and Publishing Company of Brooklyn, developed a cooling solution which ended up revolutionalizing the world we live in.

Dr. Carrier had grown up an only child, surrounded by a large extended family on a farm in Angola, NY. He worked three jobs during his college years at Cornell to pay for his room and board, and showed a work ethic and tirelessness that carried over into his career as a mechanical engineer. His first job after graduation was with the Buffalo Forge Company planning heating mechanisms for the drying of coffee and lumber. It was soon after a promotion to head of the Forge Company's department of experimental engineering that he made his breakthrough with the control of heat and humidity for the Sackett-Williams Company that led to modern air conditioning.

Several years later, he and six friends formed their own company in Syracuse, NY, Carrier, that now has current annual revenues of $9 billion and clients in 170 countries. Indeed, not only has this company grown over the past century, but the expanding role and impact of modern air conditioning has been nothing short of tremendous. Air conditioning has afforded us such a dramatic improvement in quality of life that it is difficult now to conceive of its absence. It has increased our economic productivity and output, our comfort and our mood, and in some cases, our general health and welfare. Some have suggested that air conditioning is even responsible for keeping Washington as our Nation's capital, when long, unbearable summer months not only shortened the legislative session, but threatened to send politicians looking for a more climatically hospitable city to conduct their business in. Dr. Carrier brought air-conditioning to the House Chamber in 1928 and the Senate Chamber in 1929.

Indeed, on a 93 degree day such as today, I think we all see the special value of Dr. Carrier's life's work, and I ask my colleagues to join me remembering him today, and giving our thanks for modern air conditioner.

## AMENDMENTS SUBMITTED AND PROPOSED

SA 4299. Mr. REID (for Mr. DORGAN (for himself, Mr. WELLSTONE, Mr. JEFFORDS, Ms. STABENOW, Ms. COLLINS, Mr. LEVIN, Mr. JOHNSON, Mr. MILLER, Mr. DURBIN, Mr. FEINGOLD, and Mr. HARKIN)) proposed an amendment to the bill S. 812, to amend the Federal Food, Drug, and Cosmetic Act to provide greater access to affordable pharmaceuticals.

SA 4300. Mr. REID (for Mr. DORGAN (for himself, Mr. WELLSTONE, Mr. JEFFORDS, Ms. STABENOW, Ms. COLLINS, Mr. LEVIN, Mr. JOHNSON, Mr. MILLER, Mr. DURBIN, and Mr. FEINGOLD)) proposed an amendment to amendment SA 4299 proposed by Mr. REID (for Mr. DORGAN (for himself, Mr. WELLSTONE, Mr. JEFFORDS, Ms. STABENOW, Ms. COLLINS, Mr. LEVIN, Mr. JOHNSON, Mr. MILLER, Mr. DURBIN, Mr. FEINGOLD, and Mr. HARKIN)) to the bill (S. 812) supra.

SA 4301. Mr. COCHRAN (for himself, Mr. BREAUX, Mr. ROBERTS, Mr. SANTORUM, Mr. NICKLES, and Mr. HUTCHINSON) proposed an amendment to amendment SA 4299 proposed by Mr. REID (for Mr. DORGAN (for himself, Mr. WELLSTONE, Mr. JEFFORDS, Ms. STABENOW, Ms. COLLINS, Mr. LEVIN, Mr. JOHNSON, Mr. MILLER, Mr. DURBIN, Mr. FEINGOLD, and Mr. HARKIN)) to the bill (S. 812) supra.

SA 4302. Mr. THOMAS (for himself and Mr. ROBERTS) submitted an amendment intended to be proposed to amendment SA 4299 proposed by Mr. REID (for Mr. DORGAN (for himself, Mr. WELLSTONE, Mr. JEFFORDS, Ms. STABENOW, Ms. COLLINS, Mr. LEVIN, Mr. JOHNSON, Mr. MILLER, Mr. DURBIN, Mr. FEINGOLD, and Mr. HARKIN)) to the bill (S. 812) supra; which was ordered to lie on the table.

SA 4303. Mrs. FEINSTEIN submitted an amendment intended to be proposed by her to the bill S. 812, supra; which was ordered to lie on the table.

SA 4304. Mr. SMITH, of New Hampshire (for himself, Mr. ALLARD, Mr. GRASSLEY, Mr. HATCH, Mr. BURNS, Mr. CRAIG, Mr. CRAPO, and Mr. SANTORUM) submitted an amendment intended to be proposed by him to the bill S. 812, supra; which was ordered to lie on the table.

SA 4305. Mr. REID (for Ms. STABENOW) proposed an amendment to the bill S. 812, supra.

SA 4306. Mrs. FEINSTEIN (for herself and Mrs. HUTCHISON) proposed an amendment to the bill H.R. 5011, making appropriations for military construction, family housing, and base realignment and closure for the Department of Defense for the fiscal year ending September 30, 2003, and for other purposes.

