SA 1020. Mr. GRASSLEY submitted an amendment intended to be proposed by him to the bill S. 1082, supra; which was ordered to lie on the table.

SA 1021. Mrs. CLINTON submitted an amendment intended to be proposed by her to the bill S. 1082, supra; which was ordered to lie on the table.

SA 1022. Mr. DURBIN (for himself, Mr. ENZI, Mr. KENNEDY, Mr. ALLARD, Mr. KOHL, Ms. CANTWELL, Mr. SCHUMER, Mr. BIDEN, Mr. NELSON, of Florida, and Mr. CASEY) proposed an amendment to the bill S. 1082, supra.

SA 1023. Mr. DURBIN submitted an amendment intended to be proposed by him to the bill S. 1082, supra; which was ordered to lie on the table.

SA 1024. Mr. SALAZAR submitted an amendment intended to be proposed by him to the bill S. 1082, supra; which was ordered to lie on the table.

SA 1025. Mr. SCHUMER (for himself, Mrs. CLINTON, Mr. ENZI, Mr. HATCH, and Mr. KENNEDY) proposed an amendment to the bill S. 1082, supra.

SA 1026. Mr. FEINGOLD submitted an amendment intended to be proposed by him to the bill S. 1082, supra; which was ordered to lie on the table.

SA 1027. Mr. DURBIN submitted an amendment intended to be proposed by him to the bill S. 1082, supra; which was ordered to lie on the table.

SA 1028. Mr. ROCKEFELLER (for himself, Mr. SCHUMER, Mr. LEAHY, Mr. KOHL, and Ms. STABENOW) submitted an amendment intended to be proposed by him to the bill S. 1082, supra; which was ordered to lie on the table.

SA 1029. Mr. SANDERS submitted an amendment intended to be proposed by him to the bill S. 1082, supra; which was ordered to lie on the table.

SA 1030. Mr. SANDERS submitted an amendment intended to be proposed by him to the bill S. 1082, supra; which was ordered to lie on the table.

SA 1031. Mr. SANDERS submitted an amendment intended to be proposed by him to the bill S. 1082, supra; which was ordered to lie on the table.

SA 1032. Mr. SANDERS submitted an amendment intended to be proposed by him to the bill S. 1082, supra; which was ordered to lie on the table.

SA 1033. Mr. SANDERS submitted an amendment intended to be proposed by him to the bill S. 1082, supra; which was ordered to lie on the table.

TEXT OF AMENDMENTS

SA 1008. Mr. GRASSLEY submitted an amendment intended to be proposed by him to the bill S. 1082, to amend the Federal Food, Drug, and Cosmetic Act to reauthorize and amend the prescription drug user fee provisions, and for other purposes; which was ordered to lie on the table; as follows:

Strike section 252 and insert the following:

SEC. ___. MARIJUANA SMOKED BY PATIENTS.

(a) EVALUATION AND REPORT.—

(1) EVALUATION.—The Secretary of Health and Human Services shall conduct an evaluation of the manufacture, distribution, and use of marijuana in States that have enacted laws legalizing, decriminalizing, or otherwise allowing the use of marijuana for purported medical use to determine—

(A) whether such activity is taking place in violation of any provision of Federal law for which the Department of Health of Human Services is responsible; and

(B) whether such marijuana activities are taking place in violation of any provision of the Food, Drug, and Cosmetic Act (21 U.S.C. 301 et seq.) that is designed to ensure the safety and effectiveness of drugs used by the American public.

(2) REPORT.—Not later than 90 days after the date of enactment of this Act, the Secretary of Health and Human Services shall submit to Congress a report concerning the findings of the evaluation conducted under paragraph (1).

(b) DETERMINATION OF EFFECTIVENESS.—Not later than 30 days after the date of enactment of this Act, the Commissioner of Food and Drugs shall, based on available scientific data, make a determination, and disclose such determination to the general public, concerning—

(1) whether or not smoked marijuana is a safe or effective treatment for any medical condition; and

(2) the adverse impact to human health, both physician and mental, as a result of smoking marijuana.

SA 1009. Mr. HATCH submitted an amendment intended to be proposed by him to the bill S. 1082, to amend the Federal Food, Drug, and Cosmetic Act to reauthorize and amend the prescription drug user fee provisions, and for other purposes; which was ordered to lie on the table; as follows:

At the end of title II, insert the following:

Subtitle ___Antibiotic Safety and Innovation

SEC. 2___. DEVELOPMENT OF ANTIMICROBIALS.

(a) INCENTIVES FOR DEVELOPMENT OF NEW ANTIBIOTICS AND NEW ANTIBIOTIC USES.—Section 505 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 355), as amended by this Act, is further amended by adding at the end the following:

''(r)(1) Notwithstanding any provision of the Food and Drug Administration Modernization Act of 1997 or any other provision of law, a sponsor of a drug that is the subject of an approved application described in paragraph (2) may elect to receive, with respect to the drug—

''(A)(i) the 3-year exclusivity period referred to under clauses (iii) and (iv) of subsection (c)(3)(E) and under clauses (iii) and (iv) of subsection (j)(5)(F); and

''(ii) the 5-year exclusivity period referred to under subsection (c)(3)(E)(ii) and under subsection (j)(5)(F)(ii); or

''(B) a patent term extension under section 156 of title 35, United States Code.

''(2) An application described under this paragraph is an application for marketing submitted under this section after the date of enactment of this subsection in which—

''(A) the drug that is the subject of the application contains an antibiotic drug; and

''(B) such antibiotic drug was the subject of an application received by the Secretary under section 507 of this Act (as in effect before November 21, 1997).

''(3) Paragraph (1) shall not be construed to entitle a drug that is the subject of an approved application described in paragraph (2) for any market exclusivities or patent extensions other than those exclusivities or extensions described in paragraph (1).''.

(b) BIOEQUIVALENCE TO LISTED ANTIBIOTIC DRUG.—Section 505(j)(8) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 355(j)(8)) is amended by adding at the end the following:

''(D) Notwithstanding any other provision of this subsection, an oral antibiotic drug that is not intended to be absorbed into the bloodstream shall be considered to be bioequivalent to a listed antibiotic drug only if—

''(i) clinical trials do not show a significant difference between the antibiotic drug and the listed antibiotic drug in safety and effectiveness; or

''(ii) the Secretary has—

''(I) established alternative, scientifically valid methods that are reasonably expected to detect a significant difference between the antibiotic drug and the listed antibiotic drug in safety and effectiveness;

''(II) developed the alternative, scientifically valid methods described in subclause (I) through notice and comment rulemaking in accordance with section 553 of title 5, United States Code; and

''(III) determined that, based on the alternative, scientifically valid methods described in subclauses (I) and (II), there is no significant difference between the antibiotic drug and the listed antibiotic drug in safety and effectiveness.''.

(c) PUBLIC MEETING.—The Commissioner of Food and Drugs shall convene a public meeting and, if appropriate, issue guidance regarding which serious and life-threatening infectious diseases, such as diseases due to gram-negative bacteria and other diseases due to antibiotic-resistant bacteria, potentially qualify for available grants and contracts under subsection (a) of section 5 of the Orphan Drug Act (21 U.S.C. 360ee(a)) or other incentives for development.

(d) GRANTS AND CONTRACTS FOR THE DEVELOPMENT OF ORPHAN DRUGS.—Subsection (c) of section 5 of the Orphan Drug Act (21 U.S.C. 360ee(c)) is amended to read as follows:

''(c) For grants and contracts under subsection (a), there are authorized to be appropriated such sums as already have been appropriated for fiscal year 2007, and $35,000,000 for each subsequent fiscal year.''.

SEC. 2___. ESTABLISHMENT OF ANTIMICROBIAL BREAKPOINTS.

(a) DEFINITION.—In this section, the term ''antimicrobial breakpoint'' means specific values which characterize bacteria as clinically susceptible, intermediate, or resistant to the drug (or drugs) tested, such as Minimum Inhibitory Concentrations (MICs) or zones of inhibitions.

(b) ESTABLISHMENT OF BREAKPOINTS.—

(1) IN GENERAL.—The Secretary of Health and Human Services (referred to in this section as the ''Secretary'') shall direct the Commissioner of Food and Drugs to establish and periodically update antimicrobial breakpoints.

(2) REVIEW AND UPDATE.—Antimicrobial breakpoints shall be reviewed and updated as necessary pursuant to recommendations from the Antimicrobial Resistance Task Force and in consultation with the Centers for Disease Control and Prevention, or more frequently upon the discretion of the Commissioner of Food and Drugs, but in no case less than once every 5 years.

(c) PUBLIC AVAILABILITY.—The Secretary shall direct the Commissioner of Food and Drugs to make antimicrobial breakpoints publicly available within 30 days of the date of establishment and any update under this section.

(d) ADVISORY ORGANIZATIONS.—The Commissioner of Food and Drugs may contract with an organization or organizations to aid in the establishment of antimicrobial breakpoints under this section in a manner not inconsistent with the Federal Advisory Committee Act (5 U.S.C. App.). The Commissioner of Food and Drugs shall make the final determination regarding establishments of antimicrobial breakpoints under this section.

SEC. 2___. EXCLUSIVITY OF CERTAIN DRUGS CONTAINING ENANTIOMERS.

Section 505 of the Federal Food, Drug, and Cosmetic Act (21 U.S. C. 355), as amended by this subtitle, is amended by adding at the end the following:

''(s) DRUGS CONTAINING ENANTIOMERS.—For purposes of subsections (c)(3)(E)(ii) and (j)(5)(F)(ii), if an application is submitted under subsection (b) for a non-racemic drug containing as an active ingredient a single enantiomer that is contained in a racemic drug approved in another application under subsection (b), the single enantiomer shall not be considered the same active ingredient contained in the approved racemic drug, if—

''(1)(A) the single enantiomer has not been previously approved as an active ingredient except in the approved racemic drug; and

''(B) the application submitted under subsection (b) for the drug containing the single enantiomer includes full reports of investigations described in subsection (b)(1)(A) which do not rely on any investigations that are part of the application submitted under subsection (b) for approval of the approved racemic drug; and

''(2)(A) the application submitted under subsection (b) for the drug containing the single enantiomer is not submitted for approval of a use—

''(i) in a therapeutic area in which the approved racemic drug has been approved; or

''(ii) for which any other enantiomer of the racemic drug has been approved; or

''(B) in the case of an antibiotic drug, such drug is demonstrated through well-controlled clinical trials to be safe and effective for a use for which the racemic drug has not been approved and for which no other enantiomer of the racemic drug has been previously approved.''.

SA 1010. Mr. COCHRAN (for himself, Mr. CARPER, Mr. NELSON of Nebraska, Mr. HATCH, Mr. BENNETT, Mr. ENZI, Mr. BURR, and Mr. MENENDEZ) submitted an amendment intended to be proposed to amendment SA 990 submitted by Mr. DORGAN (for himself, Ms. SNOWE, Mr. GRASSLEY, Mr. MCCAIN, Ms. STABENOW, Mr. NELSON of Florida, Mr. PRYOR, Mr. SANDERS, Mr. WHITEHOUSE, and Mrs. MCCASKILL) to the bill S. 1082, to amend the Federal Food, Drug, and Cosmetic Act to reauthorize and amend the prescription drug user fee provisions, and for other purposes; as follows:

At the end of the amendment, add the following:

SEC. ___. PROTECTION OF HEALTH AND SAFETY.

This title, and the amendments made by this title, shall become effective only if the Secretary of Health and Human Services certifies to Congress that the implementation of this title (and amendments) will—

(1) pose no additional risk to the public's health and safety; and

(2) result in a significant reduction in the cost of covered products to the American consumer.

SA 1011. Ms. STABENOW (for herself, Mr. THUNE, Mr. LOTT, Mr. BROWN, and Mr. KOHL) submitted an amendment intended to be proposed by her to the bill S. 1082, to amend the Federal Food, Drug, and Cosmetic Act to reauthorize and amend the prescription drug user fee provisions, and for other purposes; as follows:

At the appropriate place, insert the following:

SEC. ___. CITIZENS PETITIONS AND PETITIONS FOR STAY OF AGENCY ACTION.

Section 505 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 355), as amended by this Act, is amended by adding at the end the following:

''(r) CITIZEN PETITIONS AND PETITIONS FOR STAY OF AGENCY ACTION.—

''(1) IN GENERAL.—

''(A) NO DELAY OF CONSIDERATION OR APPROVAL.—

''(i) IN GENERAL.—With respect to a pending application submitted under subsection (b)(2) or (j), if a petition is submitted to the Secretary that seeks to have the Secretary take, or refrain from taking, any form of action relating to the approval of the application, including a delay in the effective date of the application, clauses (ii) and (iii) shall apply.

