Whereas, since August 5, 2011, Ms. Tymoshenko has languished in a prison cell in Ukraine with limited outside contact and access to needed medical treatment;

Whereas the denial of proper medical assistance has left Ms. Tymoshenko in a failing state of health;

Whereas international calls for Ms. Tymoshenko's release, access to outside visitors, and adequate medical treatment have been ignored even as her health continues to deteriorate;

Whereas, on April 28, 2012, major international news organizations, including the British Broadcast Corporation and Reuters, reported on and produced photos of bruises received by Ms. Tymoshenko during an apparent beating by prison guards on April 20, 2012;

Whereas, in response to her inhumane treatment, Ms. Tymoshenko began a hunger strike on April 20, 2012;

Whereas, amid international outrage, the European Union has delayed indefinitely the signing of a free trade agreement with Ukraine, and the member countries of the Organization for Security and Co-operation in Europe currently are deliberating whether to allow Ukraine to assume the chairmanship of the organization, which has been scheduled for 2013; and

Whereas, under international pressure, Ms. Tymoshenko was moved to a hospital in Kharkiv on May 9, 2012, prompting her to end her hunger strike: Now, therefore, be it

Resolved, That the Senate—

(1) condemns the administration of President Viktor Yanukovych for the politically motivated imprisonment of former Prime Minister Yulia Tymoshenko;

(2) calls on the Yanukovych administration to release Ms. Tymoshenko immediately for medical reasons;

(3) urges the Organization for Security and Cooperation in Europe not to recognize Ukraine's scheduled 2013 chairmanship of the Organization until the release of Ms. Tymoshenko;

(4) urges the Department of State to withdraw the United States Ambassador to the Ukraine and suspend operations at the United States Embassy in Kiev until the release of Ms. Tymoshenko;

(5) calls on the Department of State to institute a visa ban against President Yanukovych, Prosecutor General Viktor Pshonka, and other officials responsible for Ms. Tymoshenko's imprisonment; and

(6) calls on the North Atlantic Treaty Organization to suspend all cooperative agreements with Ukraine and place Ukraine on indefinite probation with regard to its Distinctive Partnership with the Organization until the release of Ms. Tymoshenko.

SENATE RESOLUTION 467—DESIGNATING MAY 18, 2012, AS ''ENDANGERED SPECIES DAY''

Mr. WHITEHOUSE (for himself, Mr. AKAKA, Mr. BLUMENTHAL, Mr. CARDIN, Ms. COLLINS, Mrs. FEINSTEIN, Mr. KERRY, Mr. LAUTENBERG, Mr. LEVIN, Mr. LIEBERMAN, Mrs. MURRAY, Mr. REED of Rhode Island, Mr. SANDERS, Ms. SNOWE, and Mrs. BOXER) submitted the following resolution; which was referred to the Committee on the Judiciary:

S. RES. 467

Whereas nearly 2,000 species worldwide are listed as threatened or endangered, and many more face a heightened risk of extinction;

Whereas the actual and potential benefits that may be derived from many species have not yet been fully discovered and would be permanently lost if not for conservation efforts;

Whereas recovery efforts for species such as the bald eagle, the whooping crane, the gray whale, the American alligator, the peregrine falcon, the Louisiana black bear, and others have resulted in great improvements in the viability of those species;

Whereas saving a species requires a combination of sound research, careful coordination, and intensive management of conservation efforts, along with increased public awareness and education;

Whereas voluntary cooperative conservation programs have proven to be critical to habitat restoration and species recovery; and

Whereas education and increasing public awareness are the first steps in effectively informing the public about endangered species and species restoration efforts: Now, therefore, be it

Resolved, That the Senate—

(1) designates May 18, 2012, as ''Endangered Species Day'';

(2) encourages schools to spend at least 30 minutes on Endangered Species Day teaching and informing students about—

(A) threats to endangered species around the world; and

(B) efforts to restore endangered species, including the essential role of private landowners and private stewardship in the protection and recovery of species;

(3) encourages organizations, businesses, private landowners, and agencies with a shared interest in conserving endangered species to collaborate in developing educational information for use in schools; and

(4) encourages the people of the United States—

(A) to become educated about, and aware of, threats to species, success stories in species recovery, and opportunities to promote species conservation worldwide; and

(B) to observe Endangered Species Day with appropriate ceremonies and activities.