## TEXT OF AMENDMENTS

**SA 4299.** Mr. REID (for Mr. DORGAN (for himself, Mr. WELLSTONE, Mr. JEFFORDS, Ms. STABENOW, Ms. COLLINS, Mr. LEVIN, Mr. JOHNSON, Mr. MILLER, Mr. DURBIN, Mr. FEINGOLD, and Mr. HARKIN)) proposed an amendment to the bill S. 812), to amend the Federal Food, Drug, and Cosmetic Act to provide greater access to affordable pharmaceuticals; and follows:

S. 812

At the end, add the following:

**TITLE ____—IMPORTATION OF PRESCRIPTION DRUGS**

**SEC. ____01. IMPORTATION OF PRESCRIPTION DRUGS.**

(a) IN GENERAL.—Chapter VIII of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 381 et seq.) is amended by striking section 804 and inserting the following:

**"SEC. 804. IMPORTATION OF PRESCRIPTION DRUGS.**

"(a) DEFINITIONS.—In this section:

"(1) IMPORTER.—The term 'importer' means a pharmacist or wholesaler.

"(2) PHARMACIST.—The term 'pharmacist' means a person licensed by a State to practice pharmacy, including the dispensing and selling of prescription drugs.

"(3) PRESCRIPTION DRUG.—The term 'prescription drug' means a drug subject to section 503(b), other than—

"(A) a controlled substance (as defined in section 102 of the Controlled Substances Act (21 U.S.C. 802));

"(B) a biological product (as defined in section 351 of the Public Health Service Act (42 U.S.C. 262));

"(C) an infused drug (including a peritoneal dialysis solution);

"(D) an intravenously injected drug; or

"(E) a drug that is inhaled during surgery.

"(4) QUALIFYING LABORATORY.—The term 'qualifying laboratory' means a laboratory in the United States that has been approved by the Secretary for the purposes of this section.

"(5) WHOLESALER.—

"(A) IN GENERAL.—The term 'wholesaler' means a person licensed as a wholesaler or distributor of prescription drugs in the United States under section 503(e)(2)(A).

"(B) EXCLUSION.—The term 'wholesaler' does not include a person authorized to import drugs under section 801(d)(1).

"(b) REGULATIONS.—The Secretary, after consultation with the United States Trade Representative and the Commissioner of Customs, shall promulgate regulations permitting pharmacists and wholesalers to import prescription drugs from Canada into the United States.

"(c) LIMITATION.—The regulations under subsection (b) shall—

"(1) require that safeguards be in place to ensure that each prescription drug imported under the regulations complies with section 505 (including with respect to being safe and effective for the intended use of the prescription drug), with sections 501 and 502, and with other applicable requirements of this Act;

"(2) require that an importer of a prescription drug under the regulations comply with subsections (d)(1) and (e); and

"(3) contain any additional provisions determined by the Secretary to be appropriate as a safeguard to protect the public health or as a means to facilitate the importation of prescription drugs.

"(d) INFORMATION AND RECORDS.—

"(1) IN GENERAL.—The regulations under subsection (b) shall require an importer of a prescription drug under subsection (b) to submit to the Secretary the following information and documentation:

"(A) The name and quantity of the active ingredient of the prescription drug.

"(B) A description of the dosage form of the prescription drug.

"(C) The date on which the prescription drug is shipped.

"(D) The quantity of the prescription drug that is shipped.

"(E) The point of origin and destination of the prescription drug.

"(F) The price paid by the importer for the prescription drug.

"(G) Documentation from the foreign seller specifying—

"(i) the original source of the prescription drug; and

"(ii) the quantity of each lot of the prescription drug originally received by the seller from that source.

"(H) The lot or control number assigned to the prescription drug by the manufacturer of the prescription drug.

"(I) The name, address, telephone number, and professional license number (if any) of the importer.

"(J)(i) In the case of a prescription drug that is shipped directly from the first foreign recipient of the prescription drug from the manufacturer:

"(I) Documentation demonstrating that the prescription drug was received by the recipient from the manufacturer and subsequently shipped by the first foreign recipient to the importer.

"(II) Documentation of the quantity of each lot of the prescription drug received by the first foreign recipient demonstrating that the quantity being imported into the United States is not more than the quantity that was received by the first foreign recipient.

"(III)(aa) In the case of an initial imported shipment, documentation demonstrating that each batch of the prescription drug in the shipment was statistically sampled and tested for authenticity and degradation.

''(bb) In the case of any subsequent shipment, documentation demonstrating that a statistically valid sample of the shipment was tested for authenticity and degradation.

''(ii) In the case of a prescription drug that is not shipped directly from the first foreign recipient of the prescription drug from the manufacturer, documentation demonstrating that each batch in each shipment offered for importation into the United States was statistically sampled and tested for authenticity and degradation.

''(K) Certification from the importer or manufacturer of the prescription drug that the prescription drug—

''(i) is approved for marketing in the United States; and

''(ii) meets all labeling requirements under this Act.

''(L) Laboratory records, including complete data derived from all tests necessary to ensure that the prescription drug is in compliance with established specifications and standards.

''(M) Documentation demonstrating that the testing required by subparagraphs (J) and (L) was conducted at a qualifying laboratory.

''(N) Any other information that the Secretary determines is necessary to ensure the protection of the public health.

''(2) MAINTENANCE BY THE SECRETARY.—The Secretary shall maintain information and documentation submitted under paragraph (1) for such period of time as the Secretary determines to be necessary.