''(ii) NO DELAY OF CONSIDERATION.—The receipt of a petition is not just cause to delay consideration of an application submitted under subsection (b)(2) or (j) and consideration of a petition described in clause (i) shall be separate and apart from the review of an application submitted under either such subsection.

''(iii) NO DELAY OF APPROVAL WITHOUT DETERMINATION.—The Secretary shall not delay approval of an application submitted under subsection (b)(2) or (j) while a petition described in clause (i) is reviewed and considered unless the Secretary determines, not later than 30 days after the submission of the petition, that a delay is necessary to protect the public health.

''(B) DETERMINATION OF DELAY.—With respect to a determination by the Secretary under subparagraph (A)(iii) that a delay is necessary to protect the public health the following shall apply:

''(i) Not later than 5 days after making such determination, the Secretary shall publish on the Internet website of the Food and Drug Administration a detailed statement providing the reasons underlying the determination. The detailed statement shall include a summary of the petition and comments and supplements, the specific substantive issues that the petition raises which need to be considered prior to approving a pending application submitted under subsection (b)(2) or (j), and any clarifications and additional data that is needed by the Secretary to promptly review the petition.

''(ii) Not later than 10 days after making such determination, the Secretary shall provide notice to the sponsor of the pending application submitted under subsection (b)(2) or (j) and provide an opportunity for a meeting with appropriate staff as determined by the Commissioner to discuss the determination.

''(2) TIMING OF FINAL AGENCY ACTION ON PETITIONS.—

''(A) IN GENERAL.—Notwithstanding a determination made by the Secretary under paragraph (1)(A)(iii), the Secretary shall take final agency action with respect to a petition not later than 180 days of submission of that petition unless the Secretary determines, prior to the date that is 180 days after the date of submission of the petition, that a delay is necessary to protect the public health.

''(B) DETERMINATION OF DELAY.—With respect to a determination by the Secretary under subparagraph (A) that a delay is necessary to protect the public health the following shall apply:

''(i) Not later than 5 days after making the determination under subparagraph (A), the Secretary shall publish on the Internet website of the Food and Drug Administration a detailed statement providing the reasons underlying the determination. The detailed statement should include the state of the review of the petition, the specific outstanding issues that still need to be resolved, a proposed timeframe to resolve the issues, and any additional information that has been requested by the Secretary of the petitioner or needed by the Secretary in order to resolve the petition and not further delay an application filed under subsection (b)(2) or (j).

''(ii) Not later than 10 days after making the determination under subparagraph (A), the Secretary shall provide notice to the sponsor of the pending application submitted under subsection (b)(2) or (j) and provide an opportunity for a meeting with appropriate staff as determined by the Commissioner to discuss the determination.

''(3) VERIFICATIONS.—

''(A) PETITIONS FOR REVIEW.—The Secretary shall not accept a petition for review unless it is signed and contains the following verification: 'I certify that, to my best knowledge and belief: (a) this petition includes all information and views upon which the petition relies; and (b) this petition includes representative data and/or information known to the petitioner which are unfavorable to the petition. I further certify that the information upon which I have based the action requested herein first became known to the party on whose behalf this petition is filed on or about _____. I received or expect to receive payments, including cash and other forms of consideration, from the following persons or organizations to file this petition: _____. I verify under penalty of perjury that the foregoing is true and correct.', with the date of the filing of such petition and the signature of the petitioner inserted in the first and second blank space, respectively.

''(B) SUPPLEMENTAL INFORMATION.—The Secretary shall not accept for review any supplemental information or comments on a petition unless the party submitting such information or comments does so in written form and that the subject document is signed and contains the following verification: 'I certify that, to my best knowledge and belief: (a) I have not intentionally delayed submission of this document or its contents. I further certify that the information upon which I have based the action requested herein first became known to me on or about _____. I received or expect to receive payments, including cash and other forms of consideration, from the following persons or organizations to submit this information or its contents: _____. I verify under penalty of perjury that the foregoing is true and correct.', with the date of the submission of such document and the signature of the petitioner inserted in the first and second blank space, respectively.

''(4) ANNUAL REPORT ON DELAYS IN APPROVALS PER PETITION.—The Secretary shall annually submit to the Congress a report that specifies—

''(A) the number of applications under subsection (b)(2) and (j) that were approved during the preceding 1-year period;

''(B) the number of petitions that were submitted during such period;

''(C) the number of applications whose effective dates were delayed by petitions during such period and the number of days by which the applications were so delayed; and

''(D) the number of petitions that were filed under this subsection that were deemed by the Secretary under paragraph (1)(A)(iii) to require delaying an application under subsection (b)(2) or (j) and the number of days by which the applications were so delayed.

''(5) EXCEPTION.—This subsection does not apply to a petition that is made by the sponsor of the application under subsection (b)(2) or (j) and that seeks only to have the Secretary take or refrain from taking any form of action with respect to that application.

''(6) REPORT BY INSPECTOR GENERAL.—The Office of Inspector General of the Department of Health and Human Services shall issue a report not later than 2 years after the

date of enactment of this subsection evaluating evidence of the compliance of the Food and Drug Administration with the requirement that the consideration by the Secretary of petitions that do not raise public health concerns remain separate and apart from the review and approval of an application submitted under subsection (b)(2) or (j).

''(7) DEFINITION.—For purposes of this subsection, the term 'petition' includes any request to the Secretary, without regard to whether the request is characterized as a petition.''.

SA 1012. Mr. VITTER submitted an amendment intended to be proposed by him to the bill S. 1082, to amend the Federal Food, Drug, and Cosmetic Act to reauthorize and amend the prescription drug user fee provisions, and for other purposes; which was ordered to lie on the table; as follows:

At the appropriate place, insert the following:

SEC. ___. AUTHORIZATION OF APPROPRIATIONS FOR THE OFFICE OF GENERIC DRUGS.

Notwithstanding section 736(b) of the Federal Food, Drug, and Cosmetic Act (as amended by section 103(b) of this Act), the Secretary of Health and Human Services shall allocate $20,000,000 of the user fees generated by section 736(a) of the Federal Food, Drug, and Cosmetic Act (as amended by section 103(a) of this Act), for each fiscal year beginning with fiscal year 2009 and ending with fiscal year 2012, to the Office of Generic Drugs of the Food and Drug Administration, for the sole purpose of reviewing and approving abbreviated new drug applications.

SA 1013. Mr. VITTER submitted an amendment intended to be proposed by him to the bill S. 1082, to amend the Federal Food, Drug, and Cosmetic Act to reauthorize and amend the prescription drug user fee provisions, and for other purposes; which was ordered to lie on the table; as follows:

At the appropriate place, insert the following:

SEC. ___. OFFICE OF GENERIC DRUGS.

(a) FINDINGS.—Congress makes the following findings:

(1) More than $100,000,000,000 in blockbuster brand pharmaceutical products will lose patent protection between April 2007 and 2010. As a result, more applications for generic versions of these products will be filed with the Office of Generic Drugs of the Food and Drug Administration.

(2) The staff of the Office of Generic Drugs is backlogged. Approximately 800 generic drug applications are pending review as of April 2007.

(3) The workload of the Office of Generic Drugs has increased by 36 percent since 2004, yet the Office has the same budget and the same number of staff.

(4) The workload of the Office of Generic Drugs also has increased due to the filing of citizen petitions by brand companies designed to delay generic drug approvals.

(5) A modest investment in the Office of Generic Drugs, such as $15,000,000, would help to make more affordable medicines available in a timely manner to consumers and public and private health care purchasers, who would save billions of dollars.

(6) Those savings also would enable the Federal Government to reach more Americans through important health care initiatives, such as Medicare, Medicaid, and programs to improve children's health care, assist the chronically ill, and fight HIV/AIDS.

(b) AUTHORIZATION OF APPROPRIATIONS.—Notwithstanding section 736(b) of the Federal Food, Drug, and Cosmetic Act (as amended by section 103(b) of this Act), the Secretary of Health and Human Services shall allocate $20,000,000 of the user fees generated by section 736(a) of the Federal Food, Drug, and Cosmetic Act (as amended by section 103(a) of this Act), for each fiscal year beginning with fiscal year 2009 and ending with fiscal year 2012, to the Office of Generic Drugs of the Food and Drug Administration, for the sole purpose of reviewing and approving abbreviated new drug applications.

SA 1014. Mr. VITTER submitted an amendment intended to be proposed to amendment SA 990 submitted by Mr. DORGAN (for himself, Ms. SNOWE, Mr. GRASSLEY, Mr. MCCAIN, Ms. STABENOW, Mr. NELSON of Florida, Mr. PRYOR, Mr. SANDERS, Mr. WHITEHOUSE, and Mrs. MCCASKILL) to the bill S. 1082, to amend the Federal Food, Drug, and Cosmetic Act to reauthorize and amend the prescription drug user fee provisions, and for other purposes; which was ordered to lie on the table; as follows:

At the appropriate place in the amendment, insert the following:

SEC. ___. COUNTERFEIT-RESISTANT TECHNOLOGIES FOR PRESCRIPTION DRUGS.

(a) REQUIRED TECHNOLOGIES.—The Secretary of Health and Human Services shall require that the packaging of any prescription drug incorporate—

(1) radio frequency identification (RFID) tagging technology, or similar trace and track technologies that have an equivalent function;

(2) tamper-indicating technologies; and

(3) blister security packaging when possible.

(b) USE OF TECHNOLOGIES.—

(1) AUTHORIZED USES.—The Secretary shall require that technologies described in subsection (a)(1) be used exclusively to authenticate the pedigree of prescription drugs, including by—

(A) implementing inventory control;

(B) tracking and tracing prescription drugs;

(C) verifying shipment or receipt of prescription drugs;

(D) authenticating finished prescription drugs; and

(E) electronically authenticating the pedigree of prescription drugs.

(2) PRIVACY PROTECTION.—The Secretary shall prohibit technologies required by subsection (a)(1) from containing or transmitting any information that may be used to identify a health care practitioner or the prescription drug consumer.

(3) PROHIBITION AGAINST ADVERTISING.—The Secretary shall prohibit technologies required by subsection (a)(1) from containing or transmitting any advertisement or information about prescription drug indications or off-label prescription drug uses.

(c) RECOMMENDED TECHNOLOGIES.—The Secretary shall encourage the manufacturers and distributors of prescription drugs to incorporate into the packaging of such drugs, in addition to the technologies required under subsection (a), overt optically variable counterfeit-resistant technologies that—

(1) are visible to the naked eye, providing for visual identification of prescription drug authenticity without the need for readers, microscopes, lighting devices, or scanners;

(2) are similar to technologies used by the Bureau of Engraving and Printing to secure United States currency;

(3) are manufactured and distributed in a highly secure, tightly controlled environment; and

(4) incorporate additional layers of nonvisible covert security features up to and including forensic capability.

(d) STANDARDS FOR PACKAGING.—

(1) MULTIPLE ELEMENTS.—For the purpose of making it more difficult to counterfeit the packaging of prescription drugs, the Secretary shall require manufacturers of prescription drugs to incorporate the technologies described in paragraphs (1), (2), and (3) of subsection (a), and shall encourage manufacturers and distributors of prescription drugs to incorporate the technologies described in subsection (c), into multiple elements of the physical packaging of the drugs, including—

(A) blister packs, shrink wrap, package labels, package seals, bottles, and boxes; and

(B) at the item level.

(2) LABELING OF SHIPPING CONTAINER.—Shipments of prescription drugs shall include a label on the shipping container that incorporates the technologies described in subsection (a)(1), so that members of the supply chain inspecting the packages will be able to determine the authenticity of the shipment. Chain of custody procedures shall apply to such labels and shall include procedures applicable to contractual agreements for the use and distribution of the labels, methods to audit the use of the labels, and database access for the relevant governmental agencies for audit or verification of the use and distribution of the labels.

(e) PENALTY.—A prescription drug is deemed to be misbranded for purposes of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 301 et seq.) if the packaging or labeling of the drug is in violation of a requirement or prohibition applicable to the drug under subsection (a), (b), or (d).

