

EXECUTIVE AND OTHER COMMUNICATIONS

The following communications were laid before the Senate, together with accompanying papers, reports, and documents, which were referred as indicated:

EC-4533. A communication from the Chief of the Regulations Branch, United States Customs Service, Department of the Treasury, transmitting, pursuant to law, the report of a rule entitled "Customs Preclearance in Foreign Countries" (T.D. 01-81) received on November 5, 2001; to the Committee on Finance.

EC-4534. A communication from the Deputy Secretary of the Division of Enforcement, United States Securities and Exchange Commission, transmitting, pursuant to law, the report of a rule entitled "Debt Collection—Amendments to Collection Rules and Adoption of Wage Garnishment Rules" (RIN3235-AI34) received on November 5, 2001; to the Committee on Banking, Housing, and Urban Affairs.

EC-4535. A communication from the Deputy Secretary of the Division of Market Regulation, United States Securities and Exchange Commission, transmitting, pursuant to law, the report of a rule entitled "Final Rule Amendments to the Books and Records Requirements for Brokers and Dealers Under the Securities Exchange Act of 1934 [17 CFR 240.17a-3 and 240.17a-4] [see Exchange Act Release No. 44992, October 26, 2001]" (RIN3535-AH04) received on November 5, 2001; to the Committee on Banking, Housing, and Urban Affairs.

INTRODUCTION OF BILLS AND JOINT RESOLUTIONS

The following bills and joint resolutions were introduced, read the first and second times by unanimous consent, and referred as indicated:

By Mr. HUTCHINSON (for himself and Mr. GREGG):

S. 1635. A bill to ensure the prompt research, development, manufacture, and distribution of new life-saving drugs, biologics, and medical devices that prevent or mitigate the consequences of a chemical or biological bioterrorist attack, and for other purposes; to the Committee on Health, Education, Labor, and Pensions.

By Mr. BAUCUS:

S. 1636. A bill to authorize the negotiation of a Free Trade Agreement with Taiwan, and to provide for expedited congressional consideration of such an agreement; to the Committee on Finance.

By Mrs. CLINTON (for herself and Mr. SCHUMER):

S. 1637. A bill to waive certain limitations in the case of use of the emergency fund authorized by section 125 of title 23, United States Code, to pay the costs of projects in response to the attack on the World Trade Center in New York City that occurred on September 11, 2001; to the Committee on Environment and Public Works.

By Mr. BOND:

S. 1638. A bill to authorize the Secretary of the Interior to study the suitability and feasibility of designating the French Colonial Heritage Area in the State of Missouri as a unit of the National Park System, and for other purposes; to the Committee on Energy and Natural Resources.

By Mr. VOINOVICH (for himself and Mr. THOMPSON):

S. 1639. A bill to provide Federal managers with tools and flexibility in areas such as personnel, budgeting, property management

and disposal, and for other purposes; to the Committee on Governmental Affairs.

By Mr. CLELAND:

S. 1640. A bill to suspend temporarily the duty on certain steam turbines and generators for power generation; to the Committee on Finance.

By Mr. SESSIONS (for himself and Mr. NICKLES):

S. 1641. A bill to impose additional requirements to ensure greater use of the advance payment of the earned income credit and to extend such advanced payment to all taxpayers eligible for the credit; to the Committee on Finance.

By Mr. ENZI:

S. 1642. A bill to open certain withdrawn land in Big Horn County Wyoming, to locatable mineral development for bentonite mining; to the Committee on Energy and Natural Resources.

ADDITIONAL COSPONSORS

S. 540

At the request of Mr. DEWINE, the name of the Senator from Wyoming (Mr. ENZI) was added as a cosponsor of S. 540, a bill to amend the Internal Revenue Code of 1986 to allow as a deduction in determining adjusted gross income the deduction for expenses in connection with services as a member of a reserve component of the Armed Forces of the United States, to allow employers a credit against income tax with respect to employees who participate in the military reserve components, and to allow a comparable credit for participating reserve component self-employed individuals, and for other purposes.

S. 990

At the request of Mr. SMITH of New Hampshire, the name of the Senator from Idaho (Mr. CRAPO) was added as a cosponsor of S. 990, a bill to amend the Pittman-Robertson Wildlife Restoration Act to improve the provisions relating to wildlife conservation and restoration programs, and for other purposes.

S. 1434

At the request of Mr. SPECTER, the names of the Senator from Indiana (Mr. BAYH), the Senator from Oklahoma (Mr. NICKLES), the Senator from Alabama (Mr. SESSIONS), and the Senator from Texas (Mrs. HUTCHISON) were added as cosponsors of S. 1434, a bill to authorize the President to award posthumously the Congressional Gold Medal to the passengers and crew of United Airlines flight 93 in the aftermath of the terrorist attack on the United States on September 11, 2001.

S. 1493

At the request of Mr. BOND, the name of the Senator from Nebraska (Mr. HAGEL) was added as a cosponsor of S. 1493, a bill to forgive interest payments for a 2-year period on certain disaster loans to small business concerns in the aftermath of the terrorist attacks perpetrated against the United States on September 11, 2001, to amend the Internal Revenue Code of 1986 to provide tax relief for small business concerns, and for other purposes.

S. 1499

At the request of Mr. KERRY, the name of the Senator from Nebraska (Mr. HAGEL) was added as a cosponsor of S. 1499, a bill to provide assistance to small business concerns adversely impacted by the terrorist attacks perpetrated against the United States on September 11, 2001, and for other purposes.

S. 1593

At the request of Mr. JEFFORDS, the name of the Senator from New Jersey (Mr. CORZINE) was added as a cosponsor of S. 1593, a bill to authorize the Administrator of the Environmental Protection Agency to establish a grant program to support research projects on critical infrastructure protection for water supply systems, and for other purposes.

S. 1597

At the request of Mr. KERRY, the name of the Senator from North Carolina (Mr. EDWARDS) was added as a cosponsor of S. 1597, a bill to amend the Public Health Service Act to establish programs to alleviate the nursing profession shortage, and for other purposes.

S. 1600

At the request of Mr. DAYTON, the name of the Senator from South Dakota (Mr. JOHNSON) was added as a cosponsor of S. 1600, a bill to amend the Internal Revenue Code of 1986 to allow medicare beneficiaries a refundable credit against income tax for the purchase of outpatient prescription drugs.

S.J. RES. 12

At the request of Mr. SMITH of New Hampshire, the name of the Senator from Maine (Ms. COLLINS) was added as a cosponsor of S.J. Res. 12, a joint resolution granting the consent of Congress to the International Emergency Management Assistance Memorandum of Understanding.

AMENDMENT NO. 2039

At the request of Mrs. CLINTON, the name of the Senator from Connecticut (Mr. DODD) was added as a cosponsor of amendment No. 2039 intended to be proposed to H.R. 3061, a bill making appropriations for the Departments of Labor, Health and Human Services, and Education, and related agencies for the fiscal year ending September 30, 2002, and for other purposes.

AMENDMENT NO. 2044

At the request of Mr. DASCHLE, the name of the Senator from Indiana (Mr. BAYH) was added as a cosponsor of amendment No. 2044 proposed to H.R. 3061, a bill making appropriations for the Departments of Labor, Health and Human Services, and Education, and related agencies for the fiscal year ending September 30, 2002, and for other purposes.

STATEMENTS ON INTRODUCED BILLS AND JOINT RESOLUTIONS

By Mr. HUTCHINSON (for himself and Mr. GREGG):

S. 1635. A bill to ensure the prompt research, development, manufacture, and distribution of new life-saving drugs, biologics, and medical devices that prevent or mitigate the consequences of a chemical or biological bioterrorist attack, and for other purposes; to the Committee on Health, Education, Labor, and Pensions.

Mr. HUTCHINSON. Mr. President, I ask unanimous consent that the text of the bill be printed in the RECORD.

There being no objection, the bill was ordered to be printed in the RECORD, as follows:

S. 1635

Be it enacted by the Senate and House of Representatives of the United States of America in Congress assembled,

SECTION 1. SHORT TITLE.

This Act may be cited as the "Pathogen Research, Emergency Preparedness and Response Efforts Act of 2001" or the "PREPARE Act".

SEC. 2. AMENDMENT TO THE PUBLIC HEALTH SERVICE ACT.

The Public Health Service Act (42 U.S.C. 201 et seq.) is amended by adding at the end the following:

"TITLE XXVIII—DEVELOPING NEW COUNTERMEASURES AND PROTECTING EXISTING COUNTERMEASURES AGAINST BIOTERRORISM

"SEC. 2801. DEVELOPMENT OF DRUGS, BIOLOGICAL PRODUCTS, AND MEDICAL DEVICES TO COMBAT BIOTERRORISM.

"(a) IDENTIFICATION OF CHEMICAL OR BIOLOGICAL AGENTS OR TOXINS.—

"(1) IN GENERAL.—The Secretary, in consultation with the Secretary of Defense and the Attorney General, shall identify chemical or biological agents or toxins that may be identified, prevented, or treated through—

"(A) the development of new covered products;

"(B) the development of new uses, including pediatric uses, for approved covered products; or

"(C) the manufacture or distribution of covered products that would otherwise not be manufactured or distributed in sufficient quantities.

"(2) PUBLICATION AND AVAILABILITY.—Not later than 180 days after the date of enactment of this title, and annually thereafter, the Secretary shall publish in the Federal Register, or otherwise make available to manufacturers or potential manufacturers of covered products, a list of the chemical or biological agents and toxins identified under paragraph (1) for which the Secretary desires to encourage the development of, or new uses for, covered products or the manufacture or distribution of such covered products.

"(b) CONSULTATION.—In carrying out this section, the Secretary shall consult with experts in the pharmaceutical, biotechnology, and medical device industries, academic medical centers, and research institutions, including those with pediatric expertise.

"(c) LIMITED ANTITRUST EXEMPTION.—

"(1) COUNTERMEASURES DEVELOPMENT MEETINGS.—

"(A) SCHEDULING COUNTERMEASURES DEVELOPMENT MEETINGS.—The antitrust laws shall not apply to meetings or consultations conducted by the Secretary with parties involved in the development of countermeasures for the purpose of the development, manufacture, distribution, and sale of countermeasures that are prioritized under section 2841(c), consistent with the purposes of this title. The Secretary shall give notice to the Assistant Attorney General of Antitrust of meetings scheduled pursuant to this subsection.

"(B) MEETING CONDITIONS.—Any meeting under subparagraph (A)—

"(i) shall be chaired by the Secretary;

"(ii) shall be open to parties involved in the development of countermeasures, as determined by the Secretary;

"(iii) shall be open to the Attorney General and the Federal Trade Commission;

"(iv) shall be limited to discussions involving the development, manufacture, distribution, or sale of countermeasures that are prioritized under section 2841(c); and

"(v) shall be conducted in such manner as to ensure that national security, confidential, and proprietary information is not disclosed outside the meeting.

"(C) MINUTES.—The Secretary shall ensure that minutes of the meeting are maintained.

"(2) APPLYING FOR LIMITED EXEMPTION.—

"(A) FILING PROCEDURES.—As a result of meetings in paragraph (1), the Secretary and participating parties may file a written request with the Attorney General for a limited exemption from the antitrust laws to allow appropriate parties to enter into agreements or engage in conduct relating to the development, manufacture, distribution, or sale of countermeasures prioritized under section 2841(c). Any such request shall set forth the intended purpose of the agreement, including an explanation as to why a cooperative effort among potential competitors is necessary to achieve the objective of the agreement. The request shall state with specificity the substance of the agreement, the methods that will be utilized to achieve the objectives of the agreement, and other relevant information relating to the development and production of countermeasures that are prioritized under section 2841(c).

"(B) GRANT OF EXEMPTION.—The Attorney General, in consultation with the Chairman of the Federal Trade Commission shall grant, deny, grant in part and deny in part, or propose modifications to any request made pursuant to subparagraph (A) for exemption from the antitrust laws. In making the determination to grant, deny, grant in part and deny in part, or propose modifications to any such request, the Attorney General shall consider among other things: whether such agreement would promote the purposes of this Act, whether the exemption from the antitrust laws would promote the public interest, and the competitive impact to areas not directly related to the development and production of countermeasures prioritized under section 2841(c). The Attorney General shall make a determination on a request filed pursuant to subparagraph (A) within 60 days.

"(C) SUNSET.—The authority of the Attorney General to grant a limited antitrust exemption under this section expires at the end of the 2-year period beginning on the date of enactment of the Pathogen Research, Emergency Preparedness and Response Efforts Act of 2001.

"SEC. 2802. CONTRACTS FOR DEVELOPMENT OF COVERED PRODUCTS.

"(a) AUTHORITY.—The Secretary may enter into contracts, cooperative research and development agreements pursuant to section 11(a) of the Stevenson-Wydler Technology Innovation Act of 1980 (15 U.S.C. 3710(a)), material transfer agreements, or other agreements, or agree to the amendment or modification of existing or future contracts or agreements, for the development, manufacture or distribution of covered products for uses or new uses identified by the Secretary pursuant to section 2801(b). A contract or agreement entered into, or amended or modified, under this subsection may address 1 or more aspects of the development, manufacture, or distribution of 1 or more uses of 1 or more covered products. Such contracts or agreements may set forth guaranteed minimum quantities of products and negotiated unit prices.

"(b) TIMING OF CONTRACT.—Notwithstanding any other provision of law, the Secretary may enter into a contract or agreement under subsection (a) even prior to the development, approval, or clearance of the covered product that is the subject of the contract or agreement. Such contract or agreement may provide for the termination of the contract or agreement for the convenience of the Federal Government if the contractor fails to develop the covered product involved.

"(c) PAYMENTS.—Payments under a contract or agreement under subsection (a) may be made from—

"(1) funds obligated for the performance of the contract or agreement involved;

"(2) funds available for the development, manufacture, distribution, or purchase of covered products for uses referred to in section 2801(b); or

"(3) any other funds available to the Secretary.

"(d) CONTRACTS.—In administering the provisions of this section, the Secretary may enter into contracts in advance of appropriations and incur obligations without regard to provisions of law relating to contracts, including sections 1341, 1342, 1349, 1350, and 1351, and subchapter II of chapter 15, of title 31, United States Code.

"SEC. 2803. INDEMNIFICATION.

"The Secretary shall, in any contract or agreement for the manufacture, development, distribution, or the purchase of a covered product intended for a use identified by the Secretary pursuant to section 2801(b), indemnify and hold harmless the contractor consistent with the following principles:

"(1) USES COVERED.—Indemnification only extends to uses of the covered product pursuant to a contract entered into by the Secretary under section 2802.

"(2) ENTITIES COVERED.—The Secretary may indemnify contractors, subcontractors, distributors, persons who administer covered products, or other parties as determined appropriate by the Secretary pursuant to contracts entered into under section 2802.

"(3) LIMITS.—No indemnification shall be provided for intentional torts by the contractor or torts by the contractor involving gross negligence or recklessness.

"SEC. 2804. HIGH QUALITY PRODUCTION.

"The Secretary may, with the agreement of the manufacturer of a drug, biological product, or medical device that is approved, licensed, or cleared (or awaiting approval, licensure or clearance) under section 505, 510, 513, or 515 of the Federal Food, Drug, and Cosmetic Act, or section 351 of this Act, and is a covered product, provide intensive assistance, including on-site assistance, when necessary, in order to facilitate prompt compliance with good manufacturing practice regulations under sections 210, 211, 225, 226, 600, 601, 606, or 820 of title 21, Code of Federal Regulations, in the manufacturing, processing, packing, or holding of the drug, biological product, or medical device.

"SEC. 2805. SECURITY FOR RESEARCH AND PRODUCTION.

"(a) IN GENERAL.—The Secretary, in consultation with the Attorney General and the Secretary of Defense, may award grants, contracts, or enter into cooperative agreements, and provide technical or nonmonetary assistance, to provide security to facilities that conduct research, development, production, distribution, and storage of covered products.

"(b) BEST PRACTICES.—The Secretary shall develop guidelines and best practices to enable entities eligible for funding under this section to secure their facilities against potential bioterrorist attack.

“SEC. 2806. MOBILITY OF STOCKPILE.”

“(a) SPECIAL EVENTS.—In managing the National Pharmaceutical Stockpile, the Secretary, in consultation with State and local government officials, shall take into consideration the timing and location of special events, including designated national security events.

“(b) LOCATION OF CERTAIN STOCKS.—In carrying out subsection (a), the Secretary shall ensure that medical supplies from the National Pharmaceutical Stockpile are located in appropriate proximity to the site of the special event.

“SEC. 2807. DEFINITIONS.”

“In this title:

“(1) ANTITRUST LAWS.—The term ‘antitrust laws’—

“(A) has the meaning given such term in subsection (a) of the first section of the Clayton Act (15 U.S.C. 12(a)), except that such term includes section 5 of the Federal Trade Commission Act (15 U.S.C. 45) to the extent such section 5 applies to unfair methods of competition; and

“(B) includes any State law similar to the laws referred to in subparagraph (A).

“(2) BIOLOGICAL AGENTS OR TOXINS.—The term ‘biological agents or toxins’ has the meaning given in section 178 of title 18, United States Code.

“(3) COVERED PRODUCTS.—The term ‘covered products’ includes drugs, biological products including vaccines, and medical devices including in vitro diagnostics, that may be developed or produced to identify, prevent, or treat disease or harm in humans, including children and other vulnerable populations, resulting from an attack or threatened attack using chemical or biological agents or toxins.