''(e) TESTING.—The regulations under subsection (b) shall require—

''(1) that testing described in subparagraphs (J) and (L) of subsection (d)(1) be conducted by the importer or by the manufacturer of the prescription drug at a qualified laboratory;

''(2) if the tests are conducted by the importer—

''(A) that information needed to—

''(i) authenticate the prescription drug being tested; and

''(ii) confirm that the labeling of the prescription drug complies with labeling requirements under this Act;

be supplied by the manufacturer of the prescription drug to the pharmacist or wholesaler; and

''(B) that the information supplied under subparagraph (A) be kept in strict confidence and used only for purposes of testing or otherwise complying with this Act; and

''(3) may include such additional provisions as the Secretary determines to be appropriate to provide for the protection of trade secrets and commercial or financial information that is privileged or confidential.

''(f) REGISTRATION OF FOREIGN SELLERS.—Any establishment within Canada engaged in the distribution of a prescription drug that is imported or offered for importation into the United States shall register with the Secretary the name and place of business of the establishment.

''(g) APPROVED LABELING.—The manufacturer of a prescription drug shall provide an importer written authorization for the importer to use, at no cost, the approved labeling for the prescription drug.

''(h) PROHIBITION OF DISCRIMINATION.—

''(1) IN GENERAL.—It shall be unlawful for a manufacturer of a prescription drug to discriminate against, or cause any other person to discriminate against, a pharmacist or wholesaler that purchases or offers to purchase a prescription drug from the manufacturer or from any person that distributes a prescription drug manufactured by the drug manufacturer.

''(2) DISCRIMINATION.—For the purposes of paragraph (1), a manufacturer of a prescription drug shall be considered to discriminate against a pharmacist or wholesaler if the manufacturer enters into a contract for sale of a prescription drug, places a limit on supply, or employs any other measure, that has the effect of—

''(A) providing pharmacists or wholesalers access to prescription drugs on terms or conditions that are less favorable than the terms or conditions provided to a foreign purchaser (other than a charitable or humanitarian organization) of the prescription drug; or

''(B) restricting the access of pharmacists or wholesalers to a prescription drug that is permitted to be imported into the United States under this section.

''(i) CHARITABLE CONTRIBUTIONS.—Notwithstanding any other provision of this section, section 801(d)(1) continues to apply to a prescription drug that is donated or otherwise supplied at no charge by the manufacturer of the drug to a charitable or humanitarian organization (including the United Nations and affiliates) or to a government of a foreign country.

''(j) WAIVER AUTHORITY FOR IMPORTATION BY INDIVIDUALS.—

''(1) DECLARATIONS.—Congress declares that in the enforcement against individuals of the prohibition of importation of prescription drugs and devices, the Secretary should—

''(A) focus enforcement on cases in which the importation by an individual poses a significant threat to public health; and

''(B) exercise discretion to permit individuals to make such importations in circumstances in which—

''(i) the importation is clearly for personal use; and

''(ii) the prescription drug or device imported does not appear to present an unreasonable risk to the individual.

''(2) WAIVER AUTHORITY.—

''(A) IN GENERAL.—The Secretary may grant to individuals, by regulation or on a case-by-case basis, a waiver of the prohibition of importation of a prescription drug or device or class of prescription drugs or devices, under such conditions as the Secretary determines to be appropriate.

''(B) GUIDANCE ON CASE-BY-CASE WAIVERS.—The Secretary shall publish, and update as necessary, guidance that accurately describes circumstances in which the Secretary will consistently grant waivers on a case-by-case basis under subparagraph (A), so that individuals may know with the greatest practicable degree of certainty whether a particular importation for personal use will be permitted.

''(3) DRUGS IMPORTED FROM CANADA.—In particular, the Secretary shall by regulation grant individuals a waiver to permit individuals to import into the United States a prescription drug that—

''(A) is imported from a licensed pharmacy for personal use by an individual, not for resale, in quantities that do not exceed a 90-day supply;

''(B) is accompanied by a copy of a valid prescription;

''(C) is imported from Canada, from a seller registered with the Secretary;

''(D) is a prescription drug approved by the Secretary under chapter V;

''(E) is in the form of a final finished dosage that was manufactured in an establishment registered under section 510; and

''(F) is imported under such other conditions as the Secretary determines to be necessary to ensure public safety.

''(k) STUDIES; REPORTS.—

''(1) BY THE INSTITUTE OF MEDICINE OF THE NATIONAL ACADEMY OF SCIENCES.—

''(A) STUDY.—

''(i) IN GENERAL.—The Secretary shall request that the Institute of Medicine of the National Academy of Sciences conduct a study of—

''(I) importations of prescription drugs made under the regulations under subsection (b); and

''(II) information and documentation submitted under subsection (d).

''(ii) REQUIREMENTS.—In conducting the study, the Institute of Medicine shall—

''(I) evaluate the compliance of importers with the regulations under subsection (b);

''(II) compare the number of shipments under the regulations under subsection (b) during the study period that are determined to be counterfeit, misbranded, or adulterated, and compare that number with the number of shipments made during the study period within the United States that are determined to be counterfeit, misbranded, or adulterated; and

''(III) consult with the Secretary, the United States Trade Representative, and the Commissioner of Patents and Trademarks to evaluate the effect of importations under the regulations under subsection (b) on trade and patent rights under Federal law.

''(B) REPORT.—Not later than 2 years after the effective date of the regulations under subsection (b), the Institute of Medicine shall submit to Congress a report describing the findings of the study under subparagraph (A).