AMENDMENTS SUBMITTED AND PROPOSED

SA 2107. Mr. MCCAIN submitted an amendment intended to be proposed by him to the bill S. 3187, to amend the Federal Food, Drug, and Cosmetic Act to revise and extend the user-fee programs for prescription drugs and medical devices, to establish user-fee programs for generic drugs and biosimilars, and for other purposes; which was ordered to lie on the table.

SA 2108. Ms. MURKOWSKI (for herself, Mr. BEGICH, Mr. MERKLEY, Mr. SANDERS, Mr. LEAHY, and Ms. CANTWELL) submitted an amendment intended to be proposed by her to the bill S. 3187, supra; which was ordered to lie on the table.

SA 2109. Mr. SANDERS submitted an amendment intended to be proposed by him to the bill S. 3187, supra; which was ordered to lie on the table.

SA 2110. Mr. SANDERS submitted an amendment intended to be proposed by him to the bill S. 3187, supra; which was ordered to lie on the table.

SA 2111. Mr. BINGAMAN (for himself, Mr. VITTER, Mr. FRANKEN, Mrs. SHAHEEN, Mr. KOHL, Mr. UDALL of New Mexico, Mr. JOHNSON of South Dakota, Ms. KLOBUCHAR, Mr. MERKLEY, and Mr. SANDERS) submitted an amendment intended to be proposed by him to the bill S. 3187, supra; which was ordered to lie on the table.

SA 2112. Mr. REID (for Mrs. BOXER (for herself and Mrs. FEINSTEIN)) proposed an amendment to the bill H.R. 4849, to direct the Secretary of the Interior to issue commercial use authorizations to commercial stock operators for operations in designated wilderness within the Sequoia and Kings Canyon National Parks, and for other purposes.

TEXT OF AMENDMENTS

SA 2107. Mr. MCCAIN submitted an amendment intended to be proposed by him to the bill S. 3187, to amend the Federal Food, Drug, and Cosmetic Act to revise and extend the user-fee programs for prescription drugs and medical devices, to establish user-fee programs for generic drugs and biosimilars, and for other purposes; which was ordered to lie on the table; as follows:

At the end of title XI, add the following:

SEC. 11___. SAFE AND AFFORDABLE DRUGS FROM CANADA.

Chapter VIII of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 381 et seq.), as amended by this Act, is further amended by adding at the end the following:

''SEC. 810. IMPORTATION BY INDIVIDUALS OF PRESCRIPTION DRUGS FROM CANADA.

''(a) IN GENERAL.—Notwithstanding any other provision of this Act, not later than 180 days after the date of enactment of this section, the Secretary shall promulgate regulations permitting individuals to safely import into the United States a prescription drug (other than a controlled substance, as defined in section 102 of the Controlled Substances Act) that—

''(1) is purchased from an approved Canadian pharmacy;

''(2) is dispensed by a pharmacist licensed to practice pharmacy and dispense prescription drugs in Canada;

''(3) is purchased for personal use by the individual, not for resale, in quantities that do not exceed a 90-day supply;

''(4) is filled using a valid prescription issued by a physician licensed to practice in the United States; and

''(5) has the same active ingredient or ingredients, route of administration, dosage form, and strength as a prescription drug approved by the Secretary under chapter V.

''(b) APPROVED CANADIAN PHARMACY.—

''(1) IN GENERAL.—In this section, an approved Canadian pharmacy is a pharmacy that—

''(A) is located in Canada; and

''(B) that the Secretary certifies—

''(i) is licensed to operate and dispense prescription drugs to individuals in Canada; and

''(ii) meets the criteria under subsection (c).

''(2) PUBLICATION OF APPROVED CANADIAN PHARMACIES.—The Secretary shall publish on the Internet Web site of the Food and Drug Administration a list of approved Canadian pharmacies, including the Internet Web site address of each such approved Canadian pharmacy, from which individuals may purchase prescription drugs in accordance with subsection (a).