“(4) DEVELOPMENT.—The term ‘development’ includes the identification of suitable compounds or biological materials, the conduct of preclinical and clinical studies, the preparation of an application for marketing approval or clearance, the conduct of post-market or post-approval studies, and any other actions related to preparation of a covered product.”.

SEC. 2. EXPEDITING FDA REVIEW AND APPROVAL.

(a) AMENDMENT.—Section 506 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 356) is amended by adding at the end the following:

“(e) CHEMICAL OR BIOLOGICAL AGENTS OR TOXINS.—

“(1) IN GENERAL.—The Secretary may designate an unapproved covered product identified pursuant to section 2801(b) of the Public Health Service Act as a fast-track product pursuant to this section. Such a designation may be made prior to the submission of—

“(A) a request for designation by the sponsor; or

“(B) an application for the investigation of the drug under section 505(i) or section 351(a)(3) of the Public Health Service Act.”.

“(2) USE OF ANIMAL TRIALS.—An application for a drug for which approval is sought on the basis of evidence of effectiveness that is derived from animal studies under the last sentence of section 505(d) or section 351(a)(1) of the Public Health Service Act may be designated as a fast track product for purposes of this section.”.

(b) REVIEW.—The Secretary shall grant priority review to a submission for a covered product, unless the sponsor has filed an application for review of the product under section 506.

SEC. 3. USE OF ANIMAL TRIALS IN THE APPROVAL OF COVERED PRODUCTS.

(a) NEW DRUGS.—Section 505(d) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 355(d)) is amended by adding at the end the

following: “In the case of drugs for use against a potentially lethal or permanently disabling toxic chemical or biological agent or toxin, when adequate and well-controlled studies in humans cannot ethically be conducted because the studies would involve administering such an agent or toxin to healthy human volunteers without a proven treatment, and when adequate field trials assessing the use of the drug (in situations such as after accidental or hostile exposure to the substance) have not been feasible, the Secretary may grant approval, including approval for pediatric populations, based on evidence derived from appropriate studies in animals or other information. The Secretary may use existing authority under section 506 or other relevant provisions to order post-marketing approval studies. Drugs approved solely under the authority of the preceding two sentences shall be for purposes of identifying, treating, or preventing infection, disease, injury, or other health condition or consequence resulting from a disabling toxic chemical, biological, radiological, nuclear attack, potential attack, or other significant disease emergency as the Secretary may determine appropriate.”.

(b) NEW BIOLOGICAL PRODUCTS.—Section 351 of the Public Health Service Act (42 U.S.C. 262) is amended by adding at the end the following:

“(k) APPROVAL OF CERTAIN PRODUCTS BASED ON ANIMAL TRIALS.—

“(1) IN GENERAL.—In the case of biological products for use against a potentially lethal or permanently disabling toxic chemical, biological, radiological, nuclear, or other agent or toxins, when adequate and well-controlled studies in humans cannot ethically be conducted because the studies would involve administering such an agent or toxin to human volunteers without a proven treatment, and when adequate field trials assessing the use of the biological product (in situations such as after accidental or hostile exposure to the substance) have not been feasible, the Secretary may grant approval, including approval for pediatric populations, based on evidence derived from appropriate studies in animals or other information.

“(2) POST-APPROVAL STUDIES.—With respect to products described in paragraph (1), the Secretary may use existing authority under section 506 of the Federal Food, Drug, and Cosmetic Act to order post-marketing approval studies.

“(3) LIMITATIONS.—Biological products approved solely under the authority of this subsection shall be for purposes of identifying, treating, or preventing infection, disease, injury, or other health condition or consequence resulting from a potentially disabling toxic chemical, biological, radiological, nuclear attack, potential attack, or other significant disease emergency as the Secretary may determine appropriate.”.

(c) FINAL RULE.—Not later than 60 days after the date of enactment of Pathogen Research, Emergency Preparedness and Response Efforts Act of 2001, the Secretary shall finalize the proposed rule published on October 5, 1999 regarding the use of animal trials in the approval of products.

SEC. 4. CHEMICAL OR BIOLOGICAL AGENTS AND TOXINS.

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

“PART E—CHEMICAL OR BIOLOGICAL AGENTS AND TOXINS”**“SEC. 570. AUTHORITY TO RESTRICT TRANSPORTATION AND USE.”**

“(a) IN GENERAL.—The Secretary shall undertake a program that, through inspections and other containment procedures, will pro-

hibit the unauthorized shipment or transportation in interstate or foreign commerce, the possession or other use in or affecting commerce, or assistance to another person in such transportation, shipment, or other use by any person of chemical or biological agents or toxins or the receipt of such chemical or biological agents or toxins so shipped or transported.

“(b) DEFINITIONS.—In this section:

“(1) CHEMICAL OR BIOLOGICAL AGENTS AND TOXINS.—The term ‘chemical or biological agents and toxins’ has the meaning given such term in section 2801(a) of the Public Health Service Act refers to a biological agent or toxin listed as a ‘select agent’ in section 72.6(j) of title 42, Code of Federal Regulations, which is not exempt under section 72.6(h) or appendix A of such title and which does not include any such biological agent or toxin that is in its naturally-occurring environment and that has not been cultivated, collected, or otherwise extracted from its natural source.

“(2) PERSON.—The term ‘person’ includes an alien (other than an alien admitted for permanent residence) who is a national of a country as to which the Secretary of State has made a determination (that is in effect) that such country has repeatedly provided support for acts of international terrorism.”.

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

“(aa) The shipment, transportation, possession or other use, assistance with respect to, or receipt of a biological agent or toxin in violation of section 570.”.

SEC. 5. REGULATION OF CHEMICAL OR BIOLOGICAL AGENTS AND TOXINS POSING POTENTIAL NATIONAL SECURITY THREAT.

(a) REDESIGNATION AND CLARIFICATION OF CHEMICAL OR BIOLOGICAL AGENTS; REGULATORY PROVISIONS OF ANTITERRORISM AND EFFECTIVE DEATH PENALTY ACT OF 1996.—

(1) IN GENERAL.—Part F of title III of the Public Health Service Act (42 U.S.C. 262 et seq.) is amended by inserting after section 351, the following:

“SEC. 351A. ENHANCED CONTROL OF CHEMICAL OR BIOLOGICAL AGENTS AND TOXINS.”

“(a) REGULATORY CONTROL OF CHEMICAL OR BIOLOGICAL AGENTS AND TOXINS.—

“(1) LIST OF CHEMICAL OR BIOLOGICAL AGENTS AND TOXINS.—The Secretary shall, through regulations promulgated under subsection (c), establish and maintain a list of each biological agent and each toxin that has the potential to pose a severe threat to public health and safety.

“(2) CRITERIA.—In determining whether to include an agent or toxin on the list under subsection (a), the Secretary shall—

“(A) consider—

“(i) the effect on human health of exposure to the agent or toxin;

“(ii) the degree of contagiousness of the agent or toxin and the methods by which the agent or toxin is transferred to humans;

“(iii) the availability and effectiveness of pharmacotherapies and immunizations to treat or prevent any illness resulting from infection by the agent or toxin; and

“(iv) any other criteria that the Secretary considers appropriate; and

“(B) consult with scientific experts representing appropriate professional groups.

“(b) REGULATION OF TRANSFERS OF LISTED CHEMICAL OR BIOLOGICAL AGENTS AND TOXINS.—The Secretary shall, through regulations promulgated under subsection (c), provide for—

“(1) the establishment and enforcement of safety procedures for the transfer of chemical or biological agents and toxins listed

pursuant to subsection (a)(1), including measures to ensure—

“(A) proper training and appropriate skills to handle such agents and toxins; and

“(B) proper laboratory facilities to contain and dispose of such agents and toxins;

“(2) safeguards to prevent access to such agents and toxins for use in domestic or international terrorism or for any other criminal purpose;

“(3) the establishment of procedures to protect the public in the event of a transfer or potential transfer of a biological agent or toxin in violation of the safety procedures established under paragraph (1) or the safeguards established under paragraph (2); and

“(4) appropriate availability of chemical or biological agents and toxins for research, education and other legitimate purposes.

“(c) REGULATIONS.—The Secretary shall promulgate regulations to carry out this section.

“(d) DEFINITIONS.—For purposes of this section and section 351B, the term ‘biological agent and toxin’ shall have the meaning given such term in section 2801(a).”

(2) CONFORMING AMENDMENT.—Subsections (d), (e), (f), and (g) of section 511 of the Antiterrorism and Effective Death Penalty Act of 1996 (42 U.S.C. 262 note) are repealed.

(3) EFFECTIVE DATE.—The amendments made by this subsection shall take effect as if incorporated in the Antiterrorism and Effective Death Penalty Act of 1996.

(b) REGULATION OF CHEMICAL OR BIOLOGICAL AGENTS AND TOXINS POSING POTENTIAL NATIONAL SECURITY THREAT.—

(1) IN GENERAL.—Part F of title III of the Public Health Service Act (42 U.S.C. 262 et seq.), as amended by subsection (a)(1), is further amended by inserting after section 351A, the following:

“SEC. 351B. REGULATION OF CHEMICAL OR BIOLOGICAL AGENTS AND TOXINS POSING POTENTIAL NATIONAL SECURITY THREAT.

“(a) IN GENERAL.—

“(1) LIST OF CHEMICAL OR BIOLOGICAL AGENTS AND TOXINS POSING NATIONAL SECURITY THREAT.—The Secretary shall, through regulations promulgated under subsection (d), establish and maintain a list of those chemical or biological agents and toxins listed pursuant to section 351A(a)(1) that the Secretary determines to be a potential national security threat.

“(2) CRITERIA.—In determining whether to include an agent or toxin on the list under subsection (a), the Secretary shall—

“(A) consider the criteria specified in section 351A(a)(2)(A)(i), and any other criteria that the Secretary considers appropriate; and

“(B) consult with scientific, intelligence, and military experts representing appropriate professional groups.

(b) REGULATION OF TRANSFERS OF LISTED CHEMICAL OR BIOLOGICAL AGENTS AND TOXINS.—The Secretary shall, through regulations promulgated under subsection (d), provide for the establishment and enforcement of standards and procedures governing the possession, use, and transfer of chemical or biological agents and toxins listed pursuant to subsection (a)(1) that are designed to protect public safety and national security, including safeguards to prevent access to such agents and toxins for use in domestic or international terrorism or for any other criminal purpose.

“(c) CIVIL MONEY PENALTIES.—A violation of a requirement imposed by a regulation promulgated under this section shall be subject, in addition to any other applicable civil or criminal sanctions, to a civil money penalty in an amount not to exceed \$250,000.

“(d) REGULATIONS.—The Secretary shall promulgate regulations to carry out this section.

“(e) FREEDOM OF INFORMATION ACT EXEMPTION.—Any information provided to the Secretary pursuant to regulations issued under subsection (d) or under section 351A(c) shall not be disclosed under section 552 of title 5, United States Code.”.

(2) EFFECTIVE DATE.—The amendment made by this subsection shall take effect as if incorporated in the Antiterrorism and Effective Death Penalty Act of 1996.

SEC. 6. ADMINISTRATION.

In administering the provisions of this Act, the Secretary of Health and Human Services shall—

(1) continue to recognize and honor rights relating to patents, data, and copyrights;

(2) comply with all applicable provisions of the regulations relating to Federal acquisition, the Federal Trade Secrets Act, and all other laws protecting confidential commercial information, trade secrets, and intellectual property rights, and patent and non-patent market exclusivity rights.

SEC. 7. COORDINATION OF EFFORTS TO PROTECT AGAINST BIOTERRORISM.

The Secretary of Health and Human Services shall coordinate with the Secretary of Defense in the planning, design, and construction of a Department of Defense government-owned, contractor-operated vaccine production facility on a military installation, as appropriate.

SEC. 8. ENHANCEMENT OF PENALTIES FOR ANIMAL AND PLANT ENTERPRISE TERRORISM.

Section 43 of title 18, United States Code, is amended—

(1) in subsection (a), by striking “one year” and inserting “5 years”;

(2) in subsection (b)—

(A) by redesignating paragraph (2) as paragraph (3);

(B) by inserting after paragraph (1) the following:

“(2) EXPLOSIVES OR ARSON.—Whoever in the course of a violation of subsection (a) maliciously damages or destroys, or attempts to damage or destroy, by means of fire or an explosive, any building, vehicle, or other real or personal property used by the animal or plant enterprise shall be imprisoned for not less than 5 years and not more than 20 years, fined under this title, or both.”; and

(C) in paragraph (3), as so redesignated, by striking “under this title and” and all that follows through the period and inserting “under this title, imprisoned for life or for any term of years.”; and

(3) in subsection (c)—

(A) by striking “and” at the end of paragraph (1);

(B) by striking the period at the end of paragraph (2) and inserting “; and”; and

(C) by adding at the end the following:

“(3) for any other economic damage resulting from the violation of this section.”.

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By Mr. BAUCUS:

S. 1636. A bill to authorize the negotiation of a Free Trade Agreement with Taiwan, and to provide for expedited congressional consideration of such an agreement; to the Committee on Finance.

Mr. BAUCUS. Mr. President. I rise today to introduce the United States—Taiwan Free Trade Agreement Act of 2001. This bill authorizes the President to begin negotiations with Taiwan on a Free Trade Agreement, FTA, and provides for fast track consideration of a completed agreement by the Congress. Like the U.S.-Jordan Free Trade Agreement that was passed earlier in

the session, this bill emphasizes the importance of promoting sustainable development and maintaining strong labor laws.

Over the past two decades, Taiwan has emerged as an important U.S. ally in the Asia-Pacific region. Together, we have worked to maintain peace and promote development throughout the region. As part of this process, the United States has committed itself to defending Taiwan from aggressive attacks, and provides millions of dollars annually in military aid to the island.

Taiwan has emerged as a vocal supporter of U.S. policy throughout Asia and the world. After the September 11 terrorist attacks, Taiwan was one of the first nations to express condolences and offer whatever aid we might need.

The ties between the United States and Taiwan extend beyond political ones, however.

Taiwan is the United States’ eighth largest trading partner, despite not yet being a member of the World Trade Organization. In 2000, the U.S. exported more than \$22 billion worth of goods and services to Taiwan, more than we exported to either China or Hong Kong.

The trade relationship between the United States and Taiwan has blossomed despite the fact that Taiwan is largely excluded from the international forums that help promote economic and political liberalization. For example, Taiwan is not a member of the United Nations.

This international isolation will start to end in 2002, when Taiwan is scheduled to become a member of the World Trade Organization, WTO. As part of the membership process, Taiwan made a number of trade concessions to further liberalize its trade regime; the U.S. will benefit from the lowered tariffs and declining market barriers that were part of these concessions.

There are opportunities in the Taiwanese market that we must look to seize. For example, U.S. agricultural producers have been particularly under-represented in the list of exports to the region.

A U.S.-Taiwan FTA could eliminate the last barriers to U.S. exports to Taiwan. Exporters, particularly agricultural exporters, would finally have unfettered access to a market of more than 22 million people. Moreover, importers would benefit from reduced tariffs and easier customs regulations.

The economic rationale for a U.S.-Taiwan FTA is indisputable. But the United States has always exported more than just its goods and services. This Nation’s support of freedom and democracy throughout the world has been its most important trade policy for more than two hundred years.

Taiwan shares these values and deserves the continued support, both political and economic, of the United States. Over the past fifty years, Taiwan has evolved from single-party rule to a nation of free and open elections, where the transfer of power takes place

smoothly and peacefully. Today, it is a vibrant democracy that is continuing to progress towards open markets and liberalized trade. Supporting this process with an FTA not only encourages Taiwan to continue its economic reforms, it also serves as an explicit example of the very real benefits of opening markets for those countries that are just beginning to participate in the global trading system.

A free trade agreement with Taiwan is a concrete step that the United States can take towards supporting an ally that shares our values. The fact that such an agreement also promises concrete economic benefits to American farmers and manufacturers makes this process even more essential.

I urge my colleagues to join me in supporting the United States-Taiwan Free Trade Agreement Act of 2001.

By Mr. BOND:

S. 1638. A bill to authorize the Secretary of the Interior to study the suitability and feasibility of designating the French Colonial Heritage Area in the State of Missouri as a unit of the National Park System, and for other purposes; to the Committee on Energy and Natural Resources.

Mr. BOND. Mr President, I rise today to introduce legislation recognizing the historical significance of downtown Sainte Genevieve, MO. Sainte Genevieve was one of the first European settlements west of the Mississippi River, and still contains many structures and artifacts that have survived from its rich early history. Establishing this area as a unit of the National Park System will provide an unparalleled opportunity for Americans to be educated about our Nation's colonial past.

Sainte Genevieve was founded by French settlers in the mid Eighteenth Century. These early pioneers traveled south from French Canada, and built the rare French Colonial style structures that remain in place to this day. Today, the area contains an invaluable wealth of Native American and French Colonial sites, artifacts, and architecture. Perhaps most impressively, downtown Sainte Genevieve contains three of only five poteaux-en-terre (posts in the ground) vertical log French homes remaining in North America, dating from the 1790's.

In addition to the historic downtown district, the area adjacent to Sainte Genevieve is rich in historic sites. The "Grand Champ" common field of the French colonists still retains its original field land pattern. The area's saline salt springs were an important industry source for Native American and European settlers. And nearby ceremonial mounds are evidence of a prehistoric Native American village.

This area is a truly valuable asset to the State of Missouri, and I feel that it is only fair to share it with the entire nation by establishing the French Colonial Heritage Area as a unit of the National Park System. My legislation would take the first step toward such

an establishment by directing the National Park Service to conduct a study of the historic features of Sainte Genevieve. After a thorough study, I am confident that the National Park Service will determine that Sainte Genevieve is the best tool with which to tell the important and fascinating story of the French in the New World.

By Mr. SESSIONS (for himself and Mr. NICKLES):

S. 1641. A bill to impose additional requirements to ensure greater use of the advance payment of the earned income credit and to extend such advanced payment to all taxpayers eligible for the credit; to the Committee on Finance.

Mr. SESSIONS. Mr. President, I take this opportunity to discuss legislation I have offered that would be good public policy for the country and a terrific stimulus for the economy beginning in January. Let me explain what this is about.

We have in this country a policy of helping the working poor called the earned income tax credit. That was passed in 1975. It was designed to help lower income people working on an hourly wage have a higher income to take care of their families. It is shaded in fact pretty heavily in favor of low-income people who have children.

It has worked well on the whole. There have been a lot of people who have criticized it. They have called it welfare. In a way, it is a benefit given. But it is a benefit given in exchange for work, when a person works. It is a benefit from the Federal Government called the earned income tax credit. It is a tax credit. If you work, you earn it. It has in general been a good way to help the working poor, as we call them today. Since 1975, we have done that.

The way the person receives the money, however, is detached from their work. The way a person receives their earned income tax credit is to file their tax return in February, March, April and get a tax return the next year after working all year. For example, for the year 2001, a low-income worker with two or more children could claim \$4,008 in earned income tax credit, a worker with one child could receive up to \$2,428, and a worker with no children could receive \$364. The average earned income tax credit for a beneficiary with a qualifying child, one child, in 1999, was \$1,941. That is about \$150 a month, almost \$1 an hour when figured on 160 hours for a month. It is a significant benefit from the Federal Government.

From a public policy point of view, it has been less effective in achieving the goal we want it to achieve, which is to encourage work, because it is received at the end of the year, really the next year; and it is disconnected to the work the person has undertaken.

We want to encourage people to work. We want work to be more rewarding. We want a person making \$6 an hour making \$7 an hour, just like

that. Let's have them make \$8 an hour if they were making \$7. This could be done if we could in fact have this earned income tax credit paid at the time the person works, as part of their paycheck.

In fact, this idea had been discussed earlier, a number of years ago. We passed a bill in this Congress that would allow people to choose this and, oddly, not many people have. However, most people don't fully understand it. Others are afraid they might end up having a tax liability next year and didn't choose it. I don't think businesses have encouraged people to take it as much as they should and, as a result, only 5 percent of the people who are eligible and choose this earned income tax credit have it paid to them in advance when they work. So I think we have a problem there. We can strengthen our economy and we can strengthen the reward for a person going to work if we tie this credit to the work they do, to their paycheck.

In addition, I have discovered that the earned income tax credit is worth, for America, \$31 billion a year. That is a lot of money by any standard. As we are looking at this time how to create an infusion of cash into our economy in a way that would strengthen this economy to make it more healthy, more vibrant, to get people purchasing again, to put dollars in the hands of consumers. I can think of no better way with the least possible cost to the Treasury than to have this money that would be entitled to come in the next fiscal year actually start coming in January on a person's paycheck. I think that would be a tremendous way to pour additional money into the economy without having any impact on the Treasury, except the loss of interest on the money the Federal Government would be sitting on. This would not hurt poor people in any way. It would not withhold or delay them receiving any money. But in fact it would advance their receipt of the money. So they would be receiving in February, March, April, May, when their tax refund comes due, their refund under the earned income tax credit for this year's work, but they would have already begun on January 1 of this year to receive on their paycheck the money for next year. So it would advance that payment and would provide a real stimulus to the economy because low-income people are going to be the ones who are most likely to spend it.

Remember, it would impact their paychecks significantly in that there is no withholding from this earned income tax credit. They will have already paid their insurance, retirement benefits, Social Security, FICA, and withholding taxes. All of that would have already been paid. Whatever they get in addition would be money they could put into their pockets. So it would achieve the goal of the earned income tax credit to enhance and make work more valuable and, at the same

time, would provide a tremendous stimulus to our economy. I am excited about this possibility, and I know Senator REED, who is in the chair, and I have discussed this. He was at least intrigued by this idea.

I was pleased today that Senator NICKLES, who has been a critic of the earned income tax credit, one who has studied it carefully and has observed some of its problems, believes it is a good reform, and he is supporting and has signed onto this bill as an original cosponsor.

So we have an opportunity to do something good for the economy, to do something good for poor people, to in effect have the businesses that now have to provide the option to their employees to go on and provide this money, which is reimbursed by the Federal Government immediately—it doesn't cost them anything—and their workers would receive 50 or 60 cents an hour pay raise as a result of this payment. I think it is something they ought to be excited about doing. I think it would enhance their workers benefits from working and make them better employees.

So it is time for us to do it now. I have been concerned about the issue. I have studied it for a number of years. I had some independent research done on it several years ago, and I have been thinking and looking for an opportunity to present it in the form of legislation. At this time, when we need a financial stimulus, I can't think of a better time. So I am asking the Finance Committee, and I have talked with the Director of the OMB, Mitch Daniels, the Secretary of the Treasury, Mr. O'Neill, and his top staff person. They are all intrigued by this and believe it has merit.

I think it is time for us to consider that this be a part of our stimulus package. It has little long-term impact on the Federal Treasury, but it would provide a tremendous infusion of cash into the economy just at the time we need people to go to the store and buy things, generating demand out there that would allow factories to produce more products. It would be giving additional wages to people who may be getting less overtime now than they were a year ago—maybe not even getting 40 hours a week now as they were last year. Those people would receive higher wages for each hour they do work.

I talked to a businessperson today, and they said they were on 4-day work-weeks with their employees. They hated to do it, but there wasn't demand for their products sufficient to keep them fully engaged. Rather than lay people off, they put everybody on a 4-day workweek. So a lot of people are losing hours, and this would help keep them from losing income. I think it is good for the low-income workers in America. I think it is good for the economy, and I think it is good public policy for America.

Mr. President, we have talked with members of the Finance Committee

and with the administration. I hope they will seize this opportunity to do something that, to me, has a win-win-win all over it, with no negatives. It is the right thing to do. Some say, well, business people may not want to handle the paperwork on this. Businesspeople print their checks out by computers, and it is not difficult for them. The money is paid to them. I talked to one gentlemen who hires employees—quite a number of low-income workers. He said he thought it was a wonderful idea. It would be great for his workers, and it would be no problem at all for them to make that a part of their payroll check plan. It is just a matter of getting the person who processes that to factor it in, and it works rather easily.

Again, I believe it is a good idea, and I have submitted it to the Senate. I will be talking with the leadership and urging its passage. It is the right thing to do, and I think we ought to do it. The time is long past that we make this earned income tax credit really do what it is supposed to do, which is encourage work. It is to encourage people to work and, at the same time, when we do it by advancing it this year, we will provide a stimulus to the economy in a very significant way. We estimate that out of \$31 billion in earned income tax credit, we would be advancing at least \$15 billion next year, and that would be a healthy stimulus indeed for the economy.

By Mr. ENZI:

S. 1642. A bill to open certain withdrawn land in Big Horn County Wyoming, to locatable mineral development for bentonite mining; to the Committee on Energy and Natural Resources.

Mr. ENZI. Mr. President, I ask unanimous consent that the text of the bill be printed in the RECORD.

There being no objection, the bill was ordered to be printed in the RECORD, as follows:

S. 1642

Be it enacted by the Senate and House of Representatives of the United States of America in Congress assembled,

SECTION 1. OPENING OF CERTAIN WITHDRAWN LAND IN WYOMING TO LOCATABLE MINERAL DEVELOPMENT FOR BENTONITE MINING.

(a) IN GENERAL.—Notwithstanding any other provision of law and subject to subsection (c), the land described in subsection (b) shall be open to locatable mineral development for bentonite mining.

(b) COVERED LAND.—The land referred to in subsection (a) is approximately 40 acres of previously withdrawn land located in Big Horn County, Wyoming, at the sixth principal meridian, T. 56 N., R. 95 W., Sec. 32. E $\frac{1}{2}$ E $\frac{1}{2}$ SE $\frac{1}{4}$, adjacent to Pit No. 144L covered by State of Wyoming Mining Permit No. 321C.

(c) CLOSURE.—The Secretary of the Army may close the land opened by subsection (a) at any time if the Secretary determines that the closure of the land is required by reason of a national emergency or for purposes of national defense or security.

AMENDMENTS SUBMITTED AND PROPOSED

SA 2089. Mr. GRAMM submitted an amendment intended to be proposed by him to the bill H.R. 3061, making appropriations for the Departments of Labor, Health and Human Services, and Education, and related agencies for the fiscal year ending September 30, 2002, and for other purposes; which was ordered to lie on the table.

SA 2090. Mr. GRAMM submitted an amendment intended to be proposed by him to the bill H.R. 3061, *supra*; which was ordered to lie on the table.

SA 2091. Mr. GRAMM submitted an amendment intended to be proposed by him to the bill H.R. 3061, *supra*; which was ordered to lie on the table.

SA 2092. Mr. GRAMM submitted an amendment intended to be proposed by him to the bill H.R. 3061, *supra*; which was ordered to lie on the table.

SA 2093. Mr. GRAMM submitted an amendment intended to be proposed by him to the bill H.R. 3061, *supra*; which was ordered to lie on the table.

SA 2094. Mr. GRAMM submitted an amendment intended to be proposed by him to the bill H.R. 3061, *supra*; which was ordered to lie on the table.

SA 2095. Mr. NICKLES submitted an amendment intended to be proposed to amendment SA 2044 submitted by Mr. Daschle and intended to be proposed to the bill (H.R. 3061) *supra*; which was ordered to lie on the table.

SA 2096. Mr. NICKLES submitted an amendment intended to be proposed to amendment SA 2044 submitted by Mr. Daschle and intended to be proposed to the bill (H.R. 3061) *supra*; which was ordered to lie on the table.

SA 2097. Mr. NICKLES submitted an amendment intended to be proposed to amendment SA 2044 submitted by Mr. Daschle and intended to be proposed to the bill (H.R. 3061) *supra*; which was ordered to lie on the table.

SA 2098. Mr. NICKLES submitted an amendment intended to be proposed to amendment SA 2044 submitted by Mr. Daschle and intended to be proposed to the bill (H.R. 3061) *supra*; which was ordered to lie on the table.

SA 2099. Mr. NICKLES submitted an amendment intended to be proposed to amendment SA 2044 submitted by Mr. Daschle and intended to be proposed to the bill (H.R. 3061) *supra*; which was ordered to lie on the table.

SA 2100. Mr. NICKLES submitted an amendment intended to be proposed to amendment SA 2044 submitted by Mr. Daschle and intended to be proposed to the bill (H.R. 3061) *supra*; which was ordered to lie on the table.

SA 2101. Mr. KENNEDY submitted an amendment intended to be proposed to amendment SA 2044 submitted by Mr. Daschle and intended to be proposed to the bill (H.R. 3061) *supra*; which was ordered to lie on the table.

SA 2102. Mr. KENNEDY submitted an amendment intended to be proposed to amendment SA 2044 submitted by Mr. Daschle and intended to be proposed to the bill (H.R. 3061) *supra*; which was ordered to lie on the table.

SA 2103. Mr. KENNEDY submitted an amendment intended to be proposed to amendment SA 2044 submitted by Mr. Daschle and intended to be proposed to the bill (H.R. 3061) *supra*; which was ordered to lie on the table.

SA 2104. Mr. KENNEDY submitted an amendment intended to be proposed to amendment SA 2044 submitted by Mr.