''(2) BY THE COMPTROLLER GENERAL.—

''(A) STUDY.—The Comptroller General of the United States shall conduct a study to determine the effect of this section on the price of prescription drugs sold to consumers at retail.

''(B) REPORT.—Not later than 18 months after the effective date of the regulations under subsection (b), the Comptroller General of the United States shall submit to Congress a report describing the findings of the study under subparagraph (A).

''(l) CONSTRUCTION.—Nothing in this section limits the authority of the Secretary relating to the importation of prescription drugs, other than with respect to section 801(d)(1) as provided in this section.

''(m) AUTHORIZATION OF APPROPRIATIONS.—There are authorized to be appropriated such sums as are necessary to carry out this section.''.

(b) CONFORMING AMENDMENTS.—The Federal Food, Drug, and Cosmetic Act is amended—

(1) in section 301(aa) (21 U.S.C. 331(aa)), by striking ''covered product in violation of section 804'' and inserting ''prescription drug in violation of section 804''; and

(2) in section 303(a)(6) (21 U.S.C. 333(a)(6), by striking ''covered product pursuant to section 804(a)'' and inserting ''prescription drug under section 804(b)''.

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**SA 4300.** Mr. REID (for Mr. DORGAN (for himself, Mr. WELLSTONE, Mr. JEFFORDS, Ms. STABENOW, Ms. COLLINS, Mr. LEVIN, Mr. JOHNSON, Mr. MILLER, Mr. DURBIN, and Mr. FEINGOLD)) proposed an amendment to amendment SA 4299 proposed by Mr. REID (for Mr. DORGAN (for himself, Mr. WELLSTONE, Mr. JEFFORDS, Ms. STABENOW, Ms. COLLINS, Mr. LEVIN, Mr. JOHNSON, Mr. MILLER, Mr. DURBIN, Mr. FEINGOLD, and Mr. HARKIN)) to the bill (S. 812) to amend the Federal Food, Drug, and Cosmetic Act to provide greater access to affordable pharmaceuticals; as follows:

In the amendment strike all after the first word and insert the following:

**____—IMPORTATION OF PRESCRIPTION DRUGS**

**SEC. ____01. IMPORTATION OF PRESCRIPTION DRUGS.**

(a) IN GENERAL.—Chapter VIII of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 381 et seq.) is amended by striking section 804 and inserting the following:

**"SEC. 804. IMPORTATION OF PRESCRIPTION DRUGS.**

''(a) DEFINITIONS.—In this section:

''(1) IMPORTER.—The term 'importer' means a pharmacist or wholesaler.

''(2) PHARMACIST.—The term 'pharmacist' means a person licensed by a State to practice pharmacy, including the dispensing and selling of prescription drugs.

''(3) PRESCRIPTION DRUG.—The term 'prescription drug' means a drug subject to section 503(b), other than—

''(A) a controlled substance (as defined in section 102 of the Controlled Substances Act (21 U.S.C. 802));

''(B) a biological product (as defined in section 351 of the Public Health Service Act (42 U.S.C. 262));

''(C) an infused drug (including a peritoneal dialysis solution);

''(D) an intravenously injected drug; or

''(E) a drug that is inhaled during surgery.

''(4) QUALIFYING LABORATORY.—The term 'qualifying laboratory' means a laboratory in the United States that has been approved by the Secretary for the purposes of this section.

''(5) WHOLESALER.—

''(A) IN GENERAL.—The term 'wholesaler' means a person licensed as a wholesaler or distributor of prescription drugs in the United States under section 503(e)(2)(A).

''(B) EXCLUSION.—The term 'wholesaler' does not include a person authorized to import drugs under section 801(d)(1).

''(b) REGULATIONS.—The Secretary, after consultation with the United States Trade Representative and the Commissioner of Customs, shall promulgate regulations permitting pharmacists and wholesalers to import prescription drugs from Canada into the United States.

''(c) LIMITATION.—The regulations under subsection (b) shall—

''(1) require that safeguards be in place to ensure that each prescription drug imported under the regulations complies with section 505 (including with respect to being safe and effective for the intended use of the prescription drug), with sections 501 and 502, and with other applicable requirements of this Act;

''(2) require that an importer of a prescription drug under the regulations comply with subsections (d)(1) and (e); and

''(3) contain any additional provisions determined by the Secretary to be appropriate as a safeguard to protect the public health or as a means to facilitate the importation of prescription drugs.

''(d) INFORMATION AND RECORDS.—

''(1) IN GENERAL.—The regulations under subsection (b) shall require an importer of a prescription drug under subsection (b) to submit to the Secretary the following information and documentation:

''(A) The name and quantity of the active ingredient of the prescription drug.

''(B) A description of the dosage form of the prescription drug.

''(C) The date on which the prescription drug is shipped.

''(D) The quantity of the prescription drug that is shipped.

''(E) The point of origin and destination of the prescription drug.

''(F) The price paid by the importer for the prescription drug.

''(G) Documentation from the foreign seller specifying—

''(i) the original source of the prescription drug; and

''(ii) the quantity of each lot of the prescription drug originally received by the seller from that source.

''(H) The lot or control number assigned to the prescription drug by the manufacturer of the prescription drug.

''(I) The name, address, telephone number, and professional license number (if any) of the importer.

''(J)(i) In the case of a prescription drug that is shipped directly from the first foreign recipient of the prescription drug from the manufacturer:

''(I) Documentation demonstrating that the prescription drug was received by the recipient from the manufacturer and subsequently shipped by the first foreign recipient to the importer.

''(II) Documentation of the quantity of each lot of the prescription drug received by the first foreign recipient demonstrating that the quantity being imported into the United States is not more than the quantity that was received by the first foreign recipient.

''(III)(aa) In the case of an initial imported shipment, documentation demonstrating that each batch of the prescription drug in the shipment was statistically sampled and tested for authenticity and degradation.

''(bb) In the case of any subsequent shipment, documentation demonstrating that a statistically valid sample of the shipment was tested for authenticity and degradation.

''(ii) In the case of a prescription drug that is not shipped directly from the first foreign recipient of the prescription drug from the manufacturer, documentation demonstrating that each batch in each shipment offered for importation into the United States was statistically sampled and tested for authenticity and degradation.

''(K) Certification from the importer or manufacturer of the prescription drug that the prescription drug—

''(i) is approved for marketing in the United States; and

''(ii) meets all labeling requirements under this Act.

''(L) Laboratory records, including complete data derived from all tests necessary to ensure that the prescription drug is in compliance with established specifications and standards.

''(M) Documentation demonstrating that the testing required by subparagraphs (J) and (L) was conducted at a qualifying laboratory.

''(N) Any other information that the Secretary determines is necessary to ensure the protection of the public health.

''(2) MAINTENANCE BY THE SECRETARY.—The Secretary shall maintain information and documentation submitted under paragraph (1) for such period of time as the Secretary determines to be necessary.

''(e) TESTING.—The regulations under subsection (b) shall require—

''(1) that testing described in subparagraphs (J) and (L) of subsection (d)(1) be conducted by the importer or by the manufacturer of the prescription drug at a qualified laboratory;

''(2) if the tests are conducted by the importer—

''(A) that information needed to—

''(i) authenticate the prescription drug being tested; and

''(ii) confirm that the labeling of the prescription drug complies with labeling requirements under this Act;

be supplied by the manufacturer of the prescription drug to the pharmacist or wholesaler; and

''(B) that the information supplied under subparagraph (A) be kept in strict confidence and used only for purposes of testing or otherwise complying with this Act; and

''(3) may include such additional provisions as the Secretary determines to be appropriate to provide for the protection of trade secrets and commercial or financial information that is privileged or confidential.

''(f) REGISTRATION OF FOREIGN SELLERS.—Any establishment within Canada engaged in the distribution of a prescription drug that is imported or offered for importation into the United States shall register with the Secretary the name and place of business of the establishment.

''(g) SUSPENSION OF IMPORTATION.—The Secretary shall require that importations of a specific prescription drug or importations by a specific importer under subsection (b) be immediately suspended on discovery of a pattern of importation of the prescription drugs or by the importer that is counterfeit or in violation of any requirement under this section or poses an additional risk to the public health, until an investigation is completed and the Secretary determines that the public is adequately protected from counterfeit and violative prescription drugs being imported under subsection (b).

''(h) APPROVED LABELING.—The manufacturer of a prescription drug shall provide an importer written authorization for the importer to use, at no cost, the approved labeling for the prescription drug.

''(i) PROHIBITION OF DISCRIMINATION.—

''(1) IN GENERAL.—It shall be unlawful for a manufacturer of a prescription drug to discriminate against, or cause any other person to discriminate against, a pharmacist or wholesaler that purchases or offers to purchase a prescription drug from the manufacturer or from any person that distributes a prescription drug manufactured by the drug manufacturer.

''(2) DISCRIMINATION.—For the purposes of paragraph (1), a manufacturer of a prescription drug shall be considered to discriminate against a pharmacist or wholesaler if the manufacturer enters into a contract for sale of a prescription drug, places a limit on supply, or employs any other measure, that has the effect of—

''(A) providing pharmacists or wholesalers access to prescription drugs on terms or conditions that are less favorable than the terms or conditions provided to a foreign purchaser (other than a charitable or humanitarian organization) of the prescription drug; or

''(B) restricting the access of pharmacists or wholesalers to a prescription drug that is permitted to be imported into the United States under this section.

''(j) CHARITABLE CONTRIBUTIONS.—Notwithstanding any other provision of this section, section 801(d)(1) continues to apply to a prescription drug that is donated or otherwise supplied at no charge by the manufacturer of the drug to a charitable or humanitarian organization (including the United Nations and affiliates) or to a government of a foreign country.

''(k) WAIVER AUTHORITY FOR IMPORTATION BY INDIVIDUALS.—

''(1) DECLARATIONS.—Congress declares that in the enforcement against individuals of the prohibition of importation of prescription drugs and devices, the Secretary should—

''(A) focus enforcement on cases in which the importation by an individual poses a significant threat to public health; and

''(B) exercise discretion to permit individuals to make such importations in circumstances in which—

''(i) the importation is clearly for personal use; and

''(ii) the prescription drug or device imported does not appear to present an unreasonable risk to the individual.

''(2) WAIVER AUTHORITY.—

''(A) IN GENERAL.—The Secretary may grant to individuals, by regulation or on a case-by-case basis, a waiver of the prohibition of importation of a prescription drug or device or class of prescription drugs or devices, under such conditions as the Secretary determines to be appropriate.