''(c) ADDITIONAL CRITERIA.—To be an approved Canadian pharmacy, the Secretary shall certify that the pharmacy—

''(1) has been in existence for a period of at least 5 years preceding the date of enactment of this section and has a purpose other than to participate in the program established under this section;

''(2) operates in accordance with pharmacy standards set forth by the provincial pharmacy rules and regulations enacted in Canada;

''(3) has processes established by the pharmacy, or participates in another established process, to certify that the physical premises

and data reporting procedures and licenses are in compliance with all applicable laws and regulations, and has implemented policies designed to monitor ongoing compliance with such laws and regulations;

''(4) conducts or commits to participate in ongoing and comprehensive quality assurance programs and implements such quality assurance measures, including blind testing, to ensure the veracity and reliability of the findings of the quality assurance program;

''(5) agrees that laboratories approved by the Secretary shall be used to conduct product testing to determine the safety and efficacy of sample pharmaceutical products;

''(6) has established, or will establish or participate in, a process for resolving grievances and will be held accountable for violations of established guidelines and rules;

''(7) does not resell products from online pharmacies located outside Canada to customers in the United States; and

''(8) meets any other criteria established by the Secretary.''.

SA 2108. Ms. MURKOWSKI (for herself, Mr. BEGICH, Mr. MERKLEY, Mr. SANDERS, Mr. LEAHY, and Ms. CANTWELL) submitted an amendment intended to be proposed by her to the bill S. 3187, to amend the Federal Food, Drug, and Cosmetic Act to revise and extend the user-fee programs for prescription drugs and medical devices, to establish user-fee programs for generic drugs and biosimilars, and for other purposes; which was ordered to lie on the table; as follows:

At the end of title XI, add the following:

SEC. 11___. ANALYSES OF APPLICATION FOR APPROVAL OF GENETICALLY-ENGINEERED FISH.

Notwithstanding any other provision of law, approval by the Secretary of Health and Human Services of an application submitted under the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 301 et seq.) for approval of any genetically modified marine or anadromous organism shall not take effect until the date that the Secretary of Commerce, acting through the Under Secretary for Oceans and Atmosphere, approves such application using standards applied by the Under Secretary under the National Environmental Policy Act of 1969 (42 U.S.C. 4321 et seq.), which shall include a Regulatory Impact Review required by Executive Order 12866 (58 Fed. Reg. 51735) and Initial Regulatory Flexibility Analyses required under chapter 6 of title 5, United States Code (commonly referred to as the ''Regulatory Flexibility Act'').

SA 2109. Mr. SANDERS submitted an amendment intended to be proposed by him to the bill S. 3187, to amend the Federal Food, Drug, and Cosmetic Act to revise and extend the user-fee programs for prescription drugs and medical devices, to establish user-fee programs for generic drugs and biosimilars, and for other purposes; which was ordered to lie on the table; as follows:

At the end of title XI, add the following:

SEC. 11___. CONDITIONS ON AWARD OF DRUG EXCLUSIVITY.

Subchapter E of chapter V (21 U.S.C. 360bbb et seq.) is amended by inserting after section 569C, as added by this Act, the following:

''SEC. 569D. CONDITIONS ON AWARD OF DRUG EXCLUSIVITY.

''(a) TERMINATION OF EXCLUSIVITY.—Notwithstanding any other provision of this Act, any period of exclusivity described in subsection (b) granted to a person or assigned to a person on or after the date of enactment of this section with respect to a drug shall be terminated if the person to which such exclusivity was granted or any person to which such exclusivity is assigned—

''(1) commits a violation described in subsection (c)(1) with respect to such drug; or

''(2) fails to report such a violation as required by subsection (e).

''(b) EXCLUSIVITIES AFFECTED.—The periods of exclusivity described in this subsection are those periods of exclusivity granted under any of the following sections:

''(1) Clause (ii), (iii), or (iv) of section 505(c)(3)(E).

''(2) Clause (iv) of section 505(j)(5)(B).

''(3) Clause (ii), (iii), or (iv) of section 505(j)(5)(F).

''(4) Section 505A.

''(5) Section 505E.

''(6) Section 527.

''(7) Section 351(k)(7) of the Public Health Service Act.

''(8) Any other provision of this Act that provides for market exclusivity (or extension of market exclusivity) with respect to a drug.

''(c) VIOLATIONS.—

''(1) IN GENERAL.—A violation described in this subsection is a violation of a law described in paragraph (2) that results in—

''(A) a criminal conviction of a person described in subsection (a);

''(B) a civil judgment against a person described in subsection (a); or

''(C) a settlement agreement in which a person described in subsection (a) admits to fault.

''(2) LAWS DESCRIBED.—The laws described in this paragraph are the following:

''(A) The provisions of this Act that prohibit—

''(i) the adulteration or misbranding of a drug;

''(ii) the making of false statements to the Secretary or committing fraud; or

''(iii) the illegal marketing of a drug.

''(B) The provisions of subchapter III of chapter 37 of title 31, United States Code (commonly known as the 'False Claims Act').

''(C) Section 287 of title 18, United States Code.

''(D) The Medicare and Medicaid Patient Protection and Program Act of 1987 (commonly known as the 'Antikickback Statute').

''(E) Section 1927 of the Social Security Act.

''(F) A State law against fraud comparable to a law described in subparagraphs (A) through (E).

''(d) DATE OF EXCLUSIVITY TERMINATION.—The date on which the exclusivity shall be terminated as described in subsection (a) is the date on which, as applicable—

''(1) a final judgment is entered relating to a violation described in subparagraph (A) or (B) of subsection (c)(1); or

''(2)(A) a settlement agreement described in subsection (c)(1)(C) is approved by a court order that is or becomes final and nonappealable; or

''(B) if there is no court order approving a settlement agreement described in subsection (c)(1)(C), a court order dismissing the applicable case, issued after the settlement agreement, is or becomes final and nonappealable.

''(e) REPORTING OF INFORMATION.—A person described in subsection (a) that commits a violation described in subsection (c)(1) shall report such violation to the Secretary no later than 30 days after the date that—

''(1) a final judgment is entered relating to a violation described in subparagraph (A) or (B) of subsection (c)(1); or

''(2)(A) a settlement agreement described in subsection (c)(1)(C) is approved by a court order that is or becomes final and nonappealable; or

''(B) if there is no court order approving a settlement agreement described in subsection (c)(1)(C), a court order dismissing the applicable case, issued after the settlement agreement, is or becomes final and nonappealable.''.

SA 2110. Mr. SANDERS submitted an amendment intended to be proposed by him to the bill S. 3187, to amend the Federal Food, Drug, and Cosmetic Act to revise and extend the user-fee programs for prescription drugs and medical devices, to establish user-fee programs for generic drugs and biosimilars, and for other purposes; which was ordered to lie on the table; as follows:

At the end of title XI, add the following:

SEC. 11___. TRANSPARENCY IN NEW DRUG APPLICATIONS.

(a) GENERAL REQUIREMENTS.—Subchapter A of chapter V (21 U.S.C. 351 et seq.), as amended by section 802, is further amended by adding at the end the following:

''SEC. 524B. TRANSPARENCY IN DRUG APPLICATIONS TO THE FDA.

''(a) INITIAL DISCLOSURE OF FINANCIAL INFORMATION.—

''(1) IN GENERAL.—A drug application submitted under subsection (b) or (j) of section 505, an application for a biologics license under subsection (a) or (k) of section 351 of the Public Health Service Act, an investigational new drug application under section 505(i), an application for an extension of market exclusivity following the completion of pediatric studies under section 505A(c), an application for a priority review voucher under section 524, a request for a designation as an orphan drug under section 526, and any other application to the Food and Drug Administration with respect to approval of a drug or an extension of the market exclusivity of a drug shall include a disclosure to the Secretary of such financial information associated with the research and development of the drug as required by the Secretary, as described in paragraph (2). The Secretary shall make such information public.

''(2) REQUIRED INFORMATION.—The financial information provided to the Secretary and made public under paragraph (1) shall include—

''(A) the total amount expended for preclinical research and for each phase of clinical trials of the drug;

''(B) a description of any grant or other economic incentive for research and development of such drug the sponsor receives from private, public, or any other funding source or research institution, including the National Institutes of Health, and the amount obtained from each source; and

''(C) such other information, as the Secretary may require.

''(3) RESEARCH AND DEVELOPMENT DEFINED.—For purposes of this section, 'research and development' of a drug shall include identification of chemical compounds, proof of concepts, testing of concepts, and all phases of clinical trials, including failed tests or trials. Research and development of a particular drug does not include the costs of failed drugs other than the drug that is the subject of the application described in paragraph (1).

''(b) SUBSEQUENT FINANCIAL DISCLOSURES.—A sponsor of a drug approved under subsection (b) or (j) of section 505, or a biological product approved under subsection (a) or

(k) of section 351 of the Public Health Service Act, on an annual basis during the period during which the sponsor claims market exclusivity with respect to the drug and for 7 years thereafter, shall report to the Secretary the quarterly domestic and global unit sales and sales revenue of the drug.

''(c) PUBLIC DISCLOSURE OF CLINICAL TRIALS.—

''(1) IN GENERAL.—The Secretary shall require the sponsor of a drug to register each clinical trial of such drug on the Internet web site of the National Institutes of Health, clinicaltrials.gov (or such successor Internet website developed by the Secretary).

''(2) TDP.—In the case of a sponsor that claims test data protection, the sponsor shall register the required information of the related drug with a clinicaltrials.gov identifier supplied by the Secretary.

''(d) DISCLOSURE OF NUMBERS OF INDIVIDUALS PARTICIPATING IN CLINICAL TRIALS.—A manufacturer or sponsor who submits a request under paragraph (1) shall also submit to the Secretary the following information with respect to clinical trials of the drug, which the Secretary shall make public:

''(1) The numbers of individuals participating in each phase of clinical trials, using de-identified data.

''(2) A description of each participant's dosage of the drug, using de-identified data.

''(3) A description of each participant's results, using de-identified data.''.

(b) DISCLOSURE OF SAFETY AND EFFECTIVENESS DATA.—Section 505(l)(1) (21 U.S.C. 355(l)(1)) is amended, in the matter preceding subparagraph (A), by striking '', unless extraordinary circumstances are shown''.

SA 2111. Mr. BINGAMAN (for himself, Mr. VITTER, Mr. FRANKEN, Mrs. SHAHEEN, Mr. KOHL, Mr. UDALL of New Mexico, Mr. JOHNSON of South Dakota, Ms. KLOBUCHAR, Mr. MERKLEY, and Mr. SANDERS) submitted an amendment intended to be proposed by him to the bill S. 3187, to amend the Federal Food, Drug, and Cosmetic Act to revise and extend the user-fee programs for prescription drugs and medical devices, to establish user-fee programs for generic drugs and biosimilars, and for other purposes; which was ordered to lie on the table; as follows:

In title IX, add at the end the following:

SEC. 9___. ENSURING THAT VALID GENERIC DRUGS MAY ENTER THE MARKET.

(a) 180-DAY EXCLUSIVITY PERIOD AMENDMENTS REGARDING FIRST APPLICANT STATUS.—

(1) AMENDMENTS TO THE FEDERAL FOOD, DRUG, AND COSMETIC ACT.—

(A) IN GENERAL.—Section 505(j)(5)(B) (21 U.S.C. 355(j)(5)(B)) is amended—

(i) in clause (iv)(II)—

(I) by striking item (bb); and

(II) by redesignating items (cc) and (dd) as items (bb) and (cc), respectively; and

(ii) by adding at the end the following:

''(v) FIRST APPLICANT DEFINED.—As used in this subsection, the term 'first applicant' means an applicant—

''(I)(aa) that, on the first day on which a substantially complete application containing a certification described in paragraph (2)(A)(vii)(IV) is submitted for approval of a drug, submits a substantially complete application that contains and lawfully maintains a certification described in paragraph (2)(A)(vii)(IV) for the drug; and

''(bb) that has not entered into a disqualifying agreement described under clause (vii)(II); or

''(II)(aa) for the drug that is not described in subclause (I) and that, with respect to the applicant and drug, each requirement described in clause (vi) is satisfied; and

''(bb) that has not entered into a disqualifying agreement described under clause (vii)(II).

''(vi) REQUIREMENT.—The requirements described in this clause are the following:

''(I) The applicant described in clause (v)(II) submitted and lawfully maintains a certification described in paragraph (2)(A)(vii)(IV) or a statement described in paragraph (2)(A)(viii) for each unexpired patent for which a first applicant described in clause (v)(I) had submitted a certification described in paragraph (2)(A)(vii)(IV) on the first day on which a substantially complete application containing such a certification was submitted.

''(II) With regard to each such unexpired patent for which the applicant described in clause (v)(II) submitted a certification described in paragraph (2)(A)(vii)(IV), no action for patent infringement was brought against such applicant within the 45 day period specified in paragraph (5)(B)(iii); or if an action was brought within such time period, such an action was withdrawn or dismissed by a court (including a district court) without a decision that the patent was valid and infringed; or if an action was brought within such time period and was not withdrawn or so dismissed, such applicant has obtained the decision of a court (including a district court) that the patent is invalid or not infringed (including any substantive determination that there is no cause of action for patent infringement or invalidity, and including a settlement order or consent decree signed and entered by the court stating that the patent is invalid or not infringed).

''(III) If an applicant described in clause (v)(I) has begun commercial marketing of such drug, the applicant described in clause (v)(II) does not begin commercial marketing of such drug until the date that is 30 days after the date on which the applicant described in clause (v)(I) began such commercial marketing.''.