(f) TRANSITIONAL PROVISIONS; EFFECTIVE DATES.—

(1) NATIONAL SPECIFIED LIST OF SUSCEPTIBLE PRESCRIPTION DRUGS.—

(A) INITIAL PUBLICATION.—Not later than 180 days after the date of the enactment of this Act, the Secretary shall publish in the Federal Register a list, to be known as the National Specified List of Susceptible Prescription Drugs, consisting of not less than 30 of the prescription drugs that are most frequently subject to counterfeiting in the United States (as determined by the Secretary).

(B) REVISION.—Not less than annually through the end of calendar year 2010, the Secretary shall review and, as appropriate, revise the National Specified List of Susceptible Prescription Drugs. The Secretary may not revise the List to include fewer than 30 prescription drugs.

(2) EFFECTIVE DATES.—The Secretary shall implement the requirements and prohibitions of subsections (a), (b), and (d)—

(A) with respect to prescription drugs on the National Specified List of Susceptible Prescription Drugs, beginning not later than the earlier of—

(i) 1 year after the initial publication of such List; or

(ii) December 31, 2008; and

(B) with respect to all prescription drugs, beginning not later than December 31, 2011.

(3) AUTHORIZED USES DURING TRANSITIONAL PERIOD.—In lieu of the requirements specified in subsection (b)(1), for the period beginning on the effective date applicable under paragraph (2)(A) and ending on the commencement of the effective date applicable under paragraph (2)(B), the Secretary shall require that technologies described in subsection (a)(1) be used exclusively to verify the authenticity of prescription drugs.

(g) DEFINITIONS.—In this Act:

(1) The term ''pedigree''—

(A) means the history of each prior sale, purchase, or trade of the prescription drug involved to a distributor or retailer of the drug (including the date of the transaction and the names and addresses of all parties to the transaction); and

(B) excludes information about the sale, purchase, or trade of the drug to the drug consumer.

(2) The term ''prescription drug'' means a drug subject to section 503(b)(1) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 353(b)(1)).

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

SA 1015. Mr. HAGEL (for himself and Mrs. CLINTON) submitted an amendment intended to be proposed by him to the bill S. 1082, to amend the Federal Food, Drug, and Cosmetic Act to reauthorize and amend the prescription drug user fee provisions, and for other purposes; which was ordered to lie on the table; as follows:

At the appropriate place, insert the following:

SEC. ___. LUNG CANCER COMPUTED TOMOGRAPHY ASSESSMENT AND INTERIM QUALITY STANDARDS.

Not later than 180 days after the date of enactment of this Act, the Secretary of Health and Human Services shall submit to Congress a report that contains—

(1) an assessment of the number, quality, charges, and capabilities of sites offering computed tomography scanning for the diagnosis of lung cancer;

(2) interim quality standards for computed tomography scanning for the diagnosis of lung cancer which incorporate the protocol established by the International Early Lung Cancer Action Program and contained in the document dated October 20, 2006 entitled ''International Early Lung Cancer Action Program: Enrollment and Screening Protocol''; and

(3) recommendations, including legislative recommendations if appropriate, for the establishment of lung cancer diagnostic centers, as practicable, to collect and analyze the data as recommended under the protocol described in paragraph (2) in order to continue and accelerate research into the early detection, diagnosis, and treatment of lung cancer.

SA 1016. Mr. SPECTER submitted an amendment intended to be proposed by him to the bill S. 1082, to amend the Federal Food, Drug, and Cosmetic Act to reauthorize and amend the prescription drug user fee provisions, and for other purposes; which was ordered to lie on the table; as follows:

At the appropriate place in the bill, insert the following:

SEC. ___. NATIONAL CENTERS FOR PHARMACEUTICAL INNOVATION.

Chapter VII of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 371 et seq.) is amended by adding at the end the following:

''Subchapter ___—Establishment of the National Centers for Pharmaceutical Innovation

''SEC. ___1. ESTABLISHMENT OF THE CENTERS.

''(a) IN GENERAL.—The Commissioner of Food and Drugs, in consultation with the Secretary, shall establish through competitive selection not more than 5 university-based National Centers for Pharmaceutical Innovation (referred to in this subchapter as the 'Centers').

''(b) PURPOSE OF CENTERS.—The purpose of the Centers is to advance the Food and Drug Administration's Critical Path Initiative, as well as subsequent efforts, to modernize medical pharmaceutical product development by—

''(1) designing methodologies to dramatically increase the speed at which new drugs enter the market while significantly reducing the cost of such process;

''(2) developing new technological tools to speed the creation of safer, more effective drugs targeted at individuals;

''(3) assisting the Food and Drug Administration with drug therapy-monitoring programs to look for adverse consequences utilizing medicines;

''(4) expanding the quality and number of professionals trained in translational medicine, translational therapeutics, and the manufacture of pharmaceutical and biotechnology products; and

''(5) introducing new technologies to improve the manufacture of pharmaceutical and biotechnology products.

''SEC. ___2. CRITERIA FOR SELECTION.

''The Commissioner of Food and Drugs, in consultation with the Secretary, shall select the Centers from among qualified university or university consortium applicants on the basis of key factors in pharmaceutical product development, safety, and manufacturing technology, including—

''(1) whether the applicant has established graduate training programs that integrate the elements of translational therapeutics, including basic and clinical pharmacology, pharmaceutical science, including pharmacokinetic modeling, analytical technologies, genomics and proteomics, pharmacoepidemiology, informatics, and statistics;

''(2) demonstration of extensive experience in the development and evaluation of medicines through drug approval to the post-marketing process;

''(3) scientific programs in translational therapeutics and pharmaceutical science designed to hasten the personalization of medicine;

''(4) proficiencies in pharmaceutical and biotechnology science and engineering, including therapy development and manufacturing; and

''(5) other factors that the Commissioner of Food and Drugs determines appropriate.

''SEC. ___3. AUTHORIZATION OF APPROPRIATIONS.

''There are authorized to be appropriated to carry out this subchapter such sums as may be necessary for each of the fiscal years 2008 through 2013.''.

SA 1017. Mr. GREGG (for himself and Mr. COLEMAN) submitted an amendment intended to be proposed to amendment SA 990 submitted by Mr. DORGAN (for himself, Ms. SNOWE,, Mr. GRASSLEY, Mr. MCCAIN, Ms. STABENOW, Mr. NELSON of Florida, Mr. PRYOR, Mr. SANDERS, Mr. WHITEHOUSE, and Mrs. MCCASKILL) to the bill S. 1082, to amend the Federal Food, Drug, and Cosmetic Act to reauthorize and amend the prescription drug user fee provisions, and for other purposes; which was ordered to lie on the table; as follows:

Strike sections 7 and 8 of the amendment and insert the following:

SEC. 7. INTERNET PHARMACIES.

(a) INTERNET PHARMACIES.—Chapter V of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 351 et seq.) is amended by inserting after section 510 the following:

''SEC. 511. INTERNET PHARMACIES.

''(a) DEFINITIONS.—In this section:

''(1) ADVERTISING SERVICE PROVIDER.—The term 'advertising service provider' means an advertising company that contracts with a provider of an interactive computer service (as defined in section 230(f) of the Communications Act of 1934 (47 U.S.C. 230(f)) to provide advertising on the Internet.

''(2) DESIGNATED PAYMENT SYSTEM.—

''(A) IN GENERAL.—The term 'designated payment system' means a system used by a person described in subparagraph (B) to effect a credit transaction, electronic fund transfer, or money transmitting service that the Board determines, by regulation or order, is regularly used in connection with, or to facilitate restricted transactions.

''(B) PERSONS DESCRIBED.—A person referred to in subparagraph (A) is—

''(i) a creditor;

''(ii) a credit card issuer;

''(iii) a financial institution;

''(iv) an operator of a terminal at which an electronic fund transfer may be initiated;

''(v) a money transmitting business; or

''(vi) a participant in an international, national, regional, or local network constructed primarily to effect a credit transaction, electronic fund transfer, or money transmitting service.

''(3) FEDERAL FUNCTIONAL REGULATOR.—The term 'Federal functional regulator' has the meaning given the term in section 509 of the Gramm-Leach-Bliley Act (15 U.S.C. 6809).

''(4) INTERNET PHARMACY.—The term 'Internet pharmacy' means a person that offers to dispense or dispenses in the United States a prescription drug through an Internet website in interstate commerce, regardless of whether the physical location of the principal place of business of the Internet pharmacy is in the United States or in another country.

''(5) PRESCRIPTION DRUG.—The term 'prescription drug' means a drug described in section 503(b) that is approved by the Secretary under section 505.

''(6) RESTRICTED TRANSACTION.—The term 'restricted transaction' means a transaction or transmittal, on behalf of a individual who places an unlawful Internet pharmacy request to any person engaged in the operation of an unlicensed Internet pharmacy, of—

''(A) credit, or the proceeds of credit, extended to or on behalf of the individual for the purpose of the unlawful Internet request (including credit extended through the use of a credit card);

''(B) an electronic fund transfer or funds transmitted by or through a money transmitting business, or the proceeds of an electronic fund transfer or money transmitting service, from or on behalf of the individual for the purpose of the unlawful Internet request;

''(C) a check, draft, or similar instrument which is drawn by or on behalf of the individual for the purpose of the unlawful Internet request and is drawn on or payable at or through any financial institution; or

''(D) the proceeds of any other form of financial transaction (identified by the Board by regulation) that involves a financial institution as a payor or financial intermediary on behalf of or for the benefit of the individual for the purpose of the unlawful Internet request.

''(7) TREATING PROVIDER.—The term 'treating provider' means a health care provider licensed in the United States who is authorized to prescribe medications and who—

''(A)(i) performs a documented patient evaluation (including a patient history and physical examination) of an individual, portions of which may be conducted by other health professionals;

''(ii) discusses with the individual the treatment options of the individual and the risks and benefits of treatment; and

''(iii) maintains contemporaneous medical records concerning the individual; or

''(B) provides care to an individual as part of an on-call or cross-coverage arrangement with a health care provider described in subparagraph (A).

''(8) UNLAWFUL INTERNET PHARMACY REQUEST.—The term 'unlawful Internet pharmacy request' means the request, or transmittal of a request, made to an unlicensed Internet pharmacy for a prescription drug by mail (including a private carrier), facsimile, telephone, or electronic mail, or by a means that involves the use, in whole or in part, of the Internet.

''(9) UNLICENSED INTERNET PHARMACY.—The term 'unlicensed Internet pharmacy' means an Internet pharmacy that is not licensed under this section.

''(10) OTHER DEFINITIONS.—

''(A) BOARD.—The term 'Board' means the Board of Governors of the Federal Reserve System.

''(B) CREDIT; CREDITOR; CREDIT CARD.—The terms 'credit', 'creditor', and 'credit card' have the meanings given the terms in section 103 of the Truth in Lending Act (15 U.S.C. 1602).

''(C) ELECTRONIC FUND TRANSFER.—The term 'electronic fund transfer'—

''(i) has the meaning given the term in section 903 of the Electronic Fund Transfer Act (15 U.S.C. 1693a); and

''(ii) includes any fund transfer covered under article 4A of the Uniform Commercial Code, as in effect in any State.

''(D) FINANCIAL INSTITUTION.—The term 'financial institution'—

''(i) has the meaning given the term in section 903 of the Electronic Transfer Fund Act (15 U.S.C. 1693a); and

''(ii) includes a financial institution (as defined in section 509 of the Gramm-Leach-Bliley Act (15 U.S.C. 6809)).

''(E) MONEY TRANSMITTING BUSINESS; MONEY TRANSMITTING SERVICE.—The terms 'money transmitting business' and 'money transmitting service' have the meanings given the terms in section 5330(d) of title 31, United States Code.

''(b) IN GENERAL.—An Internet pharmacy may only dispense or offer to dispense a prescription drug to a person in the United States in accordance with this section.

''(c) LICENSING OF INTERNET PHARMACIES.—

''(1) IN GENERAL.—An Internet pharmacy shall be licensed by the Secretary in accordance with this section prior to offering to dispense or dispensing a prescription drug to an individual.

