC. 11___. STANDARDIZED PROTOCOL FOR OBTAINING INFORMED CONSENT FROM AN OLDER INDIVIDUAL WITH DEMENTIA PRIOR TO ADMINISTERING AN ANTIPSYCHOTIC FOR A USE NOT APPROVED BY THE FOOD AND DRUG ADMINISTRATION.

Part P of title III of the Public Health Service Act (42 U.S.C. 280g et seq.) is amended by adding at the end the following:

''SEC. 399V–6. STANDARDIZED PROTOCOL FOR OBTAINING INFORMED CONSENT FROM AN OLDER INDIVIDUAL WITH DEMENTIA PRIOR TO ADMINISTERING AN ANTIPSYCHOTIC FOR A USE NOT APPROVED BY THE FOOD AND DRUG ADMINISTRATION.

''(a) PROTOCOL.—Not later than 180 days after the date of the enactment of this section, the Secretary shall develop a standardized protocol for designated health care providers to obtain informed consent from an older individual with dementia prior to administering an antipsychotic to the individual for a use not approved by the Food and Drug Administration. Such protocol shall include an alternative protocol for obtaining such informed consent in the case of emergencies.

''(b) DEFINITION OF INFORMED CONSENT.—In this section, the term 'informed consent' means, with respect to an older individual with dementia, that—

''(1) the health care provider has informed the individual (or, if applicable, the individual's designated health care agent or legal representative) of—

''(A) possible side effects and risks associated with the antipsychotic;

''(B) treatment modalities that were attempted prior to the use of the antipsychotic; and

''(C) any other information the Secretary determines appropriate;

''(2) the individual (or, if applicable, the individual's designated health care agent or legal representative) has provided authorization for the administration of the antipsychotic; and

''(3) the administration of the antipsychotic is in accordance with any plan of care that the individual has in place, including non-pharmacological interventions as appropriate that can effectively address underlying medical and environmental causes of behavioral disorders.''.

SEC. 11___. PRESCRIBER EDUCATION PROGRAMS.

(a) IN GENERAL.—Part P of title III of the Public Health Service Act (42 U.S.C. 280g et seq.), as amended by section 11__, is amended by adding at the end the following:

''SEC. 399V–7. PRESCRIBER EDUCATION PROGRAMS.

''(a) IN GENERAL.—The Secretary, acting through the Director of the Agency for Healthcare Research and Quality and in consultation with the Commissioner of Food and Drugs, shall establish and implement prescriber education programs.

''(b) IMPLEMENTATION.—The Secretary shall establish and begin implementation of prescriber education programs under this section by not later than 6 months after the date on which funds are first made available under section 3734 of title 31, United States Code.

''(c) PRESCRIBER EDUCATION PROGRAM DEFINED.—In this section, the term 'prescriber education program' means a program to promote high quality evidence-based treatment and non-pharmacological interventions through the provision of objective, educational, and informational materials to physicians and other prescribing practitioners, including such a program developed by the Agency for Healthcare Research and Quality.''.

(b) FUNDING.—

(1) IN GENERAL.—Chapter 37 of title 31, United States Code, is amended by adding at the end the following:

''SEC. 3734. FUNDING FOR PRESCRIBER EDUCATION PROGRAMS.

''(a) FUNDING.—In each fiscal year, the Attorney General may make some portion of the covered funds paid to the United States in that fiscal year available for prescriber education programs in accordance with section 399V–7 of the Public Health Service Act.

''(b) DEFINITIONS.—In this section:

''(1) COVERED FUNDS.—The term 'covered funds' means all funds payable to the United States Government from any judgement or settlement of a civil action brought by the Attorney General under section 3730 of this title, relating to off-label marketing of any prescription drug.

''(2) OFF-LABEL MARKETING.—The term 'off-label marketing' means the marketing of a prescription drug for an indication or use in a manner for which the drug has not been approved by the Food and Drug Administration.''.

AUTHORITY FOR COMMITTEES TO MEET

COMMITTEE ON BANKING, HOUSING, AND URBAN AFFAIRS

Mr. CARDIN. Mr. President, I ask unanimous consent that the Committee on Banking, Housing, and Urban Affairs be authorized to meet during the session of the Senate on May 22, 2012, at 10 a.m., to conduct a committee hearing entitled ''Implementing Derivatives Reform: Reducing Systemic Risk and Improving Market Oversight.''