''(B) GUIDANCE ON CASE-BY-CASE WAIVERS.—The Secretary shall publish, and update as necessary, guidance that accurately describes circumstances in which the Secretary will consistently grant waivers on a case-by-case basis under subparagraph (A), so that individuals may know with the greatest practicable degree of certainty whether a particular importation for personal use will be permitted.

''(3) DRUGS IMPORTED FROM CANADA.—In particular, the Secretary shall by regulation grant individuals a waiver to permit individuals to import into the United States a prescription drug that—

''(A) is imported from a licensed pharmacy for personal use by an individual, not for resale, in quantities that do not exceed a 90-day supply;

''(B) is accompanied by a copy of a valid prescription;

''(C) is imported from Canada, from a seller registered with the Secretary;

''(D) is a prescription drug approved by the Secretary under chapter V;

''(E) is in the form of a final finished dosage that was manufactured in an establishment registered under section 510; and

''(F) is imported under such other conditions as the Secretary determines to be necessary to ensure public safety.

''(l) STUDIES; REPORTS.—

''(1) BY THE INSTITUTE OF MEDICINE OF THE NATIONAL ACADEMY OF SCIENCES.—

''(A) STUDY.—

''(i) IN GENERAL.—The Secretary shall request that the Institute of Medicine of the National Academy of Sciences conduct a study of—

''(I) importations of prescription drugs made under the regulations under subsection (b); and

''(II) information and documentation submitted under subsection (d).

''(ii) REQUIREMENTS.—In conducting the study, the Institute of Medicine shall—

''(I) evaluate the compliance of importers with the regulations under subsection (b);

''(II) compare the number of shipments under the regulations under subsection (b) during the study period that are determined to be counterfeit, misbranded, or adulterated, and compare that number with the number of shipments made during the study period within the United States that are determined to be counterfeit, misbranded, or adulterated; and

''(III) consult with the Secretary, the United States Trade Representative, and the Commissioner of Patents and Trademarks to evaluate the effect of importations under the regulations under subsection (b) on trade and patent rights under Federal law.

''(B) REPORT.—Not later than 2 years after the effective date of the regulations under subsection (b), the Institute of Medicine shall submit to Congress a report describing the findings of the study under subparagraph (A).

''(2) BY THE COMPTROLLER GENERAL.—

''(A) STUDY.—The Comptroller General of the United States shall conduct a study to determine the effect of this section on the price of prescription drugs sold to consumers at retail.

''(B) REPORT.—Not later than 18 months after the effective date of the regulations under subsection (b), the Comptroller General of the United States shall submit to Congress a report describing the findings of the study under subparagraph (A).

''(m) CONSTRUCTION.—Nothing in this section limits the authority of the Secretary relating to the importation of prescription drugs, other than with respect to section 801(d)(1) as provided in this section.

''(n) AUTHORIZATION OF APPROPRIATIONS.—There are authorized to be appropriated such sums as are necessary to carry out this section.''.

(b) CONFORMING AMENDMENTS.—The Federal Food, Drug, and Cosmetic Act is amended—

(1) in section 301(aa) (21 U.S.C. 331(aa)), by striking ''covered product in violation of section 804'' and inserting ''prescription drug in violation of section 804''; and

(2) in section 303(a)(6) (21 U.S.C. 333(a)(6), by striking ''covered product pursuant to section 804(a)'' and inserting ''prescription drug under section 804(b)''.

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**SA 4301.** Mr. COCHRAN (for himself, Mr. BREAUX, Mr. ROBERTS, Mr. SANTORUM, Mr. NICKLES, and Mr. HUTCHINSON) proposed an amendment to amendment SA 4299 proposed by Mr. REID (for Mr. DORGAN (for himself, Mr. WELLSTONE, Mr. JEFFORDS, Ms. STABENOW, Ms. COLLINS, Mr. LEVIN, Mr. JOHNSON, Mr. MILLER, Mr. DURBIN, Mr. FEINGOLD, and Mr. HARKIN)) to the bill (S. 812) to amend the Federal Food, Drug, and Cosmetic Act to provide greater access to affordable pharmaceuticals; as follows:

On page 15, line 17, strike ''section.''.'' and insert ''section.'' and insert the following new subsection:

''(e) CONDITIONS.—This section shall become effective only if the Secretary of Health and Human Services certifies to the Congress that the implementation of this section will—

''(A) pose no additional risk to the public's health and safety, and

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

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**SA 4302.** Mr. THOMAS (for himself and Mr. ROBERTS) submitted an amendment intended to be proposed to amendment SA 4299 proposed by Mr. REID (for Mr. DORGAN (for himself, Mr. WELLSTONE, Mr. JEFFORDS, Ms. STABENOW, Ms. COLLINS, Mr. LEVIN, Mr. JOHNSON, Mr. MILLER, Mr. DURBIN, Mr. FEINGOLD, and Mr. HARKIN)) to the bill (S. 812), to amend the Federal Food, Drug, and Cosmetic Act to provide greater access to affordable pharmaceuticals; which was ordered to lie on the table, as follows:

Strike subsection (h) of section 804 of the Federal Food, Drug, and Cosmetic Act (as added by the amendment) and insert the following:

''(h) LABELING.—

''(1) APPROVED LABELING.—The manufacturer of a prescription drug shall provide an importer written authorization for the importer to use, at no cost, the approved labeling for the prescription drug.

''(2) DISCLAIMER.—The importer of any prescription drug under this section shall provide a labeling statement prominently displayed and in bold face type as follows:

**''THIS DRUG HAS BEEN IMPORTED FROM CANADA.**

**SA 4303.** Mrs. FEINSTEIN submitted an amendment intended to be proposed by her to the bill S. 812, to amend the Federal Food, Drug, and Cosmetic Act to provide greater access to affordable pharmaceuticals, which was ordered to lie on the table; as follows:

At the end, add the following:

**SEC. ___. ELIGIBILITY OF CHILDREN ENROLLED IN THE STATE CHILDREN'S HEALTH INSURANCE PROGRAM FOR THE PEDIATRIC VACCINE DISTRIBUTION PROGRAM.**

(a) IN GENERAL.—Section 1928(b)(2)(B)(ii)(I) of the Social Security Act (42 U.S.C. 1396s(b)(2)(B)(ii)(I)) is amended by inserting ''(other than a State child health plan under title XXI)'' after ''policy or plan''.

(b) EFFECTIVE DATE.—The amendment made by subsection (a) applies with respect to vaccines administered on or after the date of the enactment of this Act.

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**SA 4304.** Mr. SMITH of New Hampshire (for himself, Mr. ALLARD, Mr. GRASSLEY, Mr. HATCH, Mr. BURNS, Mr. CRAIG, Mr. CRAPO, and Mr. SANTORUM) submitted an amendment intended to be proposed by him to the bill S. 812, to amend the Federal Food, Drug, and Cosmetic Act to provide greater access to affordable pharmaceuticals, which was ordered to lie on the table; as follows:

(The amendment will be printed in the RECORD of Thursday, July 18, 2002.)

**SA 4305.** Mr. REID (for Ms. STABENOW) proposed an amendment to the bill S. 812, to amend the Federal Food, Drug, and Cosmetic Act to provide greater access to affordable pharmaceuticals; as follows:

At the end, add the following:

**SEC. ___. CLARIFICATION OF STATE AUTHORITY RELATING TO MEDICAID DRUG REBATE AGREEMENTS.**

Section 1927 of the Social Security Act (42 U.S.C. 1396r–8) is amended by adding at the end the following:

''(l) RULE OF CONSTRUCTION.—Nothing in this section shall be construed as prohibiting a State from—

''(1) directly entering into rebate agreements that are similar to a rebate agreement described in subsection (b) with a manufacturer for purposes of ensuring the affordability of outpatient prescription drugs in order to provide access to such drugs by residents of a State who are not otherwise eligible for medical assistance under this title; or

''(2) making prior authorization (that satisfies the requirements of subsection (d) and that does not violate any requirements of this title that are designed to ensure access to medically necessary prescribed drugs for individuals enrolled in the State program under this title) a condition of not participating in such a similar rebate agreement.''.

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**SA 4306.** Mrs. FEINSTEIN (for herself and Mrs. HUTCHISON) proposed an amendment to the bill H.R. 5011, making appropriations for Military Construction, family housing, and base realignment and closure for the Department of Defense for the fiscal year ending September 30, 2003, and for other purposes; as follows:

Viz: At the appropriate place, insert the following:

SEC. Of the amount appropriated in this Act under the heading ''Military Construction, Army'', $8,000,000 may be provided for a parking garage at Walter Reed Army Medical Center, District of Columbia.

SEC. Of the amount appropriated in this Act under the heading ''Military Construction, Army'', $3,000,000 may be provided for

an Anechoic Chamber at White Sands Missile Range, New Mexico.

SEC. Of the amount appropriated in this Act under the heading ''Military Construction, Air Force'', $7,500,000 may be provided for a control tower at Dover Air Force Base, Delaware.

SEC. Of the amount appropriated in this Act under the heading ''Military Construction, Army National Guard'', $9,000,000 may be provided for a Joint Readiness Center at Eugene, Oregon.

SEC. Of the amount appropriated in this Act under the heading ''Military Construction, Air National Guard'', $8,400,000 may be provided for a composite Maintenance Complex, Phase II in Nashville, Tennessee.

## NOTICES OF HEARINGS/MEETINGS

COMMITTEE ON ENERGY AND NATURAL RESOURCES

Mr. BINGAMAN. Mr. President, I would like to announce for the information of the Senate and the public that a full Committee hearing has been scheduled before the Committee on Energy and Natural Resources.

The hearing will take place on Wednesday, July 24, at 3:00 pm in SD–366.

The purpose of the hearing is to conduct oversight to examine issues related to the need for and barriers to development of electricity infrastructure. The hearing will focus on the Department of Energy's National Transmission Grid Study, and on information developed in a series of technical conferences held by the Federal Energy Regulatory Commission starting in November of 2001.

Those wishing to submit written statements on this subject should address them to the Committee on Energy and Natural Resources, Attn: Leon Lowery, United States Senate, Washington, D.C. 20510.

For further information, please call Leon Lower at 202/224–2209 or Jonathan Black at 202/224–6722.

## AUTHORITY FOR COMMITTEES TO MEET

COMMITTEE ON AGRICULTURE, NUTRITION, AND FORESTRY

Mr. REID. Mr. President, I ask unanimous consent that the Committee on Agriculture, Nutrition, and Forestry be allowed to conduct a hearing during the session of the Senate on Wednesday, July 17, 2002. The purpose of this hearing will be to discuss homeland security at 2:00 pm.

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

COMMITTEE ON COMMERCE, SCIENCE, AND TRANSPORTATION

Mr. REID. Mr. President, I ask unanimous consent that the Committee on Commerce, Science, and Transportation be authorized to meet on Wednesday, July 17, 2002, at 9:30 am on the FTC Reauthorization.

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

COMMITTEE ON FINANCE

Mr. REID. Mr. President, I ask unanimous consent that the Committee on Finance be authorized to meet during the session of the Senate on Wednesday, July 17, 2002 at 10:00 a.m., to hear testimony on Schemes, Scams and Cons, Part IV: Fuel Tax Fraud.

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

COMMITTEE ON FOREIGN RELATIONS

Mr. REID. Mr. President, I ask unanimous consent that the Committee on Foreign Relations be authorized to meet during the session of the Senate on Wednesday, July 17, 2002 at 10:30 a.m. to hold a hearing on the Moscow Treaty.

AGENDA

WITNESSES

The Honorable Donald L. Rumsfeld, Secretary of Defense, Washington, DC; General Richard B. Myers, Chairman, Joint Chiefs of Staff, Washington, DC.

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

COMMITTEE ON GOVERNMENTAL AFFAIRS

Mr. REID. Mr. President, I ask unanimous consent that the Committee on Governmental Affairs be authorized to meet on Wednesday, July 17, 2002 at 2:00 pm to hold a hearing to consider the nomination of Mark W. Everson to be Deputy Director for Management, Office of Management and Budget.

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

COMMITTEE ON HEALTH, EDUCATION, LABOR AND PENSIONS

Mr. REID. Mr. President, I ask unanimous consent that the Committee on Health, Education, Labor, and Pensions be authorized to meet in executive session during the session of the Senate after the first vote of the day on Wednesday, July 17, 2002, in S–216 of the Capitol.

AGENDA

Richard H. Carmona, of Arizona, to be U.S. Surgeon General of the Public Health Service.

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

COMMITTEE ON INDIAN AFFAIRS

Mr. REID. Mr. President, I ask unanimous consent that the Committee on Indian Affairs be authorized to meet on Wednesday, July 17, 2002, at 10:00 a.m. in Room 485 of the Russell Senate Office Building to conduct an Oversight Hearing on the Protection of Native American Sacred Places.

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

SUBCOMMITTEE ON HOUSING AND TRANSPORTATION

Mr. REID. Mr. President, I ask unanimous consent that the Subcommittee on Housing and Transportation of the Committee on Banking, Housing, and Urban Affairs be authorized to meet during the session of the Senate on Wednesday, July 17, 2002, at 2:30 p.m. to conduct an oversight hearing on ''Transit: A Lifeline For America's Citizens.''

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

SUBCOMMITTEE ON THE CONSTITUTION

Mr. REID. Mr. President, I ask unanimous consent that the Committee on the Judiciary Subcommittee on the Constitution be authorized to meet to conduct a hearing on ''S.J. Res. 35, Proposing A Victim's Rights Amendment to the United States Constitution,'' on Wednesday, July 17, 2002, at 10:00 a.m. in SD226.

TENTATIVE WITNESS LIST

PANEL I

The Honorable John Gillis, Director, Office for Victims of Crime, U.S. Department of Justice, Washington, DC.

PANEL II

Arwen Bird, Survivors Advocating for an Effective System, Portland, OR.

Julie Goldscheid, Esq., General Counsel, Safe Horizon, New York, NY.

James Orenstein, Esq., Baker & Hostetler LLP, New York, NY.

Roger Pilon, Director, Center for Constitutional Studies, CATO Institute, Washington, DC.

Roberta Roper, Director, Stephanie Roper Committee and Foundation, Upper Marlboro, MD.

Steven J. Twist, Esq., General Counsel, National Victims Constitutional Amendment Network, Scottsdale, AZ.

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

## PRIVILEGES OF THE FLOOR

Mr. GREGG. Mr. President, I ask unanimous consent that Madhavi Patt, with Senator HATCH, be granted the privileges of the floor during consideration of S. 812.

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

Mr. VOINOVICH. Mr. President, I ask unanimous consent that Lynn Borkon of my staff be granted the privilege of the floor during my statement.

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

## EXECUTIVE SESSION

### NOMINATION OF RICHARD R. CLIFTON, OF HAWAII, TO BE UNITED STATES CIRCUIT JUDGE FOR THE NINTH CIRCUIT

Mr. REID. Mr. President, I move to proceed to executive session to consider Calendar No. 825, Richard Clifton, to be United States Circuit Judge for the Ninth Circuit.

The PRESIDING OFFICER. The question is on agreeing to the motion.

The motion was agreed to.

CLOTURE MOTION

Mr. REID. Mr. President, we have no objection to the confirmation on this side of the aisle. We have, however, been advised there is an objection on the Republican side. As a result of that, I send a cloture motion to the desk.

The PRESIDING OFFICER. The cloture motion having been presented under rule XXII, the Chair directs the clerk to read the motion.

The assistant legislative clerk read as follows:

CLOTURE MOTION

We, the undersigned Senators, in accordance with the provisions of Rule XXII of the