SEC. 1009. Mr. HATCH submitted an amendment intended to be proposed by him to the bill S. 1082, supra, which was ordered to lie on the table.

SA 1009A. 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 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. Mr. 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 submitted an amendment intended to be proposed by him to the bill S. 1082, supra; which was ordered to lie on the table.

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, Mr. 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. STABILE) 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. 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 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 1008A. 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:

SEC. 1002. [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 purposes and determine, supra:

(A) whether such activity is taking place in violation of any provision of Federal law for which the Department of Health and 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 . MARIJUANA SMOKED BY PATIENTS.

SEC. 1002. EVALUATION AND REPORT.

(a) 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 purposes, and determine, supra:

(A) whether such activity is taking place in violation of any provision of Federal law for which the Department of Health and 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 1009A. 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.

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

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, Mr. 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. STABILE) 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. 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 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.

SA 1034. Mr. ROCKEFELLER (for himself, Mr. SCHUMER, Mr. LEAHY, Mr. KOHL, and Ms. STABILE) submitted an amendment intended to be proposed by him to the bill S. 1082, supra; which was ordered to lie on the table.

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 a given 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 consultations from the Antimicrobial Resistance Task Force and in consultation with the Centers for Disease Control and Prevention, or more frequently upon the recommendation 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 . . . EXCLUSION OF CERTAIN DRUGS CONTAINING ENANTIOMERS.

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

‘‘(ii) the Secretary has—

(1) 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), and notified the manufacturer of the product that the antibiotic drug and the listed antibiotic drug in safety and effectiveness;’’
"(a) 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 an active ingredient and 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 as the racemic drug approved in the previous approval for a use for which the racemic drug has been approved; or

"(1) the single enantiomer has not been previously approved as an active ingredient of the approved racemic drug; and

"(2) the application submitted under subsection (b) for the drug containing the single enantiomer includes full reports of investigations which do not rely on any investigations that are part of the application submitted under subsection (b) for approval of the approved racemic drug.

"(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.

"(2)(A) the application submitted under subsection (b) for the drug containing the single enantiomer is not submitted for approval of a use for which the racemic drug has been approved;

"(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 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. BURIS, 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. PYOR, Mr. SANDERS, Mr. WHITEHOUSE, and Mrs. McCASKILL) to the bill S. 1062, 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 submits to the Congress a report that 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. KORIL) submitted an amendment intended to be proposed by her to the bill S. 1062, 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. 360c), as amended by this Act, is amended by adding at the end the following:

"(c) CITIZEN'S PETITIONS AND PETITIONS FOR STAY OF AGENCY ACTION—

"(1) General.—

"(A) No delay of consideration or approval.

"(i) In general.—With respect to a pending application submitted under subsection (b)(2) or (j), a petition is submitted to the Secretary for a delay of any action on a petition, 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 to delay consideration of an application submitted under subsection (b)(2) or (j) and consideration of a petition described in clause (i) shall be promptly performed 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 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 any determination made by the Secretary under paragraph (1)(A)(ii), the Secretary shall take final agency action with respect to a petition not later than 180 days of submission of the petition by 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 shall 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 a schedule that would include the date 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) Verification.—

"(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, 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 the date I received or expect to receive payments, including cash and other forms of consideration, from the following persons or organizations to which I am a representative of, or (j) and that seeks only to have the Secretary issue a report not later than 2 years after the

"(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 the subject petition is signed under penalty of perjury that the foregoing is true and correct., with the date of the filing on the Internet website of the petitioner, that a delay is necessary to protect the public health. From the following persons or organizations to which I am a representative of, or (j) and that seeks only to have the Secretary issue a report not later than 2 years after the

"(C) the number of applications under subsection (b)(2) or (j) 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 during the preceding 1-year period that were not accepted

"(3) Exception.—This subsection does not apply to a petition that is made by the sponsor of the application under subsection (b)(2) or (j) to the Secretary to request a delay of any action under subsection (b)(2) or (j) and the number of days by which the applications were so delayed.

"(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) or (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 during the preceding 1-year period that were not accepted for review by the Secretary as a delay of any action 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) to the Secretary to request a delay of any action under subsection (b)(2) or (j) and the number of days by which the applications were so delayed.