(B) CONFORMING AMENDMENT.—Section 505(j)(5)(D)(i)(IV) (21 U.S.C. 355(j)(5)(D)(i)(IV)) is amended by striking ''The first applicant'' and inserting ''The first applicant, as defined in subparagraph (B)(v)(I),''.

(2) APPLICABILITY.—The amendments made by paragraph (1) shall apply only with respect to an application filed under section 505(j) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 355(j)) to which the amendments made by section 1102(a) of the Medicare Prescription Drug, Improvement, and Modernization Act of 2003 (Public Law 108 173) apply.

(b) 180-DAY EXCLUSIVITY PERIOD AMENDMENTS REGARDING AGREEMENTS TO DEFER COMMERCIAL MARKETING.—

(1) AMENDMENTS TO FEDERAL FOOD, DRUG, AND COSMETIC ACT.—

(A) LIMITATIONS ON AGREEMENTS TO DEFER COMMERCIAL MARKETING DATE.—Section 505(j)(5)(B) (21 U.S.C. 355(j)(5)(B)), as amended by subsection (a), is further amended by adding at the end the following:

''(vii) AGREEMENT BY FIRST APPLICANT TO DEFER COMMERCIAL MARKETING; LIMITATION ON ACCELERATION OF DEFERRED COMMERCIAL MARKETING DATE.—

''(I) AGREEMENT TO DEFER APPROVAL OR COMMERCIAL MARKETING DATE.—An agreement described in this subclause is an agreement between a first applicant and the holder of the application for the listed drug or an owner of one or more of the patents as to which any applicant submitted a certification qualifying such applicant for the 180-day exclusivity period whereby that applicant agrees, directly or indirectly, (aa) not to seek an approval of its application that is made effective on the earliest possible date under this subparagraph, subparagraph (F) of this paragraph, section 505A, or section 527, (bb) not to begin the commercial marketing of its drug on the earliest possible date after receiving an approval of its application that is made effective under this subparagraph, subparagraph (F) of this paragraph, section 505A, or section 527, or (cc) to both items (aa) and (bb).

''(II) AGREEMENT THAT DISQUALIFIES APPLICANT FROM FIRST APPLICANT STATUS.—An agreement described in this subclause is an agreement between an applicant and the holder of the application for the listed drug or an owner of one or more of the patents as to which any applicant submitted a certification qualifying such applicant for the 180-day exclusivity period whereby that applicant agrees, directly or indirectly, not to seek an approval of its application or not to begin the commercial marketing of its drug until a date that is after the expiration of the 180-day exclusivity period awarded to another applicant with respect to such drug (without regard to whether such 180-day exclusivity period is awarded before or after the date of the agreement).

''(viii) LIMITATION ON ACCELERATION.—If an agreement described in clause (vii)(I) includes more than 1 possible date when an applicant may seek an approval of its application or begin the commercial marketing of its drug—

''(I) the applicant may seek an approval of its application or begin such commercial marketing on the date that is the earlier of—

''(aa) the latest date set forth in the agreement on which that applicant can receive an approval that is made effective under this subparagraph, subparagraph (F) of this paragraph, section 505A, or section 527, or begin the commercial marketing of such drug, without regard to any other provision of such agreement pursuant to which the commercial marketing could begin on an earlier date; or

''(bb) 180 days after another first applicant begins commercial marketing of such drug; and

''(II) the latest date set forth in the agreement on which that applicant can receive an approval that is made effective under this subparagraph, subparagraph (F) of this paragraph, section 505A, or section 527, or begin the commercial marketing of such drug, without regard to any other provision of such agreement pursuant to which commercial marketing could begin on an earlier date, shall be the date used to determine whether an applicant is disqualified from first applicant status pursuant to clause (vii)(II).''.

(B) NOTIFICATION OF FDA.—Section 505(j) (21 U.S.C. 355(j)) is amended by adding at the end the following:

''(11)(A) The holder of an abbreviated application under this subsection shall submit to the Secretary a notification that includes—

''(i)(I) the text of any agreement entered into by such holder described under paragraph (5)(B)(vii)(I); or

''(II) if such an agreement has not been reduced to text, a written detailed description of such agreement that is sufficient to disclose all the terms and conditions of the agreement; and

''(ii) the text, or a written detailed description in the event of an agreement that has not been reduced to text, of any other agreements that are contingent upon, provide a contingent condition for, or are otherwise related to an agreement described in clause (i).

''(B) The notification described under subparagraph (A) shall be submitted not later than 10 business days after execution of the agreement described in subparagraph (A)(i). Such notification is in addition to any notification required under section 1112 of the

Medicare Prescription Drug, Improvement, and Modernization Act of 2003.

''(C) Any information or documentary material filed with the Secretary pursuant to this paragraph shall be exempt from disclosure under section 552 of title 5, United States Code, and no such information or documentary material may be made public, except as may be relevant to any administrative or judicial action or proceeding. Nothing in this paragraph is intended to prevent disclosure to either body of the Congress or to any duly authorized committee or subcommittee of the Congress.''.

(C) PROHIBITED ACTS.—Section 301(e) (21 U.S.C. 331(e)) is amended by striking ''505 (i) or (k)'' and inserting ''505 (i), (j)(11), or (k)''.

(2) INFRINGEMENT OF PATENT.—Section 271(e) of title 35, United States Code, is amended by adding at the end the following:

''(7) The exclusive remedy under this section for an infringement of a patent for which the Secretary of Health and Human Services has published information pursuant to subsection (b)(1) or (c)(2) of section 505 of the Federal Food, Drug, and Cosmetic Act shall be an action brought under this subsection within the 45-day period described in subsection (j)(5)(B)(iii) or (c)(3)(C) of section 505 of the Federal Food, Drug, and Cosmetic Act.''.

(3) APPLICABILITY.—

(A) LIMITATIONS ON ACCELERATION OF DEFERRED COMMERCIAL MARKETING DATE.—The amendment made by paragraph (1)(A) shall apply only with respect to—

(i) an application filed under section 505(j) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 355(j)) to which the amendments made by section 1102(a) of the Medicare Prescription Drug, Improvement, and Modernization Act of 2003 (Public Law 108 173) apply; and

(ii) an agreement described under section 505(j)(5)(B)(vii)(I) of the Federal Food, Drug, and Cosmetic Act (as added by subsection (a)(1)) executed after the date of enactment of this Act.

(B) NOTIFICATION OF FDA.—The amendments made by subparagraphs (B) and (C) of paragraph (1) shall apply only with respect to an agreement described under section 505(j)(5)(B)(vii)(I) of the Federal Food, Drug, and Cosmetic Act (as added by paragraph (1)(A)) executed after the date of enactment of this Act.

(c) TECHNICAL AMENDMENT.—Section 744B(n), as added by section 302 of this Act, is amended by striking ''505(j)(5)(B)(iv)(II)(cc)'' and inserting ''505(j)(5)(B)(iv)(II)(bb)''.

SA 2112. Mr. REID (for Mrs. BOXER (for herself and Mrs. FEINSTEIN)) proposed an amendment to the bill H.R. 4849, to direct the Secretary of the Interior to issue commercial use authorizations to commercial stock operators for operations in designated wilderness within the Sequoia and Kings Canyon National Parks, and for other purposes; as follows:

Strike all after the enacting clause and insert the following:

SECTION 1. SHORT TITLE.

This Act may be cited as the ''Sequoia and King Canyon National Parks Backcountry Access Act''.

SEC. 2. COMMERCIAL SERVICES AUTHORIZATIONS IN WILDERNESS WITHIN THE SEQUOIA AND KINGS CANYON NATIONAL PARKS.

(a) CONTINUATION OF AUTHORITY.—Until the date on which the Secretary of the Interior (referred to in this Act as the ''Secretary'') completes any analysis and determination required under the Wilderness Act (16 U.S.C. 1131 et seq.), the Secretary shall continue to issue authorizations to provide commercial services for commercial stock operations (including commercial use authorizations and concession contracts) within any area designated as wilderness in the Sequoia and Kings Canyon National Parks (referred to in this section as the ''Parks)'' at use levels determined by the Secretary to be appropriate and subject to any terms and conditions that the Secretary determines to be appropriate.

(b) WILDERNESS STEWARDSHIP PLAN.—Not later than 3 years after the date of enactment of this Act, the Secretary shall complete a wilderness stewardship plan with respect to the Parks.

(c) TERMINATION OF AUTHORITY.—The authority of the Secretary to issue authorizations under subsection (a) shall terminate on the earlier of—

(1) the date on which the Secretary begins to issue authorizations to provide commercial services for commercial stock operations within any areas designated as wilderness in the Parks, as provided in a record of decision issued in accordance with a wilderness stewardship plan completed under subsection (b); or

(2) the date that is 4 years after the date of enactment of this Act.

AUTHORITY FOR COMMITTEES TO MEET

COMMITTEE ON ENERGY AND NATURAL RESOURCES

Mr. SCHUMER. Mr. President, I ask unanimous consent that the Committee on Energy and Natural Resources be authorized to meet during the session of the Senate on May 17, 2012, at 9:30 a.m., in room SD 366 of the Dirksen Senate Office Building.

The PRESIDING OFFICER. Without objection, it is so ordered.

COMMITTEE ON FINANCE

Mr. SCHUMER. Mr. President, I ask unanimous consent that the Committee on Finance be authorized to meet during the session of the Senate on May 17, 2012, at 10 a.m., in room SD 215 of the Dirksen Senate Office Building, to conduct a hearing entitled ''The Social Security Administration: Is it Meeting its Responsibilities to Save Taxpayer Dollars and Serve the Public?''

The PRESIDING OFFICER. Without objection, it is so ordered.

COMMITTEE ON FOREIGN RELATIONS

Mr. SCHUMER. Mr. President, I ask unanimous consent that the Committee on Foreign Relations be authorized to meet during the session of the Senate on May 17, 2012, at 2:30 p.m.,

The PRESIDING OFFICER. Without objection, it is so ordered.

COMMITTEE ON INDIAN AFFAIRS

Mr. SCHUMER. Mr. President, I ask unanimous consent that the Committee on Indian Affairs be authorized to meet during the session of the Senate on May 17, 2012, in room SD 628 of the Dirksen Senate Office Building, at 2:15 p.m., to conduct a hearing entitled ''Fulfilling the Federal Trust Responsibility: The Foundation of the Government-to-Government Relationship.''

The PRESIDING OFFICER. Without objection, it is so ordered.

COMMITTEE ON THE JUDICIARY

Mr. SCHUMER. Mr. President, I ask unanimous consent that the Committee on the Judiciary be authorized to meet during the session of the Senate on May 17, 2012, at 10 a.m., in SD 226 of the Dirksen Senate Office Building, to conduct an executive business meeting.

The PRESIDING OFFICER. Without objection, it is so ordered.

SUBCOMMITTEE ON OCEANS, ATMOSPHERE, FISHERIES, AND THE COAST GUARD

Mr. SCHUMER. Mr. President, I ask unanimous consent that the Subcommittee on Oceans, Atmosphere, Fisheries, and the Coast Guard of the Committee on Commerce, Science, and Transportation be authorized to hold a meeting during the session of the Senate on May 17, 2012, at 10:30 a.m., in room SR 253 of the Russell Senate Office Building.

The Committee will hold a hearing entitled, ''Stemming the Tide: The U.S. Response to Tsunami Generated Marine Debris.''

The PRESIDING OFFICER. Without objection, it is so ordered.

PRIVILEGES OF THE FLOOR

Mr. REID. Mr. President, I ask unanimous consent that Marc Labonte, a detailee on Senator JOHNSON's Banking Committee staff, be granted floor privileges for the remainder of today's session.

The ACTING PRESIDENT pro tempore. Without objection, it is so ordered.

TROOPER JOSHUA D. MILLER POST OFFICE BUILDING

MASTER SERGEANT DANIEL L. FEDDER POST OFFICE

PRIVATE ISAAC T. CORTES POST OFFICE

Mr. REID. Mr. President, I ask unanimous consent that the Senate proceed to the consideration of the following postal naming bills en bloc: Calendar No. 401, H.R. 2415; Calendar No. 402, H.R. 3220; and Calendar No. 403, H.R. 3413.

The PRESIDING OFFICER. The clerk will report the bills by title en bloc.

The legislative clerk read as follows:

A bill (H.R. 2415) to designate the facility of the United States Postal Service located at 11 Dock Street in Pittston, Pennsylvania, as the ''Trooper Joshua D. Miller Post Office Building.''

A bill (H.R. 3220) to designate the facility of the United States Postal Service located at 170 Evergreen Square SW in Pine City, Minnesota, as the ''Master Sergeant Daniel L. Fedder Post Office.''

A bill (H.R. 3413) to designate the facility of the United States Postal Service located at 1449 West Avenue in Bronx, New York, as the ''Private Isaac T. Cortes Post Office.''

There being no objection, the Senate proceeded to consider the bills en bloc.