''(2) CONDITIONS FOR LICENSING.—

''(A) APPLICATION REQUIREMENTS.—An Internet pharmacy shall submit to the Secretary an application that includes—

''(i)(I) in the case of an Internet pharmacy located in the United States, verification that, in each State in which the Internet pharmacy engages in dispensing or offering to dispense prescription drugs, the Internet pharmacy, and all employees and agents of the Internet pharmacy, is in compliance with applicable Federal and State laws regarding—

''(aa) the practice of pharmacy, including licensing laws and inspection requirements; and

''(bb) the manufacturing and distribution of controlled substances, including with respect to mailing or shipping controlled substances to consumers; or

''(II) in the case of an Internet pharmacy whose principal place of business is located outside the United States, verification that—

''(aa) all employees and agents of the Internet pharmacy are in compliance with applicable Federal and State laws regarding the practice of pharmacy, including licensing laws and inspection requirements;

''(bb) the Internet pharmacy is in compliance with applicable Federal and State laws regarding the practice of pharmacy, including licensing laws and inspection requirements;

''(cc) the Internet pharmacy expressly and affirmatively agrees to provide and maintain an agent for service of process in the United States;

''(dd) the Internet pharmacy expressly and affirmatively agrees to be subject to the jurisdiction of the United States and any of its States or territories where it engages in commerce; and

''(ee) the Internet pharmacy agrees to affix to each shipping container of drugs to be shipped in the United States such markings as the Secretary determines to be necessary to identify that the shipment is from a licensed Internet pharmacy, which may include anticounterfeiting or track-and-trace technologies;

''(ii) verification that the person that owns the Internet pharmacy has not had a license for an Internet pharmacy terminated by the Secretary, and that no other Internet pharmacy owned by the person has had a license under this subsection that has been terminated by the Secretary;

''(iii) verification from the person that owns the Internet pharmacy that the person will permit inspection of the facilities and business practices of the Internet pharmacy by the Secretary to the extent necessary to determine whether the Internet pharmacy is in compliance with this subsection;

''(iv) in the case of an agreement between a patient and an Internet pharmacy that releases the Internet pharmacy, and any employee or agent of the Internet pharmacy, from liability for damages arising out of the negligence of the Internet pharmacy, an assurance that such a limitation of liability shall be null and void;

''(v) verification that the Internet pharmacy expressly and affirmatively agrees to provide the Secretary with the identity of any providers of interactive computer services that provide host services or advertising services for the Internet pharmacy; and

''(vi) assurance that the Internet pharmacy will comply with the requirements under subparagraphs (B) and (C).

''(B) IDENTIFICATION REQUIREMENTS.—An Internet pharmacy shall post in a clear and visible manner, on each page of the website of the Internet pharmacy or by a link to a separate page, the following information:

''(i) The street address, city, ZIP Code or comparable mail code, State (or comparable entity), country, and telephone number of—

''(I) each place of business of the Internet pharmacy; and

''(II) the name of the supervising pharmacist of the Internet pharmacy and each individual who serves as a pharmacist for purposes of the Internet pharmacy website.

''(ii) The names of all States in which the Internet pharmacy and the pharmacists employed by the Internet pharmacy are licensed or otherwise authorized to dispense prescription drugs.

''(iii) If the Internet pharmacy makes referrals to, or solicits on behalf of, a health care practitioner or group of practitioners in the United States for prescription services—

''(I) the name, street address, city, ZIP Code or comparable mail code, State, and telephone number of the practitioner or group; and

''(II) the name of each State in which each practitioner is licensed or otherwise authorized to prescribe drugs.

''(iv) A statement that the Internet pharmacy will dispense prescription drugs only after receipt of a valid prescription from a treating provider.

''(v) A distinctive tamper resistant seal to identify that the Internet pharmacy is licensed.

''(C) PROFESSIONAL SERVICES REQUIREMENTS.—An Internet pharmacy shall carry out the following:

''(i) Maintain patient medication profiles and other related data in a readily accessible format organized to facilitate consultation with treating providers, caregivers, and patients.

''(ii) Conduct prospective drug use reviews before dispensing medications or medical devices.

''(iii) Ensure patient confidentiality and the protection of patient identity and patient-specific information, in accordance with the regulations promulgated under section 264(c) of the Health Insurance Portability and Accountability Act of 1996.

''(iv) Offer interactive and meaningful consultation by a licensed pharmacist to the caregiver or patient before and after the time at which the Internet pharmacy dispenses the drug.

''(v)(I) Establish a mechanism for patients to report errors and suspected adverse drug reactions.

''(II) Document in the reporting mechanism the response of the Internet pharmacy to those reports.

''(III) Submit those reports within 3 days of receipt and the response of the Internet pharmacy to the Food and Drug Administration in a manner determined appropriate by the Secretary.

''(vi) Develop a system to inform caregivers and patients about drug recalls.

''(vii) Educate caregivers and patients about the appropriate means of disposing of expired, damaged, or unusable medications.

''(viii) Assure that the sale of a prescription drug is in accordance with a valid prescription from the treating provider of the individual.

''(ix)(I) Verify the validity of the prescription of an individual by using 1 of the following methods:

''(aa) If the prescription for any drug other than a controlled substance (as defined in section 102 of the Controlled Substances Act (21 U.S.C. 802)) is received from an individual or the treating provider of the individual by mail (including a private carrier), or from the treating provider of the individual by electronic mail, the validity of the prescription shall be confirmed in accordance with all applicable Federal and State laws.

''(bb) If the prescription is for a controlled substance (as defined in section 102 of the Controlled Substances Act), the validity of the prescription shall be confirmed with the treating provider as described in subclause (II).

''(II) When seeking verification of a prescription of an individual under subclause (I)(bb), an Internet pharmacy shall provide to the treating provider the following information:

''(aa) The full name and address of the individual.

''(bb) Identification of the prescription drug.

''(cc) The quantity of the prescription drug to be dispensed.

''(dd) The date on which the individual presented the prescription to the Internet pharmacy.

''(ee) The date and time of the verification request.

''(ff) The name of a contact person at the Internet pharmacy, including a voice telephone number, electronic mail address, and facsimile telephone number.

''(III) A prescription is verified under subclause (I)(bb) only if 1 of the following occurs:

''(aa) The treating provider confirms, by direct communication with the Internet pharmacy, that the prescription is accurate.

''(bb) The treating provider informs the Internet pharmacy that the prescription is inaccurate and provides the accurate prescription.

''(IV) An Internet pharmacy shall not fill a prescription if—

''(aa) a treating provider informs the Internet pharmacy within 72 hours after receipt of a communication under subclause (I)(bb) that the prescription is inaccurate or expired; or

''(bb) the treating provider does not respond within that time.

''(x) Maintain, for such period of time as the Secretary shall prescribe by regulation, a record of all direct communications with a treating provider regarding the dispensing of a prescription drug, including verification of the prescription.

''(3) LICENSURE PROCEDURE.—

''(A) ACTION BY SECRETARY.—On receipt of a complete licensing application from an Internet pharmacy under paragraph (2), the Secretary shall—

''(i) assign an identification number to the Internet pharmacy;

''(ii) notify the applicant of the receipt of the licensing application; and

''(iii) if the Internet pharmacy is in compliance with the conditions under paragraph (2), issue a license not later than 60 days after receipt of a licensing application from the Internet pharmacy.

''(B) ELECTRONIC FILING.—

''(i) IN GENERAL.—For the purpose of reducing paperwork and reporting burdens, the Secretary shall require the use of electronic methods of submitting to the Secretary a licensing application required under this section and provide for electronic methods of receiving the applications.

''(ii) AUTHENTICATION.—In providing for the electronic submission of such licensing applications under this section, the Secretary shall ensure that adequate authentication protocols are used to allow identification of the Internet pharmacy and validation of the data as appropriate.

''(4) DATABASE.—

''(A) IN GENERAL.—The Secretary shall compile, maintain, and periodically update a database of the Internet pharmacies licensed under this section.

''(B) AVAILABILITY.—The Secretary shall make the database described under subparagraph (A) and information submitted by the licensee under paragraph (2)(B) available to the public on an Internet website and through a toll-free telephone number.

''(5) FEES.—

''(A) IN GENERAL.—

''(i) LICENSING APPLICATION FEE.—The Secretary shall establish a licensing application fee to be paid by all applicants.

''(ii) RENEWAL FEE.—The Secretary shall establish a yearly renewal fee to be paid by all Internet pharmacies licensed under this section.

''(B) COLLECTION.—

''(i) COLLECTION OF LICENSING APPLICATION FEE.—A licensing application fee payable for the fiscal year in which the Internet pharmacy submits a licensing application, as established under subparagraph (C), shall be payable upon the submission to the Secretary of such licensing application.

''(ii) COLLECTION OF RENEWAL FEES.—After the licensing application fee is paid for the first fiscal year of licensure, the yearly renewal fee, as established under subparagraph (C), shall be payable on or before October 1 of each subsequent fiscal year.

''(iii) ONE FEE PER INTERNET PHARMACY.—The licensing application fee and yearly renewal fee shall be paid only once for each Internet pharmacy for a fiscal year in which the fee is payable.

''(C) FEE AMOUNT.—The amount of the licensing application fee and the yearly renewal fee for an Internet pharmacy shall be determined each year by the Secretary based on the anticipated costs to the Secretary of enforcing the requirements of this section in the subsequent fiscal year.

''(D) ANNUAL FEE DETERMINATION.—

''(i) IN GENERAL.—Not later than 60 days before the beginning of each fiscal year beginning after September 30, 2007, the Secretary shall determine the amount of the licensing application fee and the yearly renewal fee for that fiscal year.

''(ii) PUBLICATION OF FEE AMOUNT.—Not later than 60 days before each fiscal year, the Secretary shall publish the amount of the licensing application fee and the yearly renewal fee under this section for that fiscal year and provide for a period of 30 days for the public to provide written comments on the fees.

''(E) USE OF FEES.—The fees collected under this section shall be used, without further appropriation, to carry out this section.

''(F) FAILURE TO PAY FEE.—

''(i) DUE DATE.—A fee payable under this section shall be paid by the date that is 30 days after the date on which the fee is due.

''(ii) FAILURE TO PAY.—If an Internet pharmacy subject to a fee under this section fails to pay the fee by the date specified under clause (i), the Secretary shall not permit the Internet pharmacy to engage in the dispensing of drugs as described under this section until all such fees owed by the Internet pharmacy are paid.

''(G) REPORTS.—Beginning with fiscal year 2008, not later than 60 days after the end of each fiscal year during which licensing application fees are collected under this section, the Secretary 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 that describes—

''(i) implementation of the licensing fee authority during the fiscal year; and

''(ii) the use by the Secretary of the licensing fees collected during the fiscal year for which the report is made.

''(6) SUSPENSION.—

''(A) IN GENERAL.—If the Secretary determines that an Internet pharmacy is engaged in a pattern of violations of any of the requirements of this Act, the Secretary may immediately order the suspension of the license of the Internet pharmacy.

''(B) APPEAL OF SUSPENSION ORDER.—An Internet pharmacy subject to a suspension order under subparagraph (A) may appeal the suspension order to the Secretary. Not later than 30 days after an appeal is filed, the Secretary, after providing opportunity for an informal hearing, shall affirm or terminate the order.

''(C) FAILURE TO ACT.—If, during the 30-day period specified in subparagraph (B), the Secretary fails to provide an opportunity for a hearing or to affirm or terminate the order, the order shall be deemed to be terminated.

''(D) NO JUDICIAL REVIEW.—An order under this paragraph shall not be subject to judicial review.

''(7) TERMINATION OF LICENSE.—The Secretary may terminate a license issued under this subsection, after notice to the Internet pharmacy and an opportunity for a hearing, and if the Secretary determines that the Internet pharmacy—

''(A) has demonstrated a pattern of noncompliance with this section;

''(B) has made an untrue statement of material fact in its licensing application; or

''(C) is in violation of any applicable Federal or State law relating to the dispensing of a prescription drug.

''(8) RENEWAL EVALUATION.—

''(A) IN GENERAL.—Before renewing a license of an Internet pharmacy under this subsection, the Secretary shall conduct an evaluation to determine whether the Internet pharmacy is in compliance with this section.

''(B) EVALUATION OF INTERNET PHARMACIES.—At the discretion of the Secretary and as applicable, an evaluation under subparagraph (A) may include testing of the Internet pharmacy website or other systems through which the Internet pharmacy communicates with consumers, and a physical inspection of the records and premises of the pharmacy.

''(9) CONTRACT FOR OPERATION OF PROGRAM.—

''(A) IN GENERAL.—The Secretary may award a contract under this subsection for the operation of the licensing program.

''(B) TERM.—The duration of a contract under subparagraph (A) shall not exceed 5 years and may be renewable.

''(C) PERFORMANCE REVIEW.—The Secretary shall annually review performance under a contract under subparagraph (A).

''(d) PROVIDERS OF INTERACTIVE COMPUTER SERVICES OR ADVERTISING SERVICES.—No provider of interactive computer services (as defined in section 230(f) of the Communications Act of 1934 (47 U.S.C. 230(f)) or an advertising service provider shall be liable under this section on account of another person's selling or dispensing of a prescription drug, so long as the provider of the interactive computer service or the advertising service provider does not own or exercise corporate control over such person.

''(e) POLICIES AND PROCEDURES REQUIRED TO PREVENT PAYMENTS FOR UNLAWFUL INTERNET PHARMACY REQUESTS.—

''(1) REGULATIONS.—Not later than 180 days after designating a system under subsection (a)(2), the Board shall promulgate regulations that require—

''(A) an operator of a credit card system that is a designated payment system, an operator of an international, national, or local network used to effect a credit transaction, electronic fund transfer, or money transmitting service that is a designated payment system, and an operator of any other designated payment system specified by the Board that is centrally managed and is primarily engaged in the transmission and settlement of credit transactions, electronic transfers, or money transmitting services where at least 1 party to the transaction or transfer is an individual; and

''(B) in the case of a designated payment system, other than a designated payment system described in subparagraph (A), a person described in subsection (a)(2)(B);

to establish policies and procedures that are reasonably designed to prevent the introduction of restricted transactions into a designated payment system or the completion of restricted transactions using a designated payment system.

''(2) REQUIREMENTS FOR POLICIES AND PROCEDURES.—In promulgating regulations under paragraph (1), the Board shall—

''(A) identify types of policies and procedures, including nonexclusive examples, that shall be considered to be reasonably designed to identify and reasonably designed to prevent the introduction of a restricted transaction in a designated payment or the completion of restricted transactions using a designated payment system; and

''(B) to the extent practicable, permit any designated payment system, or person described in subsection (a)(2)(B), as applicable, to choose among alternative means of preventing the introduction or completion of restricted transactions.

''(3) NO LIABILITY FOR BLOCKING OR REFUSING TO HONOR RESTRICTED TRANSACTION.—

''(A) IN GENERAL.—A designated payment system, or a person described in subsection (a)(2)(B), that is subject to a regulation or an order issued under this subsection, and any participant in such payment system, that—

''(i) prevents or otherwise refuses to honor restricted transactions, in an effort to implement the policies and procedures required under this subsection or to otherwise comply with this section, shall not be liable to any party for such action; and

''(ii) prevents or otherwise refuses to honor a nonrestricted transaction in an effort to implement the policies and procedures under this subsection or to otherwise comply with this section, shall not be liable to any party for such action.

''(B) COMPLIANCE WITH THIS SUBSECTION.—A person described in subsection (a)(2)(B) meets the requirements of this subsection, if any, if the person relies on and complies with the policies and procedures of a designated payment system of which the person is a member or in which the person is a participant, and such policies and procedures of the designated payment system comply with the requirements of the regulations under paragraph (1)(B).

''(4) ENFORCEMENT.—

''(A) IN GENERAL.—This subsection shall be enforced by the Federal functional regulators and the Federal Trade Commission under applicable law in the manner provided in section 505(a) of the Gramm-Leach-Bliley Act (21 U.S.C. 6805(a)).

''(B) FACTORS TO BE CONSIDERED.—In considering any enforcement action under this subsection against a payment system or person described in subsection (a)(2)(B), the Federal functional regulators and the Federal Trade Commission shall consider the following factors:

''(i) The extent to which the payment system or person knowingly permits restricted transactions.

''(ii) The history of the payment system or person in connection with permitting restricted transactions.

''(iii) The extent to which the payment system or person has established and is maintaining policies and procedures in compliance with regulations prescribed under this subsection.

''(iv) The feasibility that any specific remedy prescribed can be implemented by the payment system or person without substantial deviation from normal business practice.

''(v) The costs and burdens the specific remedy will have on the payment system or person.

''(f) REPORTS REGARDING INTERNET-RELATED VIOLATIONS OF FEDERAL AND STATE LAWS ON DISPENSING OF DRUGS.—The Secretary shall, pursuant to the submission of an application meeting criteria prescribed by the Secretary, make an award of a grant or contract to an entity with experience in developing and maintaining systems for the purpose of—

''(1) identifying Internet pharmacy websites that are not licensed or that appear to be operating in violation of Federal or State laws concerning the dispensing of drugs;

''(2) reporting such Internet pharmacy websites to State medical licensing boards and State pharmacy licensing boards, and to the Attorney General and the Secretary, for further investigation; and

''(3) submitting, for each fiscal year for which the award under this subsection is made, a report to the Secretary describing investigations undertaken with respect to violations described in paragraph (1).

''(g) TRANSACTIONS PERMITTED.—A designated payment system or person subject to a regulation or an order issued under subsection (e) may engage in transactions with licensed and unlicensed Internet pharmacies in connection with investigating violations or potential violations of any rule or requirement adopted by the payment system or person in connection with complying with subsection (e). A person subject to a regulation or an order issued under subsection (e) and the agents and employees of that person shall not be found to be in violation of, or liable under, any Federal, State, or other law for engaging in any such transaction.

''(h) RELATION TO STATE LAWS.—No requirement, prohibition, or liability may be imposed on a designated payment system or person subject to a regulation or an order issued under subsection (e) under the laws of any State with respect to any payment transaction by an individual because the payment transaction involves a payment to an Internet pharmacy.

''(i) TIMING OF REQUIREMENTS.—A designated payment system or a person subject to a regulation under subsection (e) shall adopt policies and procedures reasonably designed to comply with any regulations required under subsection (e) not later than 180 days after the date on which such final regulations are issued.''.

(b) PROHIBITED ACTS.—Section 301 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 331) is amended by adding at the end the following:

''(hh)(1) The sale, under section 511, of a drug that is not a prescription drug, the sale of such a prescription drug without a valid prescription from a treating provider, or the ownership or operation of an Internet pharmacy, in violation of section 511.

''(2) The representation by advertisement, sales presentation, direct communication (including telephone, facsimile, or electronic mail), or otherwise by an Internet pharmacy, that a prescription drug may be obtained from the Internet pharmacy without a prescription, in violation of section 511.

''(3) The advertisement related to a prescription drug through any media including sales presentation, direct communication (including telephone, facsimile, or electronic mail), by an unlicensed Internet pharmacy.

''(4) The provision of an untrue statement of material fact in the licensing application of an Internet pharmacy.

''(5) For purposes of this subsection, any term used in this subsection that is also used in section 511 shall have the meaning given that term in section 511.''.

(c) LINKS TO UNLICENSED INTERNET PHARMACIES.—Section 302 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 332) is amended by adding at the end the following:

''(c)(1) In the case of a violation of section 511 relating to an unlicensed Internet pharmacy (as defined in such section 511), the district courts of the United States and the United States courts of the territories shall have jurisdiction to order a provider of an interactive computer service to remove, or disable access to, links to a website violating that section that resides on a computer server that the provider controls or operates.

''(2) Relief under paragraph (1)—

''(A) shall be available only after provision to the provider of notice and an opportunity to appear;

''(B) shall not impose any obligation on the provider to monitor its service or to affirmatively seek facts indicating activity violating section 511;

''(C) shall specify the provider to which the relief applies; and

''(D) shall specifically identify the location of the website to be removed or to which access is to be disabled.''.

(d) REGULATIONS.—

(1) IN GENERAL.—Not later than 1 year after the date of enactment of this Act, the Secretary of Health and Human Services shall promulgate interim final regulations to carry out the amendments made by this section.

(2) EFFECTIVE DATE.—The requirement of licensure under section 511 of the Federal Food, Drug, and Cosmetic Act (as added by this section) shall take effect on the date determined by the Secretary of Health and Human Services but in no event later than 90 days after the effective date of the interim final regulations under paragraph (1).

(e) PENALTIES.—Section 303 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 333) is amended by adding at the end the following:

''(g) Notwithstanding subsection (a), any person who knowingly violates paragraph (1), (2), (3), or (4) of section 301(hh) shall be imprisoned for not more than 10 years or fined in accordance with title 18, United States Code, or both.''.

SA 1018. Mr. DEMINT (for himself, Mr. INHOFE, Mr. BROWNBACK, Mr. MARTINEZ, Mr. VITTER, and Mr. COBURN) submitted an amendment intended to be proposed by him to the bill S. 1082, to amend the Federal Food, Drug, and Cosmetic Act to reauthorize and amend the prescription drug user fee provisions, and for other purposes; as follows:

In section 214(b)(3)(B) of the bill, insert '', except with respect to the drug Mifeprex (mifepristone), such assessment shall be submitted 6 months after the applicant is so notified'' before the period at the end.

SA 1019. Mr. CASEY (for himself and Mr. SPECTER) submitted an amendment intended to be proposed by him to the bill S. 1082, to amend the Federal Food, Drug, and Cosmetic Act to reauthorize and amend the prescription drug user fee provisions, and for other purposes; which was ordered to lie on the table; as follows:

At the appropriate place, insert the following:

SEC. ___. ORPHAN DISEASE TREATMENT IN CHILDREN.

(a) FINDING.—The Senate finds that parents of children suffering from rare genetic diseases known as orphan diseases face multiple obstacles in obtaining safe and effective treatment for their children due mainly to the fact that many Food and Drug Administration-approved drugs used in the treatment of orphan diseases in children may not be approved for pediatric indications.

(b) SENSE OF THE SENATE.—It is the sense of the Senate that the Food and Drug Administration should enter into a contract with the Institute of Medicine for the conduct of a study concerning measures that may be taken to improve the likelihood that Food and Drug Administration-approved drugs that are safe and effective in treating children with orphan diseases are made available and affordable for pediatric indications.

SA 1020. Mr. GRASSLEY submitted an amendment intended to be proposed by him to the bill S. 1082, to amend the Federal Food, Drug, and Cosmetic Act

to reauthorize and amend the prescription drug user fee provisions, and for other purposes; which was ordered to lie on the table; as follows:

Strike clause (i) of section 402(j)(3)(A) of the Public Health Service Act, as added by this bill, and insert the following:

''(i) IN GENERAL.—

''(I) REQUIREMENT.—Not later than 90 days after the date of enactment of the Food and Drug Administration Revitalization Act, for all clinical trials (except as provided in subclause (II)), whether federally or privately funded, conducted to test the safety or efficacy (including comparative efficacy), of any drug or device (including those drugs or devices approved or cleared by the Secretary), the Secretary shall ensure that the registry data bank includes links to results information for such clinical trial—

''(aa) not earlier than 30 days after the date of the approval of the drug involved or clearance or approval of the device involved; or

''(bb) not later than 30 days after such information becomes publicly available, as applicable.

''(II) EXCEPTION.—The requirement of subclause (I) shall not apply to phase I clinical investigations conducted to test solely the safety of an unapproved drug or unlicensed biological product, or pilot or feasibility studies conducted to confirm the design and operating specifications of an unapproved or not yet cleared medical device.

''(III) VOLUNTARY SUBMISSION.—A responsible party for a clinical trial that is not an applicable drug clinical trial or an applicable device clinical trial may submit to the Secretary results information for a clinical trial described in subclause (II).

''(IV) EXPANDED REGISTRY DATA BANK.—Notwithstanding any other provision of law, the clinical trials described in subclause (I) shall be clinical trials of which the results information with respect to such trials is appropriate for adding to the expanded registry data bank, as described in subparagraph (C).

At the end section 402(j)(4) of the Public Health Service Act, as added by this bill, insert the following:

''(F) TRIALS CONDUCTED OUTSIDE OF THE UNITED STATES.—

''(i) IN GENERAL.—With respect to clinical trials described in clause (ii), the responsible party shall submit to the Secretary the information required under this subsection. The Secretary shall ensure that such information and the results of such clinical trials are made available to the public in a timely manner and as soon as practicable after receiving such information. Failure to comply with this paragraph shall be deemed to be a failure to submit information as required under this subsection, and the appropriate remedies and sanctions under this section shall apply.

''(ii) CLINICAL TRIAL DESCRIBED.—A clinical trial is described in this clause if—

''(I) such trial is conducted outside of the United States; and

''(II) the data from such trial is—

''(aa) submitted to the Secretary as part of an application, including a supplemental application, for a drug or device under section 505, 510, 515, or 520 of the Federal Food, Drug, and Cosmetic Act or for the biological product under section 351 of this Act; or

''(bb) used in advertising or labeling to make a claim about the drug or device involved.

''(iii) EXPANDED REGISTRY DATA BANK.—Notwithstanding any other provision of law, the clinical trials described in clause (ii) shall be clinical trials of which the results information with respect to such trials is appropriate for adding to the expanded registry data bank, as described in paragraph (3)(C).

SA 1021. Mrs. CLINTON submitted an amendment intended to be proposed by her to the bill S. 1082, to amend the Federal Food, Drug, and Cosmetic Act to reauthorize and amend the prescription drug user fee provisions, and for other purposes; which was ordered to lie on the table; as follows:

At the end of the bill, add the following:

SEC. ___. NO SUNSET FOR SECTION 505B.

Notwithstanding any provision of this Act, an amendment made by this Act, or any other provision of law, section 505B of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 355c) and the authority provided for under such section shall not sunset but shall remain in effect.

SA 1022. Mr. DURBIN (for himself, Mr. ENZI, Mr. KENNEDY, Mr. ALLARD, Mr. KOHL, Ms. CANTWELL, Mr. SCHUMER, Mr. BIDEN, Mr. NELSON of Florida, and Mr. CASEY) proposed an amendment to the bill S. 1082, to amend the Federal Food, Drug, and Cosmetic Act to reauthorize and amend the prescription drug user fee provisions, and for other purposes; as follows:

At the end of the bill, insert the following:

TITLE ___—FOOD SAFETY

SEC. __01. FINDINGS.

(a) FINDINGS.—Congress finds that—

(1) the safety and integrity of the United States food supply is vital to the public health, to public confidence in the food supply, and to the success of the food sector of the Nation's economy;

(2) illnesses and deaths of individuals and companion animals caused by contaminated food—

(A) have contributed to a loss of public confidence in food safety; and

(B) have caused significant economic losses to manufacturers and producers not responsible for contaminated food items;

(3) the task of preserving the safety of the food supply of the United States faces tremendous pressures with regard to—

(A) emerging pathogens and other contaminants and the ability to detect all forms of contamination; and

(B) an increasing volume of imported food from a wide variety of countries; and

(C) a shortage of adequate resources for monitoring and inspection;

(4) the United States is increasing the amount of food that it imports such that —

(A) from 2003 to the present, the value of food imports has increased from $45,600,000,000 to $64,000,000,000; and

(B) imported food accounts for 13 percent of the average Americans diet including 31 percent of fruits, juices, and nuts, 9.5 percent of red meat and 78.6 percent of fish and shellfish; and

(5) the number of full time equivalent Food and Drug Administration employees conducting inspections has decreased from 2003 to 2007.

SEC. __02. ENSURING THE SAFETY OF PET FOOD.

(a) PROCESSING AND INGREDIENT STANDARDS.—Not later than 18 months after the date of enactment of this Act, the Secretary of Health and Human Services (referred to in this title as the ''Secretary''), in consultation with the Association of American Feed Control Officials, and other relevant stakeholder groups, including veterinary medical associations, animal health organizations, and pet food manufacturers, shall by regulation establish—

(1) processing and ingredient standards with respect to pet food, animal waste, and ingredient definitions; and

(2) updated standards for the labeling of pet food that includes nutritional information and ingredient information.

(b) EARLY WARNING SURVEILLANCE SYSTEMS AND NOTIFICATION DURING PET FOOD RECALLS.—Not later than 180 days after the date of enactment of this Act, the Secretary shall by regulation establish an early warning and surveillance system to identify adulteration of the pet food supply and outbreaks of illness associated with pet food. In establishing such system, the Secretary shall—

(1) use surveillance and monitoring mechanisms similar to, or in coordination with, those mechanisms used by the Centers for Disease Control and Prevention to monitor human health, such as the Foodborne Diseases Active Surveillance Network (FoodNet) and PulseNet;

(2) consult with relevant professional associations and private sector veterinary hospitals; and

(3) work with the Health Alert Network and other notification networks to inform veterinarians and relevant stakeholders during any recall of pet food.

SEC. __03. ENSURING EFFICIENT AND EFFECTIVE COMMUNICATIONS DURING A RECALL.

The Secretary shall, during an ongoing recall of human or pet food—

(1) work with companies, relevant professional associations, and other organizations to collect and aggregate information pertaining to the recall;

(2) use existing networks of communication including electronic forms of information dissemination to enhance the quality and speed of communication with the public; and

(3) post information regarding recalled products on the Internet website of the Food and Drug Administration in a consolidated, searchable form that is easily accessed and understood by the public.

SEC. __04. STATE AND FEDERAL COOPERATION.

(a) IN GENERAL.—The Secretary shall work with the States in undertaking activities and programs that assist in improving the safety of fresh and processed produced so that State food safety programs involving the safety of fresh and processed produce and activities conducted by the Secretaries function in a coordinated and cost-effective manner. With the assistance provided under subsection (b), the Secretary shall encourage States to—

(1) establish, continue, or strengthen State food safety programs, especially with respect to the regulation of retail commercial food establishments; and

(2) establish procedures and requirements for ensuring that processed produce under the jurisdiction of the State food safety programs is not unsafe for human consumption.

(b) ASSISTANCE.—The Secretary may provide to a State, for planning, developing, and implementing such a food safety program—

(1) advisory assistance;

(2) technical assistance, training, and laboratory assistance (including necessary materials and equipment); and

(3) financial and other assistance.

(c) SERVICE AGREEMENTS.—The Secretary may, under an agreement entered into with a Federal, State, or local agency, use, on a reimbursable basis or otherwise, the personnel, services, and facilities of the agency to carry out the responsibilities of the agency under this section. An agreement entered into with a State agency under this subsection may provide for training of State employees.

SEC. __05. ADULTERATED FOOD REGISTRY.

(a) FINDINGS.—Congress makes the following findings:

(1) In 1994, Congress passed the Dietary Supplement Health and Education Act (P.L. 103-417) to provide the Food and Drug Administration with the legal framework to ensure that dietary supplements are safe and properly labeled foods.

(2) In 2006, Congress passed the Dietary Supplement and Nonprescription Drug Consumer Protection Act (P.L. 109-462) to establish a mandatory reporting system of serious adverse events for non-prescription drugs and dietary supplements sold and consumed in the United States.

(3) The adverse event reporting system created under the Dietary Supplement and Nonprescription Drug Consumer Protection Act will serve as the early warning system for any potential public health issues associated with the use of these food products.

(4) A reliable mechanism to track patterns of adulteration in food would support efforts by the Food and Drug Administration to effectively target limited inspection resources to protect the public health.

(b) IN GENERAL.—Chapter IV of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 341 et seq.) is amended by adding at the end the following:

''SEC. 417. ADULTERATED FOOD REGISTRY.

''(a) DEFINITIONS.—In this section:

''(1) IMPORTER.—The term 'importer', with respect to an article of food, means the person who submitted the notice with respect to such article of food under section 801(m).

''(2) RESPONSIBLE PARTY.—The term 'responsible party', with respect to an article of food, means any registered food facility under section 415(a), including those responsible for the manufacturing, processing, packaging or holding of such food for consumption in the United States.

''(3) REPORTABLE ADULTERATED FOOD.—The term 'reportable adulterated food' for purposes of this section means a food that is adulterated or—

''(A) presents a situation in which there is a reasonable probability that the use of, or exposure to, a violative product will cause serious adverse health consequences or death as defined in section 7.3(m)(1) of title, Code of Federal Regulations (or any successor regulations); or

''(B) meets the threshold established in section 304(h).

''(b) ESTABLISHMENT.—

''(1) IN GENERAL.—Not later than 180 days after the date of enactment of this section, the Secretary shall establish within the Food and Drug Administration an Adulterated Food Registry to which instances of reportable adulterated food may be submitted by the Food and Drug Administration after receipt of reports of adulteration, via an electronic portal, from—

''(A) Federal, State, and local public health officials;

''(B) an importer;

''(C) a responsible party; or

''(D) a consumer or other individual.

''(2) REVIEW BY SECRETARY.—The Secretary shall review and determine the validity of the information submitted under paragraph (1) for the purposes of identifying adulterated food, submitting entries to the Adulterated Food Registry, acting under subsection (c), and exercising other existing food safety authorities under the Act to protect the public health.

''(c) ISSUANCE OF AN ALERT BY THE SECRETARY.—

''(1) IN GENERAL.—The Secretary shall issue an alert with respect to an adulterated food if the Adulterated Food Registry shows that the food—

''(A) has been associated with repeated and separate outbreaks of illness or has been repeatedly determined to be adulterated; or

''(B) is a reportable adulterated food.

''(2) SCOPE OF ALERT.—An alert under paragraph (1) may apply to a particular food or to food from a particular producer, manufacturer, shipper, growing area, or country, to the extent that elements in subparagraph (A) or (B) of paragraph (1) are associated with the particular food, producer, manufacturer, shipper, growing area, or country.

''(d) SUBMISSION BY A CONSUMER OR OTHER INDIVIDUAL.—A consumer or other individual may submit a report to the Food and Drug Administration using the electronic portal data elements described in subsection (e). Such reports shall be evaluated by the Secretary as specified in subsection (b)(2).

''(e) NOTIFICATION AND REPORTING OF ADULTERATION.—

''(1) DETERMINATION BY RESPONSIBLE PARTY OR IMPORTER.—If a responsible party or importer determines that an article of food it produced, processed, manufactured, distributed, or otherwise handled is a reportable adulterated food, the responsible party shall provide the notifications described under paragraph (2).

''(2) NOTIFICATION OF ADULTERATION.—

''(A) IN GENERAL.—Not later than 5 days after a responsible party or importer receives a notification, the responsible party or importer, as applicable, shall review whether the food referenced in the report described in paragraph (1) is a reportable adulterated food.

''(B) NOTIFICATION.—If a determination is made by such responsible party or importer that the food is a reportable adulterated food, such responsible party or importer shall, no later than 5 days after such determination is made, notify other responsible parties directly linked in the supply chain to which and from which the article of reportable adulterated food was transferred.

''(3) SUBMISSION OF REPORTS TO THE FOOD AND DRUG ADMINISTRATION BY A RESPONSIBLE PARTY OR IMPORTER.—The responsible party or importer, as applicable, shall submit a report to the Food and Drug Administration through the electronic portal using the data elements described in subsection (f) not later than 2 days after a responsible party or importer—

''(A) makes a notification under paragraph (2)(B); or

''(B) determines that an article of food it produced, processed, manufactured, distributed, imported, or otherwise handled is a reportable adulterated food, except that if such adulteration was initiated with such responsible party or importer, was detected prior to any transfer of such article of food, and was destroyed, no report is necessary.

''(f) DATA ELEMENTS IN THE REGISTRY.—A report submitted to the Food and Drug Administration electronic portal under subsection (e) shall include the following data elements:

''(1) Contact information for the individual or entity submitting the report.

''(2) The date on which an article of food was determined to be adulterated or suspected of being adulterated.

''(3) A description of the article of food including the quantity or amount.

''(4) The extent and nature of the adulteration.

''(5) The disposition of the article.

''(6) Product information typically found on packaging including product codes, use by dates, and names of manufactures or distributors.

''(7) Information about the place of purchase or process by which the consumer or other individual acquired the article of adulterated food.

''(8) In the case of a responsible party or an importer, the elements required for the registration of food facilities under section 415(a).

''(9) The contact information for parties directly linked in the supply chain and notified under subsection (e)(2).

''(10) In the case of an importer, the elements required for the prior notice of imported food shipments under section 801(m).

''(g) MAINTENANCE AND INSPECTION OF RECORDS.—The responsible person or importer shall maintain records related to each report received, notification made, and report submitted to the Food and Drug Administration under this section and permit inspection of such records as provided for in section 414. Such records shall also be made available during an inspection under section 704.

''(h) REQUEST FOR INFORMATION.—Section 552 of title 5, United States Code, shall apply to any request for information regarding a record in the Adulterated Food Registry.

''(i) HOMELAND SECURITY NOTIFICATION.—If, after receiving a report under subsection (e), the Secretary suspects such food may have been deliberately adulterated, the Secretary shall immediately notify the Secretary of Homeland Security. The Secretary shall make the data in the Adulterated Imported Food Registry available to the Secretary of Homeland Security.''.

(c) DEFINITION.—Section 201(ff) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 321(ff)) is amended by striking ''section 201(g)'' and inserting ''sections 201(g) and 417''.

(d) PROHIBITED ACTS.—Section 301 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 331), as amended by this Act, is further amended by adding at the end the following:

''(kk) The failure to provide a report as required under section 417(e)(3).

''(ll) The falsification a report as required under section 417(e)(3).''.

(e) SUSPECTED FOOD ADULTERATION REGULATIONS.—The Secretary shall, within 180 days of enactment of this Act, promulgate regulations that establish standards and thresholds by which importers and responsible parties shall be required and consumers may be able to, under section 417 of the Federal Food, Drug, and Cosmetic Act (as added by this section)—

(1) report instances of suspected reportable adulteration of food to the Food and Drug Administration for possible inclusion in the Adulterated Food Registry after evaluation of such report; and

(2) notify, in keeping with subsection (e)(2) of such section 417, other responsible parties directly linked in the supply chain, including establishments as defined in section 415(b) of such Act.

(f) EFFECTIVE DATE.—The requirements of section 417(e) of the Federal Food, Drug, and Cosmetic Act, as added by subsection (a), shall become effective 180 days after the date of enactment of this Act.

SEC. _06. SENSE OF THE SENATE.

It is the sense of the Senate that—

(1) it is vital for Congress to provide the Food and Drug Administration with additional resources, authorities, and direction with respect to ensuring the safety of the food supply of the United States;

(2) additional inspectors are required to improve the Food and Drug Administration's ability to safeguard the food supply of the United States;

(3) because of the increasing volume of international trade in food products the Secretary of Health and Human Services should make it a priority to enter into agreements with the trading partners of the United States with respect to food safety; and

(4) the Senate should work to develop a comprehensive response to the issue of food safety.

SEC. __07. ANNUAL REPORT TO CONGRESS.

The Secretary shall, on an annual basis, submit to the Committee on Health, Education, Labor, and Pensions and the Committee on Appropriations of the Senate and the Committee on Energy and Commerce and the Committee on Appropriations of the House of Representatives a report that includes, with respect to the preceding 1-year period—

(1) the number and amount of food products regulated by the Food and Drug Administration imported into the United States, aggregated by country and type of food;

(2) a listing of the number of Food and Drug Administration inspectors of imported food products referenced in paragraph (1) and the number of Food and Drug Administration inspections performed on such products; and

(3) aggregated data on the findings of such inspections, including data related to violations of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 201 et seq.), and enforcement actions used to follow-up on such findings and violations.

SEC. __08. RULE OF CONSTRUCTION.

Nothing in this title (or an amendment made by this title) shall be construed to affect—

(1) the regulation of dietary supplements under the Dietary Supplement Health and Education Act; or

(2) the adverse event reporting system for dietary supplements created under the Dietary Supplement and Nonprescription Drug Consumer Protection Act.

SEC. __09. AUTHORIZATION OF APPROPRIATIONS.

There are authorized to be appropriated to carry out this title (and the amendments made by this title) such sums as may be necessary.

SA 1023. Mr. DURBIN submitted an amendment intended to be proposed by him to the bill S. 1082, to amend the Federal Food, Drug, and Cosmetic Act to reauthorize and amend the prescription drug user fee provisions, and for other purposes; which was ordered to lie on the table; as follows:

At the appropriate place, insert the following:

SEC. ___. STUDY ON FOOD INSPECTION AND SAFETY USER FEES.

(a) IN GENERAL.—The Secretary of Health and Human Services shall conduct a study to determine the feasibility of instituting a user fee program for food inspections and food safety that incorporates lessons learned from the user fee program for prescription drugs under chapter VII of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 371 et seq.) and that is designed to increase the resources and capabilities of the Food and Drug Administration to safeguard the food supply of the United States.

(b) REPORT TO CONGRESS.—Not later than 180 days after the date of enactment of this Act, the Secretary of Health and Human Services shall submit to Congress a report that—

(1) describes the findings of the study conducted under subsection (a); and

(2) includes—

(A) any recommendations for legislation related to such findings; and

(B) provides details, with respect to such recommended legislation, regarding—

(i) the expected revenues for the Food and Drug Administration;

(ii) the expected costs to the private sector, categorized by industry; and

(iii) any other relevant information.

SA 1024. Mr. SALAZAR submitted an amendment intended to be proposed by him to the bill S. 1082, to amend the Federal Food, Drug, and Cosmetic Act to reauthorize and amend the prescription drug user fee provisions, and for other purposes; which was ordered to lie on the table; as follows:

At the appropriate place, insert the following:

SEC. ___. PROHIBITION OF REORGANIZATION PLAN PENDING REVIEW.

(a) IN GENERAL.—The Commissioner of Food and Drugs may not implement a reorganization plan that reduces or consolidates the number of laboratory facilities currently in operation within the Office of Regulatory Affairs of the Food and Drug Administration pending a comprehensive review of the reorganization plan by the Comptroller General of the United States to determine—

(1) the impact of the reorganization on the mission of the Food and Drug Administration to ensure that foods, cosmetics, and medical products are safe, effective, and properly promoted and labeled;

(2) the projected cost savings; and

(3) the projected operational efficiencies.

(b) REPORT.—Not later than 1 year after the date of enactment of this section, the Comptroller General of the United States shall issue a report on the impact of the reorganization plan described in subsection (a).

SA 1025. Mr. SCHUMER (for himself, Mrs. CLINTON, Mr. ENZI, Mr. HATCH, and Mr. KENNEDY) proposed an amendment to the bill S. 1082, to amend the Federal Food, Drug, and Cosmetic Act to reauthorize and amend the prescription drug user fee provisions, and for other purposes; as follows:

At the end of the bill, add the following:

SEC. ___. SENSE OF THE SENATE WITH RESPECT TO FOLLOW-ON BIOLOGICS.

(a) FINDINGS.—The Senate finds the following:

(1) The Food and Drug Administration has stated that it requires legislative authority to review follow-on biologics.

(2) Business, consumer, and government purchasers require competition and choice to ensure more affordable prescription drug options.

(3) Well-constructed policies that balance the needs of innovation and affordability have broad bipartisan support.

(b) SENSE OF THE SENATE.—It is the sense of the Senate that—

(1) legislation should be enacted to—

(A) provide the Food and Drug Administration with the authority and flexibility to approve biopharmaceuticals subject to an abbreviated approval pathway;

(B) ensure that patient safety remains paramount in the system;

(C) establish a regulatory pathway that is efficient, effective, and scientifically-grounded and that also includes measures to ensure timely resolution of patent disputes; and

(D) provide appropriate incentives to facilitate the research and development of innovative biopharmaceuticals.

SA 1026. Mr. FEINGOLD submitted an amendment intended to be proposed by him to the bill S. 1082, to amend the Federal Food, Drug, and Cosmetic Act to reauthorize and amend the prescription drug user fee provisions, and for other purposes; which was ordered to lie on the table; as follows:

At the appropriate place, insert the following:

SEC. ___. PUBLICATION OF ANNUAL REPORTS.

(a) IN GENERAL.—The Commissioner on Food and Drugs shall annually submit to Congress and publish on the Internet website of the Food and Drug Administration, a report concerning the results of the Administration's pesticide residue monitoring program, that includes—

(1) information and analysis similar to that contained in the report entitled ''Food and Drug Administration Pesticide Program Residue Monitoring 2003'' as released in June of 2005;

(2) based on an analysis of previous samples, an identification of products or countries (for imports) that require special attention and additional study (including details on the plans for such additional studies), including in the initial report (and subsequent reports as determined necessary) the results and analysis of the Ginseng Dietary Supplements Special Survey as described on page 13 of the report entitled ''Food and Drug Administration Pesticide Program Residue Monitoring 2003'';

(3) information on the relative number of interstate and imported shipments of each tested commodity that were sampled, including recommendations on whether sampling is statistically significant, provides confidence intervals or other related statistical information, and whether the number of samples should be increased and the details of any plans to provide for such increase; and

(4) a description of whether certain commodities are being improperly imported as another commodity, including a description of additional steps that are being planned to prevent such smuggling.

(b) INITIAL REPORTS.—Annual reports under subsection (a) for fiscal years 2004 through 2006 may be combined into a single report, by not later than June 1, 2008, for purposes of publication under subsection (a). Thereafter such reports shall be completed by June 1 of each year for the data collected for the year that was 2-years prior to the year in which the report is published.

(c) MEMORANDUM OF UNDERSTANDING.—The Commissioner of Food and Drugs, the Administrator of the Food Safety and Inspection Service, and the head of the Agricultural Marketing Service shall enter into a memorandum of understanding to permit inclusion of data in the reports under subsection (a) relating to testing carried out by the Food Safety and Inspection Service and the Agricultural Marketing Service on meat, poultry, eggs, and certain raw agricultural products, respectively.

SA 1027. Mr. DURBIN submitted an amendment intended to be proposed by him to the bill S. 1082, to amend the Federal Food, Drug, and Cosmetic Act to reauthorize and amend the prescription drug user fee provisions, and for other purposes; which was ordered to lie on the table; as follows:

At the appropriate place, insert the following:

TITLE ___—FOOD SAFETY

SEC. ___. FOOD SAFETY FOR HUMANS AND PETS.

Chapter IV of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 341 et seq.) is amended by adding at the end the following:

''SEC. 417. NOTIFICATION AND RECALL.

''(a) NOTICE TO SECRETARY OF VIOLATION.—

''(1) IN GENERAL.—A person that has reason to believe that any food introduced into or in interstate commerce, or held for sale (whether or not the first sale) after shipment in interstate commerce, may be in violation of this Act shall immediately notify the Secretary of the identity and location of the food.

''(2) MANNER OF NOTIFICATION.—Notification under paragraph (1) shall be made in such manner and by such means as the Secretary may require by regulation.

''(b) RECALL AND CONSUMER NOTIFICATION; VOLUNTARY ACTIONS.—If the Secretary determines that food is in violation of this Act when introduced into or while in interstate commerce or while held for sale (whether or not the first sale) after shipment in interstate commerce and that there is a reasonable probability that the food, if consumed, would present a threat to public health, as determined by the Secretary, the Secretary shall give the appropriate persons (including the manufacturers, importers, distributors, or retailers of the food) an opportunity to—

''(1) cease distribution of the food;

''(2) notify all persons—

''(A) processing, distributing, or otherwise handling the food to immediately cease such activities with respect to the food; or

''(B) to which the food has been distributed, transported, or sold, to immediately cease distribution of the food;

''(3) recall the food;

''(4) in conjunction with the Secretary, provide notice of the finding of the Secretary—

''(A) to consumers to whom the food was, or may have been, distributed; and

''(B) to State and local public health officials; or

''(5) take any combination of the measures described in this paragraph, as determined by the Secretary to be appropriate in the circumstances.

''(c) CIVIL AND CRIMINAL PENALTIES.—

''(1) CIVIL SANCTIONS.—

''(A) CIVIL PENALTY.—Any person that commits an act that violates the notification and recall standards under subsection (b) (including a regulation promulgated or order issued under this Act) may be assessed a civil penalty by the Secretary of not more than $10,000 for each such act.

''(B) SEPARATE OFFENSE.—Each act described in subparagraph (A) and each day during which that act continues shall be considered a separate offense.

''(2) OTHER REQUIREMENTS.—

''(A) WRITTEN ORDER.—The civil penalty described in paragraph (1) shall be assessed by the Secretary by a written order, which shall specify the amount of the penalty and the basis for the penalty under subparagraph (B) considered by the Secretary.

''(B) AMOUNT OF PENALTY.—Subject to paragraph (1)(A), the amount of the civil penalty shall be determined by the Secretary, after considering—

''(i) the gravity of the violation;

''(ii) the degree of culpability of the person;

''(iii) the size and type of the business of the person; and

''(iv) any history of prior offenses by the person under this Act.

''(C) REVIEW OF ORDER.—The order may be reviewed only in accordance with subsection (d).

''(3) EXCEPTION.—No person shall be subject to the penalties of this subsection—

''(A) for having received, proffered, or delivered in interstate commerce any food, if the receipt, proffer, or delivery was made in good faith, unless that person refuses to furnish (on request of an officer or employee designated by the Secretary)—

''(i) the name, address and contact information of the person from whom that person purchased or received the food;

''(ii) copies of all documents relating to the person from whom that person purchased or received the food; and

''(iii) copies of all documents pertaining to the delivery of the food to that person; or

''(B) if that person establishes a guaranty signed by, and containing the name and address of, the person from whom that person received in good faith the food, stating that the food is not adulterated or misbranded within the meaning of this Act.