"(5) 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) or (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 during the preceding 1-year period that were not accepted for review by the Secretary as a delay of any action under subsection (b)(2) or (j) and the number of days by which the applications were so delayed.
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. 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. PYOR, 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. 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:

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.

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:

(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.

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(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.

(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.

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(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 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. 3. ESTABLISHMENT OF THE CENTERS.

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

(1) the applicant's experience in conducting preclinical and clinical studies of prescription drugs; and

(2) the extent to which the establishment meets the conditions set forth in section 512 of the Food, Drug, and Cosmetic Act.

There are authorized to be appropriated $5514,000,000 for the purpose of the unlawful Internet transaction through any financial institution; or

(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 to any person engaged in the operation of an unlicensed Internet pharmacy, or

(d) an electronic fund transfer or 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

(2) Designated Payment System.—The term 'designated payment system' means a system used by a financial institution, electronic fund transfer, or money transmitting service that the Board determines, by regulation or order, is regularly used in connection with, or facilitates restricting the electronic or print media, and in the commercial or non-commercial context, to effect a credit transaction, electronic fund transfer, or money

Referred to in subparagraph (A) is—

(i) a credit card issuer;

(ii) a financial institution;

(iii) a person described in paragraph (2); and

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

(b) Persons Described.—A person referred to in subparagraph (A) is—

(1) the Commissioner of Food and Drugs;

(2) the Secretary of Health and Human Services;

(3) the Secretary of the Treasury;

(4) the Federal Trade Commission; and

(5) the Attorney General.
“(ii) discusses with the individual the treatment options of the individual and the risks and benefits of treatment; and

“(iii) maintains contemporaneous medical records in accordance with this section.

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

“(8) UNLAWFUL INTERNET PHARMACY REQUEST.—The term ‘unlawful Internet pharmacy request’ means the request, or transmitted 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 by the term ‘creditor’ at the time of 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. 1699a); 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 Fund Transfer Act (15 U.S.C. 1699a); and

“(ii) includes a financial institution (as defined in section 599 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 5530(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 applicable Federal and State laws and inspection requirements.

“(2) APPLICABILITY.—An Internet pharmacy shall submit to the Secretary an application that includes—

“(aa) the full name and address of the individual; and

“(bb) the manufacturing and distribution of control substances, including the address, city, and telephone number of business 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 the Secretary with the identity of any providers of interactive computer services that provide host services or advertising services for the Internet pharmacy;

“(dd) the Internet pharmacy expressly and affirmatively agrees to provide the Secretary with the address of the Internet pharmacy and each employee of the Internet pharmacy.

“(3) IDENTIFICATION REQUIREMENTS.—An Internet pharmacy shall post in a clear and visible manner, on each page of the website, each page of this section, or a separate page, the following information:

“(i) The street address, city, ZIP Code or comparable mail code, State (or comparable postal code, country, and telephone number of business located outside the United States, verification that—

“(ii) 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;

“(iii) 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;

“(iv) 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;

“(v) in the case of an agreement between a patient and the 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;

“(vi) 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;

“(vii) 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, each page of this section, or a separate page, the following information:

“(i) The street address, city, ZIP Code or comparable mail code, State (or comparable postal code, country, and telephone number of business located outside the United States, verification that—

“(ii) the name of the supervising pharmacist of the Internet pharmacy and each employee who serves as a pharmacist for purposes of the Internet pharmacy website;

“(iii) the names of all States in which the Internet pharmacy is licensed or authorized to dispense prescription drugs;

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

“(B) 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 and organized to facilitate communication 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 254(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) Establish a mechanism for patients to report errors and suspected adverse drug reactions.

“(VI) Document in the reporting mechanism the response of the Internet pharmacy to those reports.

“(B) IN GENERAL.—An Internet pharmacy shall be licensed by the Secretary in accordance with applicable Federal and State laws and inspection requirements.

“(C) PROFESSIONAL SERVICES REQUIREMENTS.—An Internet pharmacy shall ensure that—

“(I) the name, street address, city, ZIP Code or comparable postal code, country, and telephone number of business located outside the United States, verification that—

“(ii) the name of each State in which each practitioner is licensed or otherwise authorized to prescribe drugs.
"(III) A prescription is verified under subclause (1)(bb) only if 1 of the following occurs:

(aa) The treating provider confirms, by direct, telephone, or data 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) the treating provider informs the Internet pharmacy within 72 hours after receipt of a communication under subclause (1)(bb) that the prescription is inaccurate or expired; or

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

(xv) The Secretary shall maintain, for each 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 completed 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) confirm that 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 may permit, by the use of standards-based 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 Internet pharmacies licensed under this section.

(B) AVAILABILITY.—The Secretary shall make the database described under subparagraph (A) 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 paid.

(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 EVALUATION.—

(i) IN GENERAL.—Not later than 60 days before the beginning of each fiscal year beginning after September 30, 2007, the Secretary shall submit to the Committee on Energy and Commerce of the House of Representatives a report that describes—

(A) the implementation of the licensing fee authority during the previous fiscal year; and

(B) the use of the fees collected during the fiscal year for which the report is made.

(ii) TERMINATION.—The Secretary shall terminate the collection of fees before renewing a license under subsection (a).

(E) USE OF FEES.—The fees collected shall be used, without further appropriation, to—

(A) pay the costs of enforcing the requirements of this section;

(B) pay the costs of conducting an evaluation to determine whether the Internet pharmacy is in compliance with this section;

(C) compensate the Secretary for the time spent in reviewing applications under this section;

(D) COMPENSATE THE SECRETARY.—The Secretary shall annually review performance under a contract under subparagraph (A).

(6) PROVIDERS OF INTERACTIVE COMPUTER SERVICES OR ADVERTISING SPACE.—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 allow any person to transmit information on 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.

(7) POLICIES AND PROCEDURES REQUIRED TO PREVENT PAYMENTS FOR UNLAWFUL INTERNET PHARMACY REQUESTS.

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

(i) 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, an operator of a designated payment system, and an operator of any other designated payment system, on which 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

(ii) 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); 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;

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

(i) 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 into a designated payment system or the completion of restricted transactions using a designated payment system;
“(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 dispensing of or completing any restricted transactions.

“(C) No liability for blocking or refusing to honor restricted transaction.—

“(1) 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 part of such payment system, that—

“(i) prevents or otherwise refuses to honor restricted transactions, in an effort to implement the policies and procedures required under subsection (a), 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, that are imposed 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 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 the applicable law in the manner provided in section 506(a) of the Gramm-Leach-Bliley Act (21 U.S.C. 6806(a)).

“(B) ACTS CONSTRUED AS VIOLATIONS.—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 would 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 described 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 (a), or in transactions with any State with respect to any payment transaction, 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 or an order issued 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.

“(J) Transactions permitted.

“(1) In general.—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—

“(A) 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;

“(B) 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

“(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.

“(2) Regulations.—

“(1) In general.—Not later than 1 year after the date of enactment of this Act, the Secretary 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 under section 541 of the Public Health Service Act but in no event later than 90 days after the effective date of the interim final regulations under paragraph (1).

“(e) Penalties.—

“(1) Notwithstanding subsection (a), any person who knowingly violates paragraph (1), (2), (3), or (4) of section 301(b)(1) shall be fined not more than $100,000 or imprisoned 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 21h(b)(3)(B) of the bill, insert ‘‘except with respect to the drug Milperex (mifepristone), such an assessment shall be submitted 6 months after the applicant is notified before the period at the end.

“SA 1019. Mr. CASEY for himself and Mr. SPECKER—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:

“At the appropriate place, insert the following:

“SEC. 4. 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.—(1) REQUIREMENT.—Not later than 90 days after the date of enactment of this Act, the Secretary shall conduct a review of the standards for drug use fees and, if the Secretary determines that such fees are excessive, the Secretary shall submit to Congress a report describing the results of such a review and such report shall be made available to the public in a timely manner.

(2) REPORT.—Notwithstanding section 513 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 1021. Mrs. CLINTON submitted an amendment intended to be proposed by her to the bill S. 1062, 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. 1. NO SUNSET FOR SECTION 508B.

Notwithstanding any provision of this Act, an amendment made by this Act, or any other provision of law, section 508B of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 358c) 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. WHITEHOUSE) submitted an amendment to the bill S. 1062, 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 1 —FOOD SAFETY

SEC. 1. FINDINGS.

(a) FINDINGS.—Congress finds that—

(1) the safety and integrity of the United States food supply is vital to the health, safety, and confidence in food safety; and

(2) the American public is concerned about the national food safety system.

(b) ASSISTANCE.

(1) Assistance.—The Secretary shall—

(A) establish a task force to carry out the responsibilities of the agency under this section.

(B) consult with relevant professional associations and other organizations to carry out the responsibilities of the agency under this section.

(C) provide funding, equipment, and personnel; and

(D) use surveillance and monitoring mechanisms to improve the quality and speed of communication with the public.

SEC. 2. ENSURING EFFICIENT AND EFFECTIVE COMMUNICATIONS DURING A RECALL.

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

(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. 3. STATE AND FEDERAL COOPERATION.

(a) IN GENERAL.—The Secretary shall—

(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 processes used to produce the food for sale in the jurisdiction of the State food safety programs is safe for human consumption.

(b) STATE ENSURING EFFICIENT AND EFFECTIVE COMMUNICATIONS DURING A RECALL.—The Secretary shall, during an ongoing recall of human or pet food products:

(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 processes used to produce the food for sale in the jurisdiction of the State food safety programs is safe for human consumption.

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

(d) STATE COOPERATION.—The Secretary may, under an agreement entered into with a State agency under this subsection may provide for training of State employees.

SA 1058. Mr. BIDEN submitted an amendment to the bill S. 1062, as amended by Mr. BIDEN, Mr. WHITEHOUSE and Mr. KOHL, by inserting, after section 506, the following:

SEC. 5. ADULTERATED FOOD REGISTRY.

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

(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—

(1) establish and ensure that the surveillance system used by the Secretary to identify adulteration of the pet food supply and outbreaks of illness associated with pet food is in place;

(2) conduct investigations conducted to test solely the safety of an unapproved or unlicensed device; and

(3) establish and maintain a registry of safety data for a clinical trial that is not an expanded registry.

SEC. 6. PART III—FOOD SAFETY REGULATIONS.
(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 a national 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 with respect to which the article of food was transferred.

(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.

(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 21, Code of Federal Regulations (or any successor regulations); or

(B) meets the threshold established in section 309(h).

(b) Establishment.—

(1) In General.—Not later than 180 days after 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) any 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) 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 a particular producer, manufacturer, shipper, or grower of such food, to the extent that elements in subparagraph (A) or (B) of paragraph (1) are associated with the particular food, producer, manufacturer, shipper, or grower.

(d) Submission by a Consumer or Other Individual.—A consumer or other individual may submit a report to the Food and Drug Administration an electronic portal containing 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 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, or otherwise handled is a reportable adulterated food, except that if such adulteration was initiated with such responsible party or importer being the initial responsible party, no report shall be submitted to the Food and Drug Administration an electronic portal containing data elements described in subsection (e) if such article of food was transferred.

(4) Subsection (e) shall also be made available during an inspection under section 801(m).

(f) Data Elements in the Registry.—

(1) It is vital for Congress to provide the Food and Drug Administration for possible inclusion in the Adulterated Food Registry after evaluation of this report by—

(A) 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; and

(B) 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.

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

SEC. 406. 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 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 inspections 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, the Secretary of Health and Human Services shall submit to Congress a report under the Dietary Supplement Health and Education Act; or

(2) the adverse event reporting system for dietary supplements created under the Dietary Supplement Health and Education Act.

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 Health and Education Act or the Food and Drug Administration Importer Program 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. 01. 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 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 study; 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. 02. 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 under the provisions of the Food, Drug, and Cosmetic Act, 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 adverse event reporting system for drugs under chapter VII of 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. 03. SENATE REPORT FOR FURTHER STUDY TO REAUTHORIZE BIOLOGIC SUBSIDIES.

(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 spent countless hours and choice to ensure more affordable prescription drug options.

(3) Well-constructed policies that balance the needs of improved affordability with broad bipartisan support.

(b) SENATE OF THE BILL.—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. 04. 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; and

(2) based on an analysis of previous samples, an identification of products or categories (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) and the determination of 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”;

(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 the end of each calendar year and be 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 consolidate data on pesticide residues in food 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 I.—FOOD SAFETY

SEC. 01. 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 who 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 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 penalty, including a regulation promulgated or order issued by the Secretary to the extent necessary, pursuant to the provisions of this paragraph.

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

(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.

(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 subsection (B) of this section.

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

(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.

(3) EXCEPTION.—No person shall be subject to the requirements 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;

(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.

(4) JUDICIAL REVIEW.—

(1) IN GENERAL.—An order assessing a civil penalty under section (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 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 entry of the final order, 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.

(5) 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 final in the court described in subsection (d), the Secretary may—

(A) require the person to pay the amount assessed.

(B) commence an action in the court, to be held as soon as practicable, to recover any 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.

(6) PENALTIES PAID INTO ACCOUNT.

(1) shall deposit penalties collected under this section in the 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 that otherwise falls under the jurisdiction of State food safety law, to determine whether that establishment is meeting the standards that are necessary, may—

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

(ii) to State and local public health officials.

(c) NON DISTRIBUTION 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 made available to the Secretary shall make available to the Secretary—

(1) copies of all documents pertaining to the food; and

(2) persons to whom the food was 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, 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—

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

(ii) specify a time in which the order shall occur;

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

(iv) provide notice of the recall to consumers to which the food was, or may have been, distributed.

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

(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.

S 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, and, after obtaining the consent of the Secretary, destroy, or order the destruction of, the food; and

(2) in the discretion of the Secretary, take any other action that is necessary, may—

(i) file a suit in equity for temporary restraining order or injunction; and

(ii) take such other action as the Secretary determines to be necessary.

(b) NON DISTRIBUTION 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.

(c) NON DISTRIBUTION 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 made available to the Secretary shall make available to the Secretary—

(1) copies of all documents pertaining to the food; and

(2) persons to whom the food was 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, 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—

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

(ii) specify a time in which the order shall occur;

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

(iv) provide notice of the recall to consumers to which the food was, or may have been, distributed.

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

(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.

SA 1028. Mr. ROGUEFELLER (for himself, Mr. SCHUMER, Mr. LEAHY, Mr.
SA 1092. 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:

"Such subsection (j)(5)(B)(iv); or"

"(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."

"(F) COMPENSATION.—Members of the Board may not receive compensation for service on the Board. Such expenses 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."

"(G) INCORPORATION.—The ex officio members of the Board shall serve as incorporators and act to incorporate the Foundation."

"(J) NONPROFIT STATUS.—The Foundation shall be considered to be a corporation under section 501(c)(3) of the Internal Revenue Code of 1986, shall be subject to the provisions of such section, and shall be considered a nonprofit organization for purposes of section 201(j) of title 35, United States Code."

"(L) 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."

"(M) 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 agency in carrying out this section;"

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

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

"(G) 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;"

"(H) modify or consent to the modification of any contract, lease, or cooperative agreement to which it is a party or in which it has an interest under this subchapter;"

"(I) take such action as may be necessary to obtain for the use of the Foundation the 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:

"Such subsection (j)(5)(B)(iv); or"

"(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."

"(F) COMPENSATION.—Members of the Board may not receive compensation for service on the Board. Such expenses 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."

"(G) INCORPORATION.—The ex officio members of the Board shall serve as incorporators and act to incorporate the Foundation."

"(J) NONPROFIT STATUS.—The Foundation shall be considered to be a corporation under section 501(c)(3) of the Internal Revenue Code of 1986, shall be subject to the provisions of such section, and shall be considered a nonprofit organization for purposes of section 201(j) of title 35, United States Code."

"(L) 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."

"(M) 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 agency in carrying out this section;"

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

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

"(G) 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;"

"(H) modify or consent to the modification of any contract, lease, or cooperative agreement to which it is a party or in which it has an interest under this subchapter;"

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