The PRESIDING OFFICER. Without objection, it is so ordered.

COMMITTEE ON ENERGY AND NATURAL RESOURCES

Mr. CARDIN. Mr. President, I ask unanimous consent that the Committee on Energy and Natural Resources be authorized to meet during the session of the Senate on May 22, 2012, at 10 a.m., in room 366 of the Dirksen Senate Office Building.

The PRESIDING OFFICER. Without objection, it is so ordered.

SELECT COMMITTEE ON INTELLIGENCE

Mr. CARDIN. Mr. President, I ask unanimous consent that the Select Committee on Intelligence be authorized to meet during the session of the Senate on May 22, 2012, at 2:30 p.m.

The PRESIDING OFFICER. Without objection, it is so ordered.

SUBCOMMITTEE ON AIRLAND

Mr. CARDIN. Mr. President, I ask unanimous consent that the Subcommittee on Airland of the Committee on Armed Services be authorized to meet during the session of the Senate on May 22, 2012, at 3:30 p.m.

The PRESIDING OFFICER. Without objection, it is so ordered.

SUBCOMMITTEE ON EMERGING THREATS AND CAPABILITIES

Mr. CARDIN. Mr. President, I ask unanimous consent that the Subcommittee on Emerging Threats and Capabilities of the Committee on Armed Services be authorized to meet during the session of the Senate on May 22, 2012, at 2 p.m.

The PRESIDING OFFICER. Without objection, it is so ordered.

SUBCOMMITTEE ON PERSONNEL

Mr. CARDIN. Mr. President, I ask unanimous consent that the Subcommittee on Personnel of the Committee on Armed Services be authorized to meet during the session of the Senate on May 22, 2012, at 5 p.m.

The PRESIDING OFFICER. Without objection, it is so ordered.

SUBCOMMITTEE ON READINESS AND MANAGEMENT SUPPORT

Mr. CARDIN. Mr. President, I ask unanimous consent that the Subcommittee on Readiness and Management Support of the Committee on Armed Services be authorized to meet during the session of the Senate on May 22, 2012, at 11 a.m.

The PRESIDING OFFICER. Without objection, it is so ordered.

SUBCOMMITTEE ON SEAPOWER

Mr. CARDIN. Mr. President, I ask unanimous consent that the Subcommittee on Seapower of the Committee on Armed Services be authorized to meet during the session of the Senate on May 22, 2012, at 9:30 a.m.

The PRESIDING OFFICER. Without objection, it is so ordered.

PRIVILEGES OF THE FLOOR

Mr. REID. Mr. President, I ask unanimous consent that Tiffany Griffin, a fellow in the office of Senator BINGAMAN, be granted the privilege of the floor during consideration of S. 3187, the Food and Drug Administration Safety and Innovation Act.

The PRESIDING OFFICER. Without objection, it is so ordered.

Mr. HARKIN. Mr. President, I ask unanimous consent that Lauren Boyer and Jimmy Fremgen of my staff be granted the privilege of the floor for the duration of today's session.

The PRESIDING OFFICER. Without objection, it is so ordered.

Mr. BROWN of Massachusetts. Mr. President, I ask unanimous consent that my military fellow, Major Jay Rose, be granted floor privileges for the duration of my remarks.

The PRESIDING OFFICER. Without objection, it is so ordered.

Mr. HATCH. Mr. President, I ask unanimous consent that Paul Williams, a detailee to the Senate Finance Committee from the Food and Drug Administration; Jesse Baker, a detailee to the Senate Finance Committee from the U.S. Secret Service; Angela Sheldon, a detailee to the Senate Judiciary Committee; and Maureen McLaughlin, a detailee to the Senate Finance Committee from the Federal Communications Commission, all be granted privileges of the floor for the remainder of the second session of the 112th Congress.

The PRESIDING OFFICER. Without objection, it is so ordered.

MEASURES READ THE FIRST TIME EN BLOC—S. 3220 AND S. 3221

Mr. BROWN of Ohio. Mr. President, I understand there are two bills at the desk, and I ask for their first reading en bloc.

The PRESIDING OFFICER. Without objection, the clerk will report the bills by title.

The bill clerk read as follows: