following concurrent resolution, which was referred to the Committee on Health, Education, Labor, and Pensions:

S. CON. RES. 33

Whereas school music programs enhance intellectual development and enrich the academic environment for students of all ages:

Whereas students who participate in school music programs are less likely to be involved with drugs, gangs, or alcohol, and have better attendance in class;

Whereas the skills gained through sequential music instruction, including discipline and the ability to analyze, solve problems, communicate, and work cooperatively, are vital for success in the 21st century workplace;

Whereas the majority of students attending public schools in inner city neighborhoods have virtually no access to music education, which places them at a disadvantage compared to their peers in other communities;

Whereas the arts are a core academic subject, and music is an essential element of the curriculum and should be available to every student of a well-rounded academic curriculum; and

Whereas representatives (Mr. Coburn, Mr. Martinez, Mr. Kennedy, Mr. Hatch, Mr. Harkin, Mr. Burr, and Mr. Coburn) submitted an amendment intended to be proposed by him to the bill S. 1082, supra; which was ordered to lie on the table;

SA 1054. 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 1055. Mr. BURTRUST submitted an amendment intended to be proposed by him to the bill S. 1082, supra; which was ordered to lie on the table.

SA 1056. Mr. REED (for himself and Mr. ISAKSON) submitted an amendment intended to be proposed by him to the bill S. 1082, supra; which was ordered to lie on the table.

SA 1057. Mr. GREGG submitted an amendment intended to be proposed by him to the bill S. 1082, supra; which was ordered to lie on the table.

SA 1058. Mr. DEMINT (for himself, Mr. Coburn, and Mr. Martinez) submitted an amendment intended to be proposed by him to the bill S. 1082, supra; which was ordered to lie on the table.

SA 1059. Mr. SESSIONS (for himself, Mrs. Lincoln, Mr. Pryor, Mr. Lott, and Mr. Shelby) submitted an amendment intended to be proposed by him to the bill S. 1082, supra; which was ordered to lie on the table.

SA 1060. Mr. HATCH (for himself and Mr. Kennedy) submitted an amendment intended to be proposed by him to the bill S. 1082, supra; which was ordered to lie on the table.

SA 1061. Mr. STEVENS (for himself and Ms. Murkowski) submitted an amendment intended to be proposed by him to the bill S. 1082, supra; which was ordered to lie on the table.

SA 1062. Mr. CORKER submitted an amendment intended to be proposed by him to the bill S. 1082, supra; which was ordered to lie on the table.

SA 1063. Mr. ENZI (for himself, Mr. Kennedy, Mr. Dodd, and Mrs. Clinton) submitted an amendment intended to be proposed by him to the bill S. 1082, supra; which was ordered to lie on the table.
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) Expiration of the Petition—

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

"(B) Supplemental Information.—The Secretary shall not accept for review any supplemental information or comments on a petition for review without submitting such information or comments does so in written form and that the subject document is signed and contains the following verification of that, to my best knowledge and belief: (a) I have not intentionally delayed submission of this document or its contents; and (b) the information upon which I have based the action requested herein first became known to me on or about________. I received or expect to receive payments, including cash and other forms of consideration, from the following persons or organizations to submit this information or its contents:________. I verify under penalty of perjury that the foregoing is true and correct., with the date of the submission of such document and the signature of the petitioner inserted in the first and second blank space, respectively.

"(4) Annual Report on Delays in Approvals per Petition.—The Secretary shall annually submit to the Congress a report that specifies—

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

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

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

"(D) the number of petitions that were filed under this subsection that were denied by the Secretary under paragraph (1)(A)(i) to require delaying an application under subsection (b)(2) or (j) and that seeks only to have the Secretary take or refrain from taking any form of action with respect to that application.

"(6) Report by Inspector General.—The Office of Inspector General of the Department of Health and Human Services shall issue a report not later than 2 years after the date of enactment of this subsection evaluating the effectiveness of the Food and Drug Administration with the requirement that the consideration by the Secretary of petitions that do not raise public health concerns remain separate and apart from the review and approval of an application submitted under subsection (b)(2) or (j).

"(7) Definition.—For purposes of this subsection, the term ‘petition’ includes any request for an action described in paragraph (1)(A)(i) to the Secretary, without regard to whether the request is characterized as a petition.’’.

SA 1047. Mr. ROBERTS (for himself, Mr. HARKIN, Mr. BURR, and Mr. COBURN) submitted 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 subparagraphs (E) and (F) of section 505(o)(5) of the Federal Food, Drug, and Cosmetic Act, as added by this Act, and insert the following:

“(E) Specific disclosures.—

“(1) Serious risk; safety protocol.—If the Secretary determines that advertisements lacking a specific disclosure about a serious risk listed in the labeling of a drug or about a protocol to ensure safe use described in the labeling of the drug would be false or misleading, the risk evaluation and mitigation strategy for the drug may require that the applicant include in advertisements of the drug such disclosure.

“(ii) Date of approval.—If the Secretary determines that advertisements lacking a specific disclosure of the date a drug was approved and disclosure of a serious risk would be false or misleading, the risk evaluation and mitigation strategy for the drug may require that the applicant include in advertisements of the drug such disclosure.

“(3) Verifications.—

“(A) Whether the applicant submitted the advertisement or a similar advertisement for review under section 736A.

“(B) Whether the applicant submitted the advertisement for prereview if required under section 505(o)(5)(D).

“(C) Whether, after submission of the advertisement as described in subparagraph (A) or (B), the applicant disseminated the advertisement before the end of the 45-day comment period.

“(D) Whether the applicant failed to incorporate any comments made by the Secretary with regard to the advertisement or a similar advertisement into the advertisement prior to its dissemination.

“(E) Whether the applicant ceased distribution of the advertisement upon receipt of the written notice referred to in paragraph (2) for such advertisement.

“(F) Whether the applicant had the advertisement reviewed by qualified medical, regulatory, and legal reviewers prior to its dissemination.

“(G) Whether the violations were material.

“(H) Whether the applicant who created the advertisement acted in good faith.

“(I) Whether the advertisement prior to the advertisement or a similar advertisement has been assessed a civil penalty under this provision within the previous 1-year period.

“(J) The scope and extent of any voluntary, subsequent remedial action by the applicant.

“(K) Such other matters, as justice may require.

“(4) A Subject to subparagraph (B), no applicant shall be required to pay a civil penalty under paragraph (1) if the applicant submits a voluntary, subsequent remedial action under this paragraph and provides a reasonable time for modification or correction of the advertisement prior to seeking any civil penalty under paragraph (1).

“(6) The Secretary may compromise, modify, remit, with or without conditions, any civil penalty which may be assessed under section 505(o)(5) who disseminates a direct-to-consumer advertisement for a prescription drug that is false or misleading and the violation of section 502(n) shall be liable to the United States for a civil penalty in an amount not to exceed $150,000 for the first violation of such section and not to exceed $300,000 for each subsequent violation committed after the applicant has been penalized under this paragraph any time in the preceding 3-year period. For the purposes of this paragraph, repeated dissemination of the same or similar advertisement prior to the receipt of the written notice referred to in paragraph (2) for such advertisements shall be considered as 1 violation.

“(1) A civil penalty under paragraph (1) shall be assessed by the Secretary by an order made on the record after providing written notice to the applicant to be assessed a civil penalty and an opportunity for a hearing in accordance with this paragraph and section 504 of title 5, United States Code. If upon receipt of the written notice, the applicant requests a hearing, and requests a hearing, then in the course of any investigation related to such hearing, the Secretary may issue subpoenas requiring the attendance and testimony of witnesses and the production of evidence that relates to the matter under investigation, including information pertaining to the factors described in paragraph (3).

“(3) Until the request of the applicant to be assessed a civil penalty, the Secretary, in determining the amount of a civil penalty, shall be guided by the factors, circumstances, extent, and gravity of the violation or violations, including the following factors:________. I received or expect to receive payments, including cash and other forms of consideration, from the following persons or organizations to file this petition:________. I verify under penalty of perjury that the foregoing is true and correct., with the date of the filing of such petition and the signature of the petitioner inserted in the first and second blank space, respectively.
paragraph (1). The amount of such penalty, when finally determined, or the amount charged upon in compromise, may be deducted from any sums owned by the United States to which the person charged may be subject.

"(6) Any applicant who requested, in accordance with paragraph (2), a hearing with respect to the assessment of a civil penalty and who is aggrieved by an order assessing a civil penalty, may file a petition for de novo judicial review of such order with the United States Court of Appeals for the District of Columbia Circuit or for any other circuit in which such applicant resides or transacts business. Such a petition may only be filed within 30 days after the date of the order making such assessment was issued.

"(7) Any applicant fails to pay an assessment of a civil penalty—

"(A) after the order making the assessment becomes final, and if such applicant does not file a petition for judicial review of the order in accordance with paragraph (6); or

"(B) after a court in an action brought under paragraph (1) has entered a final judgment in favor of the Secretary, the Attorney General shall recover the amount of such assessment from the United States Court of Federal Claims or any other court in the appropriate district court of the United States. In such an action, the validity, amount, and appropriateness of such penalty shall not be subject to review.

"(b) DIRECT-TO-CONSUMER ADVERTISEMENT.—

"(1) IN GENERAL.—Section 502(n) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 352(n)) is amended by inserting after the first sentence the following: "In the case of an advertisement for a prescription drug presented to consumers in television or radio format that states the name of the drug and its conditions of use, the major contraindications, and effectiveness referred to in the previous sentence shall be stated in a clear and conspicuous (neutral) manner.

"(2) REGULATIONS TO DETERMINE NEUTRAL MANNER.—The Secretary of Health and Human Services shall by regulation establish standards for determining whether a major statement, relating to side effects, contraindications, and effectiveness referred to in the previous sentence shall be stated in a clear and conspicuous (neutral) manner.

"SEC. 1A. MARKETING OF CERTAIN CRUSTACEANS.

"(a) IN GENERAL.—Notwithstanding any other provision of law, for purposes of the Federal Food, Drug, and Cosmetic Act to reauthorize and amend the prescription drug user fee provisions, and for other purposes; which was ordered to lie on the table; as follows:

"Beginning on page 104, strike line 23 and all that follows through line 14 on page 105 and insert the following:

"(1) the amount equal to one-fifth of the excess amount in item (bb), provided that—

"(aa) the amount of the total appropriation for the Food and Drug Administration for such fiscal year (excluding the amount of fees appropriated for such fiscal year) exceeds the amount of the total appropriation for the Food and Drug Administration for fiscal year 2007 (excluding the amount of fees appropriated for such fiscal year), adjusted as provided under subsection (c)(1); and

"(bb) the amount of the total appropriations for the process of human drug review at the Food and Drug Administration for such fiscal year (excluding the amount of fees appropriated for such fiscal year) exceeds the amount of appropriations for the process of human drug review at the Food and Drug Administration for fiscal year 2007 (excluding fees appropriated for such fiscal year), adjusted as provided under subsection (c)(1).

"In making the adjustment under subclause (B) for the fiscal year 2008 through fiscal year 2012, section (c)(1) shall be applied by substituting '2007' for '2008'.

"SEC. 1B. COLOR CERTIFICATION REPORTS.

"(a) IN GENERAL.—The Secretary shall submit to Congress a performance report for such fiscal year which contains a number of batches of color additives approved, the average turn around time for approval, and quantifiable goals for improving laboratory efficiencies; and

"(b) DIRECT-TO-CONSUMER ADVERTISEMENT.—

"(1) 90 days after the close of a fiscal year in which color certification fees are collected, the Secretary shall submit to Congress a performance report for such fiscal year on the number of batches of color additives approved, the average turn around time for approval, and quantifiable goals for improving laboratory efficiencies; and

"(2) 120 days after the close of a fiscal year in which color certification fees are collected, the Secretary shall submit to Congress a performance report for such fiscal year which includes all fees and expenses of the color certification program, the balance remaining in the fund at the end of the fiscal year, and anticipated costs during the next fiscal year for equipment needs and laboratory improvements of such program.

"SEC. 1C. CONSULTATION REGARDING GENETICALLY ENGINEERED SEAFOOD PRODUCTS.

"The Commission of Food and Drugs shall consult with the Assistant Administrator of the National Marine Fisheries Service of the National Oceanic and Atmospheric Administration and the Administrator of the Food and Drug Administration before granting final approval to use or produce a genetically engineered seafood product.

"SEC. 1D. DOCUMENTATION OF COMMITTEE ACTION.

"The committee established under this section shall maintain a record of its activities in a public filing system available online at the committee website.
paraphrase shall document for each function under paragraphs (2) and (3), which members of the committee participated in such function.

On page 234, line 1, strike "determine" and insert "make a recommendation to the Secretary".

On page 235, line 2, strike "and".

On page 235, line 6, strike ": " and insert ": and".

On page 235, between lines 6 and 7, insert the following:

"(H) the number of times the committee established under paragraph (1) made a recommendation to the Secretary under paragraph (4); (I) the number of times the Secretary did not follow such a recommendation to accept reports under subsection (d)(3), and the number of times the Secretary did not follow such a recommendation to reject such reports under section (d)(3).

"(5) COMMITTEE.—The committee established under paragraph (1) is the committee established under section 505B(f)(1)."

On page 260, lines 17 through 19, strike "of a letter, or a written request under section 505A that was declined by the sponsor or holder" and insert "of a written request under section 505A that was declined by the sponsor or holder, or a letter referencing such a written request."

On page 261, line 3, strike "appropriate" and insert "appropriate, for the labeled indication, in indigent patients."

On page 263, line 14, insert ", such as expertise in child and adolescent psychiatry," after "expertise."

On page 265, between lines 19 and 20, insert the following and redesignate the remaining paragraphs accordingly:

"(2) ACTION BY THE COMMITTEE.—The committee established under paragraph (1) may perform a function under this section using appropriate members of the committee under paragraph (1) and need not convene all members of the committee under paragraph (1) in order to perform a function under this section.

(3) DOCUMENTATION OF COMMITTEE ACTION.—For each drug or biological product, the committee established under this paragraph shall document for each function under paragraph (4) or (5), which members of the committee participated in such function.

On page 265, between lines 18 and 19, insert the following:

"(7) COMMITTEE.—The committee established under paragraph (1) is the committee established under section 505A(f)(1)."

On page 269, line 16, strike "SURVEILLANCE" and insert "SURVEILLANCE and INSERT "MARKETPLACE SURVEILLANCE".

On page 269, line 17, strike "SURVEILLANCE" and insert "SURVEILLANCE and INSERT "MARKETPLACE SURVEILLANCE".

On page 269, strike lines 9 through 12 and insert the following:

"(iii) that is intended to be—

(I) implanted in the human body for more than 1 year; or

(II) a life-sustaining or life-supporting device used outside a device user facility.

On page 271, strike "of an" and all that follows through "section 510(k) only for" on line 19, and insert "or clearance of".

SA 1054 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 require the prescription drug fee provisions, and for other purposes; which was ordered to lie on the table; as follows:

At the appropriate place, insert the following:

SEC. 1. PUBLICATION OF ANNUAL REPORTS.

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

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

(2) based on an analysis of previous samples, an identification of products or countries (for imports) that require special attention and additional study based on a comparison with equivalent products manufactured, distributed, or sold in the U.S. (including data on subgroups for which additional studies), including in the initial report (and subsequent reports as determined necessary) the results and analysis of the Gingter Digestive Supplements Special Survey described on page 13 of the report entitled "Food and Drug Administration Pesticide Program Residue Monitoring 2003."

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

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

(b) INITIAL REPORTS.—Annual reports under subsection (a) for fiscal years 2004 through 2006 may be combined into a single report, by not later than June 1, 2008, for purposes of publication under subsection (a). Thereafter such reports shall be compiled into a report for the last fiscal year of the last completed fiscal 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, the Department of Commerce, and the head of the Agricultural Marketing Service shall enter into a memorandum of understanding to permit inclusion of data in the reports under subsection (a) relating to testing conducted by the Food Safety and Inspection Service and the Agricultural Marketing Service on meat, poultry, eggs, and certain raw agricultural products, respectively.

SA 1055 Mr. LEVIN submitted an amendment intended to be proposed by him to the bill S. 1082, to amend the Federal Food, Drug, and Cosmetic Act to require the prescription drug fee provisions, and for other purposes; which was ordered to lie on the table; as follows:

At the appropriate place, insert the following:

SEC. 1. SAFETY OF FOOD ADDITIVES.

Not later than 90 days after the date of enactment of this Act, the Food and Drug Administration shall issue a report on the question of whether substances used to preserve the appearance of 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. 2. INTERNET PHARMACIES.

This title may be cited as the "Safe Internet Pharmacy Act of 2007."

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

"SEC. 511. INTERNET PHARMACIES.

"(a) DEFINITIONS.—In this section:

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

"(2) DESIGNATED PAYMENT SYSTEM.—

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

(2) the term "unlawful Internet pharmacy request" means the request, or transmission of the 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 in section 103 of the Truth in Lending Act (15 U.S.C. 1693).

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

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

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

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

(1) has the meaning given the term in section 5330(d) of title 31, United States Code.

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

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

(F) 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.

(G) LICENSING REQUIREMENTS.—

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

(ii) The names of all States in which the Internet pharmacy is located, verification that the Internet pharmacy is in compliance with applicable Federal and State laws regarding—

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

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

(ii) In the case of an Internet pharmacy whose place of business is located outside the United States, verification that—

(A) 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; and

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

(2) CONDITIONS FOR LICENSING.—

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

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

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

(III) the name of the Internet pharmacy and the pharmacist or group of pharmacists in the United States or territories where it engages in business;

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

(1) An Internet pharmacy shall identify to the extent necessary to identify that the shipment is from a licensed Internet pharmacy, which may include anticounterfeiting or track-and-trace technologies;

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

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

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

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

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

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

(ii) The names of all States in which the Internet pharmacy is located, verification that the Internet pharmacy is in compliance with applicable Federal and State laws regarding—

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

(B) the manufacturing and distribution of substances, including with respect to mailing or shipping controlled substances to consumers.

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

(II) the name, street address, city, ZIP Code or comparable mail code, State (or comparable entity), country, and telephone number of—

(1) in the case of a pharmacist for purposes of the Internet pharmacy website;

(B) all persons of whom the Internet pharmacy and the pharmacists employed by the Internet pharmacy are licensed or otherwise authorized to dispense prescription drugs.

(ii) If the Internet pharmacy makes referrals to, or solicits on behalf of, a health care practitioner or group of practitioners in the United States or territories where it engages in business;

(II) the name, street address, city, ZIP Code or comparable mail code, State (or comparable entity), country, and telephone number of—

(1) in the case of a pharmacist for purposes of the Internet pharmacy website;

(B) all persons of whom the Internet pharmacy and the pharmacists employed by the Internet pharmacy are licensed or otherwise authorized to dispense prescription drugs.

(3) The Internet pharmacy shall, at the request of the Secretary, and at such time as the Secretary may require, 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.

(4) The agreement by the Internet pharmacy with treating providers, caregivers, and patients;
“(i) Conduct prospective drug use reviews before dispensing medications or medical devices.

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

“(iii) Implement an electronic application filing system that is capable of being used by the Internet pharmacy.

“(iv) In filing an application under subsection (I)(bb), the Internet pharmacy shall provide the Substance Abuse and Mental Health Services Administration with a communication under subclause (I)(bb) that the prescription is inaccurate or expired; or

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

“(c) 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.

“(III) When seeking verification of a prescription drug under subsection (I)(bb), an Internet pharmacy shall provide to the treating provider the following information:

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

“(bb) Identification of the prescription drug;

“(cc) The quantity of the prescription drug to be dispensed;

“(dd) The date on which the individual presented the prescription to the Internet pharmacy;

“(ee) The date and time of the verification request;

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

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

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

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

“(II) When seeking verification of a prescription under paragraph (2), the treating provider shall provide to the treating provider the following information:

“(aa) The prescription is accurate;

“(bb) The prescription is not a refilling of a previously dispensed prescription drug.

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

“(aa) The prescription is verified under subclause (I)(bb) only if 1 of the following occurs:

“(bb) The treating provider informs the Internet pharmacy of the prescription by a facsimile telephone number.

“(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 (I)(bb) that the prescription is inaccurate or expired; or

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

“(V) 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.

“(III) When seeking verification of a prescription drug under subsection (I)(bb), an Internet pharmacy shall provide to the treating provider of the individual by mail (including a private carrier), or from the treating provider of the individual by electronic mail, the validity of the prescription shall be confirmed in accordance with all applicable Federal and State laws.

“(a) The treating provider confirms, by electronic methods of submitting to the Secretary a licensing application required under this section, and provide for electronic methods of receiving the information described in subparagraph (C), the Secretary shall ensure that adequate authentication protocols are used to allow identification of the Internet pharmacy.

“(bb) Identification of the prescription drug;

“(cc) The quantity of the prescription drug to be dispensed;”

“(bb) Identification of the prescription drug;

“(cc) The quantity of the prescription drug to be dispensed;”

“(dd) The date on which the individual presented the prescription to the Internet pharmacy;

“(ee) The date and time of the verification request;

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

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

“(aa) The prescription is accurate;

“(bb) The prescription is not a refilling of a previously dispensed prescription drug.

“(IV) 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.

“(II) Document in the reporting mechanism the response of the Internet pharmacy to the report, including a complete licensing application from an Internet pharmacy under paragraph (2), the Secretary shall:

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

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

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

“(B) Electronic Filing.

“(i) In General. —For the purpose of reducing paperwork and reporting burdens, the Secretary shall require the use of electronic methods of submitting to the Secretary a licensing application required under this section, and provide for electronic methods of receiving the information described in subparagraph (C), the Secretary shall ensure that adequate authentication protocols are used to allow identification of the Internet pharmacy.

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

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

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

“(B) IN GENERAL. —The Secretary shall establish a licensing application fee to be paid by all Internet pharmacies licensed under this section.

“(ii) Collection of Renewal Fees. —After the licensing application fee is paid for the fiscal year in which the Internet pharmacy submits a licensing application, the Secretary shall establish a yearly renewal fee to be paid by all Internet pharmacies licensed under this section.

“(I) COLLECTION. —A licensing fee payable for the fiscal year in which the Internet pharmacy submits a licensing application, as established under subparagraph (C), shall be payable upon receipt of the Secretary of such licensing application.

“(ii) Collection of Renewal Fees. —After the licensing application fee is paid for the fiscal year in which the Internet pharmacy submits a licensing application, the Secretary shall establish a yearly renewal fee to be paid by all Internet pharmacies licensed under this section.

“(B) IN GENERAL. —The license fee payable for the fiscal year in which the Internet pharmacy submits a licensing application, as established under subparagraph (C), shall be payable upon receipt of the Secretary of such licensing application.

“(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 133 percent of the anticipated costs to the Secretary of enforcing the requirements of this section in the subsequent fiscal year.

“(D) ANNUAL FEE DETERMINATION. —

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

“(F) FAILURE TO PAY FEE. —

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

“(ii) FAILURE TO PAY. —If an Internet pharmacy subject to a fee under this section fails to pay the fee by the date specified under clause (i), the Secretary shall not permit the Internet pharmacy to dispense a prescription drug.

“(G) Reports. —Beginning with fiscal year 2008, not later than 60 days after the end of each fiscal year during which licensing application fees are collected under this section, the Secretary shall submit to the Committee on Health, Education, Labor, and Pensions of the Senate and the Committee on Energy and Commerce of the House of Representatives a report that describes:

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

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

“(G) SUSPENSION. —

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

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

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

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

“(H) TERMINATION OF LICENSE. —The Secretary may terminate a license issued under this section to an Internet pharmacy and an opportunity for a hearing, and if the Secretary determines that the Internet pharmacy has demonstrated a pattern of non-compliance with this section;

“(I) Termination of License. —The Secretary may terminate a license issued under this section to an Internet pharmacy and an opportunity for a hearing, and if the Secretary determines that the Internet pharmacy has demonstrated a pattern of non-compliance with this section;

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evaluation to determine whether the Internet pharmacy is in compliance with this section.

"(B) Evaluation of Internet pharmacy.—The Secretary may award a grant under this subsection for the operation of the licensing program.

"(C) Performance review.—The Secretary shall annually review performance under a contract under subparagraph (A).

"(D) Payment of Interactive Computer Services or Advertising Services.—No provider of interactive computer services (as defined in section 512 of the Communications Act of 1934 (47 U.S.C. 151)) or an advertising service provider shall be liable under this section on account of another person's selling of a prescription drug, so long as the provider of the interactive computer service or the advertising service provider does not own or exercise corporate control over such person.

"(E) Policies and Procedures Required To Prevent Payments for Unlawful Internet Pharmacy Transactions.—

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

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

"(B) in the case of a designated payment system of which the person described in subsection (a)(2)(B) is an operator does not own or exercise corporate control over such person.

"(2) Relief under paragraph (1)—

"(A) In general.—This subsection shall be enforced by—


"(ii) the Secretary, under this section, shall not be liable under, any Federal, State, or other law for engaging in any such transaction.

"(B) Factors to be considered.—In considering any enforcement action under this subsection against a payment system or person subject to a regulation under section (e), 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 complying with regulations prescribed under subsection (a)(2).

"(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 substantive deviation from normal business practice.

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

"(C) Reports Regarding Internet—Related State Laws on Dispensing of Drugs.—The Secretary shall, pursuant to the submission of an application meeting criteria prescribed by the Secretary, make an award of a grant or contract to an entity with experience in developing and maintaining systems for the purpose of—

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

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

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

"(D) Penalty.—

"(1) Definition.—A designated payment system or person subject to a regulation or an order issued under subsection (e) that engages in activities described in paragraph (1) shall be subject to a civil penalty of not more than $10,000 per day for each violation.

"(2) No liability for blocking or refusing to honor restricted transactions.—

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

"(i) prevents or otherwise refuses to honor restricted transactions, in an effort to comply with a requirement of this subsection or to otherwise comply with this section, shall not be liable to any party for such action; and

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

"(B) Compliance with this subsection.—A person subject to a regulation under subsection (e) shall be considered to be reasonably designed to prevent the introduction of a restricted transaction into a designated payment system, other than a designated payment system described in subsection (a)(2)(B);

"(C) Contract for operation of program.—

"(A) In general.—The Secretary may award a grant under this subsection for the operation of the licensing program.

"(B) Term.—The duration of a contract under subparagraph (A) shall not exceed 5 years and may be renewed.

"(C) Performance review.—The Secretary shall annually review performance under a contract under subparagraph (A).

"(D) Payment of Interactive Computer Services or Advertising Services.—No provider of interactive computer services (as defined in section 290B of the Communications Act of 1934 (47 U.S.C. 151)) or an advertising service provider shall be liable under this section on account of another person's selling of a prescription drug, so long as the provider of the interactive computer service or the advertising service provider does not own or exercise corporate control over such person.

"(E) Policies and Procedures Required To Prevent Payments for Unlawful Internet Pharmacy Transactions.—

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

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

"(B) in the case of a designated payment system of which the person described in subsection (a)(2)(B) is an operator does not own or exercise corporate control over such person.

"(2) Relief under paragraph (1)—

"(A) In general.—This subsection shall be enforced by—


"(ii) the Secretary, under this section, shall not be liable under, any Federal, State, or other law for engaging in any such transaction.

"(B) Factors to be considered.—In considering any enforcement action under this subsection against a payment system or person subject to a regulation under section (e), 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 complying with regulations prescribed under subsection (a)(2).

"(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 substantive deviation from normal business practice.

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

"(C) Reports Regarding Internet—Related State Laws on Dispensing of Drugs.—The Secretary shall, pursuant to the submission of an application meeting criteria prescribed by the Secretary, make an award of a grant or contract to an entity with experience in developing and maintaining systems for the purpose of—

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

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

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

"(D) Penalty.—

"(1) Definition.—A designated payment system or person subject to a regulation or an order issued under subsection (e) that engages in activities described in paragraph (1) shall be subject to a civil penalty of not more than $10,000 per day for each violation.

"(2) No liability for blocking or refusing to honor restricted transactions.—

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

"(i) prevents or otherwise refuses to honor restricted transactions, in an effort to comply with a requirement of this subsection or to otherwise comply with this section, shall not be liable to any party for such action; and

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

"(B) Compliance with this subsection.—A person subject to a regulation under subsection (e) shall be considered to be reasonably designed to prevent the introduction of a restricted transaction into a designated payment system, or a person described in subsection (a)(2)(B);
Trade Representative to deal with violations of intellectual property rights, including—
(A) bilateral engagement with United States trading partners;
(B) transatlantic annual “Special 301” review and reviews of compliance with the intellectual property requirements of countries with respect to which the United States grants reciprocal trade concessions;
(C) negotiation of intellectual property provisions as part of bilateral and regional trade agreements; and
(D) multilateral engagement through the World Trade Organization (WTO); and
(2) the United States Trade Representative should develop and implement a strategic plan to address countries that infringe upon American pharmaceutical intellectual property rights and the problem of countries that engage in price manipulation.

SEC. 1059. MR. SESSIONS (for himself, Mrs. Lincoln, Mr. Cochran, Mr. Pryor, Mr. Lott, and Mr. Shelby) 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. __. SENSE OF THE SENATE REGARDING CERTAIN PATENT INFRINGEMENTS.

(a) FINDINGS.—The Senate makes the following findings:

(1) The value of American innovation in developing life-saving prescription drugs saves millions of lives around the world each year.
(2) The protection of intellectual property is vital to the continued development of new and life-saving drugs and future growth of the United States economy.
(3) In order to maintain the global competitiveness of the United States, the United States Trade Representative’s Office of Intellectual Property and Innovation develops and implements trade policy in support of vital American innovations, including innovation in the pharmaceutical and medical technology industries.
(4) The United States Trade Representative also provides trade policy leadership and expertise across the full range of interagency initiatives to enhance protection and enforcement of intellectual property rights.
(5) When other countries do not respect the intellectual property of American drug companies, it is not an effective way to diminish incentives to develop new life-saving medications and the American economy is unfairly harmed.
(6) Strong intellectual property protection, including patent, copyright, trademark, and data protection plays an integral role in fostering economic growth and development and ensuring patient access to the most effective medicines around the world.

(7) Certain countries have engaged in unfair price manipulation and abuse of compulsory licensing, resulting in a loss of revenues for the United States Treasury.

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

(1) the United States Trade Representative should use all the tools at the disposal of

for the purpose of identifying the processing plant of origin of such products.

d) PARTNERSHIPS WITH STATES.—Upon the request by any State, the Secretary may enter into partnership agreements, as soon as practicable after the request is made, to implement inspection programs regarding the inspection of aquaculture and seafood.

e) AUTHORIZATION OF APPROPRIATIONS.—

There are authorized to be appropriated such sums as may be necessary to carry out this section.

SEC. 1060. MR. HATCH (for himself and Mr. Kennedy) 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:

FOOD AND DRUG ADMINISTRATION FUNDING SUBMISSION.

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

SEC. 714. FOOD AND DRUG ADMINISTRATION FUNDING SUBMISSION.

“"For each of fiscal years 2009 through 2013, the Commissioner of Food and Drugs shall prepare and submit, directly to the President for review and transmittal to Congress, an annual Food and Drug Administration funding submission estimate (including the number and type of personnel needs for the Food and Drug Administration), after reasonable opportunity for comment (but without change) by the Secretary.”

NOTICE OF HEARING

SUBCOMMITTEE ON PUBLIC LANDS AND FORESTS

Mr. Bingaman. Mr. President, I would like to announce for the information of the Senate and the public that a hearing has been scheduled for the Subcommittee on Public Lands and Forests of the Committee on Energy and Natural Resources.

The hearing will be held on Wednesday, May 30, at 12 p.m. in the Medford City Council Chambers at 411 West 8th Street in Medford, Oregon.

The purpose of this hearing is to receive testimony on the impacts of the Chinese hardwood plywood trade on the National Forest System and other public lands, and the communities that depend on them.

Because of the limited time available for the hearing, witnesses may testify by invitation only. However, those wishing to submit written testimony for the hearing record should send it to the Committee on Energy and Natural Resources, United States Senate, Washington, D.C. 20510-6150, or by e-mail to Rachel.Pasternack@energy.senate.gov.

For further information, please contact Scott Miller at (202) 224-5488 or Rachel Pasternack at (202) 224-0883.

UNANIMOUS-CONSENT AGREEMENT—EXECUTIVE CALENDAR

Mr. Brown. Mr. President, I ask unanimous consent that at 11:50 tomorrow, the Senate proceed to execute