''(d) JUDICIAL REVIEW.—

''(1) IN GENERAL.—An order assessing a civil penalty under subsection (c) shall be a final order unless the person—

''(A) not later than 30 days after the effective date of the order, files a petition for judicial review of the order in the United States court of appeals for the circuit in which that person resides or has its principal place of business or the United States Court of Appeals for the District of Columbia; and

''(B) simultaneously serves a copy of the petition by certified mail to the Secretary.

''(2) FILING OF RECORD.—Not later than 45 days after the service of a copy of the petition under paragraph (1)(B), the Secretary shall file in the court a certified copy of the administrative record upon which the order was issued.

''(3) STANDARD OF REVIEW.—The findings of the Secretary relating to the order shall be set aside only if found to be unsupported by substantial evidence on the record as a whole.

''(e) COLLECTION ACTIONS FOR FAILURE TO PAY.—

''(1) IN GENERAL.—If any person fails to pay a civil penalty assessed under subsection (c) after the order assessing the penalty has become a final order, or after the court of appeals described in subsection (d) has entered final judgment in favor of the Secretary, the Secretary shall refer the matter to the Attorney General, who shall institute in a United States district court of competent jurisdiction a civil action to recover the amount assessed.

''(2) LIMITATION ON REVIEW.—In a civil action under paragraph (1), the validity and appropriateness of the order of the Secretary assessing the civil penalty shall not be subject to judicial review.

''(f) PENALTIES PAID INTO ACCOUNT.—The Secretary—

''(1) shall deposit penalties collected under this section in an account in the Treasury; and

''(2) may use the funds in the account, without further appropriation or fiscal year limitation—

''(A) to carry out enforcement activities under food safety law; or

''(B) to provide assistance to States to inspect retail commercial food establishments, such as an establishment that holds, stores, or transports food or food ingredients, or other food or firms under the jurisdiction of State food safety programs.

''(g) DISCRETION OF THE SECRETARY TO PROSECUTE.—Nothing in this section or section 418 requires the Secretary to report for prosecution, or for the commencement of an action, the violation of this Act in a case in which the Secretary finds that the public interest will be adequately served by the assessment of a civil penalty under this section.

''(h) REMEDIES NOT EXCLUSIVE.—The remedies provided in this section may be in addition to, and not exclusive of, other remedies that may be available.

''SEC. 418. MANDATORY RECALL ACTION.

''(a) MANDATORY ACTIONS.—If a person referred to in section 417(b) refuses to or does not adequately carry out the actions described in that section within the time period and in the manner prescribed by the Secretary, the Secretary shall—

''(1) have authority to control and possess the food, including ordering the shipment of the food from a food establishment, such as an establishment that holds, stores, or transports food or food ingredients, to the Secretary—

''(A) at the expense of such food establishment; or

''(B) in an emergency (as determined by the Secretary), at the expense of the Secretary; and

''(2) by order, require, as the Secretary determines to be necessary, the person to immediately—

''(A) cease distribution of the food; and

''(B) notify all persons—

''(i) processing, distributing, or otherwise handling the food to immediately cease such activities with respect to the food; or

''(ii) if the food has been distributed, transported, or sold, to immediately cease distribution of the food.

''(b) NOTIFICATION TO CONSUMERS BY SECRETARY.—The Secretary shall, as the Secretary determines to be necessary, provide notice of the finding of the Secretary under paragraph (1)—

''(1) to consumers to whom the food was, or may have been, distributed; and

''(2) to State and local public health officials.

''(c) NONDISTRIBUTION BY NOTIFIED PERSONS.—A person that processes, distributes, or otherwise handles the food, or to which the food has been distributed, transported, or sold, and that is notified under section 417(b)(2) or subsection (a)(2)(B) of this section shall immediately cease distribution of the food.

''(d) AVAILABILITY OF RECORDS TO SECRETARY.—Each person referred to in section 417 that processed, distributed, or otherwise handled food shall make available to the Secretary information necessary to carry out this subsection, as determined by the Secretary, regarding—

''(1) persons that processed, distributed, or otherwise handled the food; and

''(2) persons to which the food has been transported, sold, distributed, or otherwise handled.

''(e) INFORMAL HEARINGS ON ORDERS.—

''(1) IN GENERAL.—The Secretary shall provide any person subject to an order under subsection (a) with an opportunity for an informal hearing, to be held as soon as practicable but not later than 2 business days after the issuance of the order.

''(2) SCOPE OF THE HEARING.—In a hearing under paragraph (1), the Secretary shall consider the actions required by the order and any reasons why the food that is the subject of the order should not be recalled.

''(f) POST-HEARING RECALL ORDERS.—

''(1) AMENDMENT OF ORDER.—If, after providing an opportunity for an informal hearing under subsection (e), the Secretary determines that there is a reasonable probability that the food that is the subject of an order under subsection (a), if consumed, would present a threat to the public health, the Secretary, as the Secretary determines to be necessary, may—

''(A) amend the order to require recall of the food or other appropriate action;

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

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

''(D) provide notice of the recall to consumers to whom the food was, or may have been, distributed.

''(2) VACATION OF ORDERS.—If, after providing an opportunity for an informal hearing under subsection (e), the Secretary determines that adequate grounds do not exist to continue the actions required by the order, the Secretary shall vacate the order.

''(g) REMEDIES NOT EXCLUSIVE.—The remedies provided in this section shall be in addition to, and not exclusive of, other remedies that may be available.''.

SA 1028. Mr. ROCKEFELLER (for himself, Mr. SCHUMER, Mr. LEAHY, Mr.

KOHL, and Ms. STABENOW) submitted an amendment intended to be proposed by him to the bill S. 1082, to amend the Federal Food, Drug, and Cosmetic Act to reauthorize and amend the prescription drug user fee provisions, and for other purposes; which was ordered to lie on the table; as follows:

At the end of the bill, add the following:

SEC. ___. PROHIBITION OF AUTHORIZED GENERICS.

Section 505 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 355), as amended by this Act, is further amended by adding at the end the following:

''(s) 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, direct 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 exclusivity with respect to such drug under subsection (j)(5)(B)(iv); or

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

SA 1029. Mr. SANDERS submitted an amendment intended to be proposed by him to the bill S. 1082, to amend the Federal Food, Drug, and Cosmetic Act to reauthorize and amend the prescription drug user fee provisions, and for other purposes; which was ordered to lie on the table; as follows:

Beginning on page 138 strike line 5 and all that follows through line 10 on page 142 and insert the following:

''(x) specify a process for annual Board review of the operations of the Foundation;

''(xi) establish specific duties of the Executive Director; and

''(xii) establish specific policies to safeguard the Federal Government's patent rights in inventions made with Federal assistance through the Foundation;

''(B) prioritize and provide overall direction to the activities of the Foundation;

''(C) evaluate the performance of the Executive Director; and

''(D) carry out any other necessary activities regarding the functioning of the Foundation.

''(3) TERMS AND VACANCIES.—

''(A) TERM.—The term of office of each member of the Board appointed under paragraph (1)(C) shall be 4 years, except that the terms of offices for the initial appointed members of the Board shall expire on a staggered basis as determined by the ex officio members.

''(B) VACANCY.—Any vacancy in the membership of the Board—

''(i) shall not affect the power of the remaining members to execute the duties of the Board; and

''(ii) shall be filled by appointment by the appointed members described in paragraph (1)(C) by majority vote.

''(C) PARTIAL TERM.—If a member of the Board does not serve the full term applicable under subparagraph (A), the individual appointed under subparagraph (B) to fill the resulting vacancy shall be appointed for the remainder of the term of the predecessor of the individual.

''(D) SERVING PAST TERM.—A member of the Board may continue to serve after the expiration of the term of the member until a successor is appointed.

''(4) COMPENSATION.—Members of the Board may not receive compensation for service on the Board. Such members may be reimbursed for travel, subsistence, and other necessary expenses incurred in carrying out the duties of the Board, as set forth in the bylaws issued by the Board.

''(e) INCORPORATION.—The ex officio members of the Board shall serve as incorporators and shall take whatever actions necessary to incorporate the Foundation.

''(f) NONPROFIT STATUS.—The Foundation shall be considered to be a corporation under section 501(c) of the Internal Revenue Code of 1986, shall be subject to the provisions of such section, and shall be considered a nonprofit organization for purpose of section 201(i) of title 35, United States Code.

''(g) EXECUTIVE DIRECTOR.—

''(1) IN GENERAL.—The Board shall appoint an Executive Director who shall serve at the pleasure of the Board. The Executive Director shall be responsible for the day-to-day operations of the Foundation and shall have such specific duties and responsibilities as the Board shall prescribe.

''(2) COMPENSATION.—The compensation of the Executive Director shall be fixed by the Board but shall not be greater than the compensation of the Commissioner.

''(h) ADMINISTRATIVE POWERS.—In carrying out this subchapter, the Board, acting through the Executive Director, may—

''(1) adopt, alter, and use a corporate seal, which shall be judicially noticed;

''(2) hire, promote, compensate, and discharge 1 or more officers, employees, and agents, as may be necessary, and define their duties;

''(3) prescribe the manner in which—

''(A) real or personal property of the Foundation is acquired, held, and transferred;

''(B) general operations of the Foundation are to be conducted; and

''(C) the privileges granted to the Board by law are exercised and enjoyed;

''(4) with the consent of the applicable executive department or independent agency, use the information, services, and facilities of such department or agencies in carrying out this section;

''(5) enter into contracts with public and private organizations for the writing, editing, printing, and publishing of books and other material;

''(6) hold, administer, invest, and spend any gift, devise, or bequest of real or personal property made to the Foundation under subsection (i);

''(7) enter into such other contracts, leases, cooperative agreements, and other transactions as the Board considers appropriate to conduct the activities of the Foundation, except that Federal rights in patented inventions made with Federal assistance shall be preserved;

''(8) modify or consent to the modification of any contract or agreement to which it is a party or in which it has an interest under this subchapter;

''(9) take such action as may be necessary to obtain patents and licenses for devices and procedures developed by the Foundation and its employees, except that Federal rights in patented inventions made with Federal assistance shall be preserved;

SA 1030. Mr. SANDERS submitted an amendment intended to be proposed by him to the bill S. 1082, to amend the Federal Food, Drug, and Cosmetic Act to reauthorize and amend the prescription drug user fee provisions, and for other purposes; which was ordered to lie on the table; as follows:

On page 171, between lines 18 and 19, insert the following:

''(C) ADDITIONAL CERTIFICATION.—At the time of the submission of an application under section 505 of the Federal Food, Drug, and Cosmetic Act, section 515 of such Act, section 520(m) of such Act or section 351 of the Public Health Service Act, or submission of a report under section 510(k) of such Act, such application or submission shall be accompanied by a certification that all applicable requirements of sections 201 through 212 of title 35, United States Code, and any other provision of Federal law relating to Federal rights in patented inventions made with Federal Government assistance, have been met, including, where applicable, the requirement under section 201(f) of such title that the benefits of such inventions be made available to the public on reasonable terms, including price.''.

SA 1031. Mr. SANDERS submitted an amendment intended to be proposed by him to the bill S. 1082, to amend the Federal Food, Drug, and Cosmetic Act to reauthorize and amend the prescription drug user fee provisions, and for other purposes; which was ordered to lie on the table; as follows:

On page 171, line 16, insert before the period the following: '', and that any patent filed or that will be filed contains a statement specifying that the invention was made with Federal Government support and that the Federal Government has certain rights in it, if such a statement is otherwise required by law''.

SA 1032. Mr. SANDERS submitted an amendment intended to be proposed by him to the bill S. 1082, to amend the Federal Food, Drug, and Cosmetic Act to reauthorize and amend the prescription drug user fee provisions, and for other purposes; which was ordered to lie on the table; as follows:

On page 156, between lines 2 and 3, insert the following:

''(VII) The rights of the Federal Government in the drug or device that is the subject of the clinical trial.''.

SA 1033. Mr. SANDERS submitted an amendment intended to be proposed by him to the bill S. 1082, to amend the Federal Food, Drug, and Cosmetic Act to reauthorize and amend the prescription drug user fee provisions, and for other purposes; which was ordered to lie on the table; as follows:

On page 145, between lines 11 and 12, insert the following:

''(n) PROTECTING FEDERAL RIGHTS IN PATENTED INVENTIONS DEVELOPED WITH FEDERAL GOVERNMENT ASSISTANCE.—Any invention developed by the Foundation or with the funds of the Foundation shall be considered a subject invention for purposes of section 201(e) of title 35, United States Code.''.