

3. S. Con. Res. 122, A concurrent resolution expressing the sense of Congress that security, reconciliation, and prosperity for all Cypriots can be best achieved within the context of membership in the European Union which will provide significant rights and obligations for all Cypriots, and for other purposes, with amendments.

4. H.R. 2121; An act to make available funds under the Foreign Assistance Act of 1961 to expand democracy, good governance, and anti-corruption programs in the Russian Federation in order to promote and strengthen democratic government and civil society in that country and to support independent media, with amendments.

5. H.R. 4558, An act to extend the Irish Peace Process Cultural and Training Program.

#### Nominations

1. Ms. Nancy J. Powell, of Iowa, to be Ambassador to the Islamic Republic of Pakistan.

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 Thursday, August 1, 2002 at 10 a.m. to hold a hearing on Iraq.

#### Agenda

#### Witnesses:

Panel IV: The Day After: Dr. Phebe Marr, Former Senior Fellow, Institute for National Strategic Studies, National Defense University, Washington, DC; Mrs. Rahim Francke, Executive Director, Iraq Foundation, Washington, DC.

Additional witnesses to be announced.

Panel V: Summing Up: National Security Perspectives: Mr. Samuel R. Berger, Chairman, Stonebridge International LLC, Washington, DC.

Additional witnesses to be announced.

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

#### COMMITTEE ON HEALTH, EDUCATION, LABOR, AND PENSION

Mr. REID. Mr. President, I ask unanimous consent that the HELP Committee be authorized to meet at 2:50 p.m. today, August 1, 2002 to consider the following attached agenda.

S. 2394. A bill to amend the Federal Food, Drug and Cosmetic Act to require labeling containing information applicable to pediatric patients

S. 2445. The Book Stamp Act

#### Presidential Nominations

Edward Fitzmaurice, Jr., of Texas, to be a Member of the National Mediation Board and Harry R. Hoglander, of Massachusetts, to be a Member of the National Mediation Board.

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 Thursday, August 1, 2002, at 10 a.m. in Room 485 of the Russell Senate Office Building to conduct a business meeting to mark up S. 1344, a bill to provide training and technical assistance to Native Americans who are interested in commercial vehicle driving careers; S. 2017, a bill to amend the Indian Financing Act of 1974 to improve the effectiveness of the Indian loan guarantee and insurance program; and S. 2711, a bill to reauthorize and improve programs relating to Native Americans, to be followed immediately by an oversight hearing on the Interior Secretary's report on the Hoopa Yurok Settlement Act.

The committee will meet again on Thursday, August 1, 2002 at 2 p.m. in Room 485 of the Russell Senate Office Building to conduct an oversight hearing on problems facing native youth.

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 Thursday, August 1, 2002, at 10 a.m. in Room 485 of the Russell Senate Office Building to conduct an oversight hearing on the Interior Secretary's report on the Hoopa Yurok Settlement Act.

I also ask unanimous consent that the Committee on Indian Affairs be authorized to meet on Thursday, August 1, 2002, at 2 p.m. in Room 485 of the Russell Senate Office Building to conduct an oversight hearing on Problems Facing Native Youth.

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

#### COMMITTEE ON THE JUDICIARY

Mr. REID. Mr. President, I ask unanimous consent that the Committee on the Judiciary be authorized to meet to conduct a hearing on "Judicial Nominations" on Thursday, August 1, 2002 in Dirksen room 226 at 2 p.m.

#### PANEL I

The Honorable Arlen Specter, U.S. Senator (R-PA); The Honorable Phil Gramm, U.S. Senator (R-TX); The Honorable Kay Bailey Hutchison, U.S. Senator (R-TX); The Honorable Rick Santorum, U.S. Senator (R-PA); The Honorable Charles Schumer, U.S. Senator (D-NY); and The Honorable Hilary Rodham Clinton, U.S. Senator (D-NY).

#### PANEL II

Reena Raggi to be a U.S. Circuit Court Judge for the 2nd Circuit.

#### PANEL III

Lawrence J. Block to be Judge for the U.S. Court of Federal Claims; James Knoll Gardner to be U.S. District Court Judge for the Eastern District of PA; and Ronald H. Clark to be U.S. District Court Judge for the Eastern District of Texas.

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

#### COMMITTEE ON SMALL BUSINESS AND ENTREPRENEURSHIP

Mr. REID. Mr. President, I ask unanimous consent that the Committee on Small Business and Entrepreneurship be authorized to meet during the session of the Senate for a roundtable en-

titled "Promoting Small Business Regulatory Compliance and Entrepreneurial Education—The Role of the SBDC Network" on Thursday, August 1, 2002, beginning at 2:00 p.m. in room 428 A of the Russell Senate Office Building.

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

#### SUBCOMMITTEE ON CRIME AND DRUGS

Mr. REID. Mr. President, I ask unanimous consent that the Committee on the Judiciary Subcommittee on Crime and Drugs be authorized to meet to conduct a hearing on "Criminal and Civil Enforcement of Environmental Laws: Do We Have All The Tools We Need?" on Thursday, August 1, 2002, at 2:15 p.m. in SD-226.

#### WITNESS LIST

#### PANEL I

The Hon. Thomas L. Sansonetti, Assistant Attorney General for the Environment and Natural Resources Division, Washington, DC.

The Hon. Timothy M. Burgess, United States Attorney for the District of Alaska, Anchorage, AK.

#### PANEL II

Eric V. Schaeffer, Former Director of the Office of Regulatory Enforcement, U.S. Environmental Protection Agency, Director, Environmental Integrity Project, Rockefeller Family Fund, Washington, DC.

Judson W. Starr, Former Chief, Environmental Crimes Section, U.S. Department of Justice, Partner, Venable LLP, Washington, DC.

Ronald A. Sarachan, Former Chief, Environmental Crimes Section, U.S. Department of Justice, Partner, Ballard Spahr Andrews & Ingersoll, LLP, Philadelphia, PA.

Michael J. Penders, Former Director of Legal Counsel, Office of Criminal Enforcement, Forensics and Training, U.S. Environmental Protection Agency, President and CEO, Environmental Protection International, Washington, DC.

Nicholas A. DiPasquale, Secretary Delaware Department of Natural Resources and Environmental Control, Dover, DC.

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

#### SUBCOMMITTEE ON INTERNATIONAL TRADE

Mr. REID. Mr. President, I ask unanimous consent that the subcommittee on international trade and finance of the committee on banking, housing, and urban affairs be authorized to meet during the session of the senate on Thursday, August 1, 2002, at 2:30 p.m. to conduct an oversight hearing on "the role of charities and N.G.O.s in the financing of terrorist activities."

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

#### PRIVILEGES OF THE FLOOR

Mr. GRASSLEY. Madam President, I ask unanimous consent that Heather Marshall Byers and Norman A. MacLean be allowed on the Senate floor for today, the first day of August.

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

Mr. REED. I ask unanimous consent that Joyce Iutovich, a fellow in my office, be granted floor privileges for the remainder of today.

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

Mr. CORZINE. Madam President, I ask unanimous consent that Angie Drumm, a fellow in my office, be granted floor privileges for the remainder of today's session.

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

# GREATER ACCESS TO AFFORDABLE PHARMACEUTICALS ACT OF 2002

(On Wednesday, July 31, 2002, the Senate passed S. 812, as follows:)

S. 812

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

## TITLE I—GREATER ACCESS TO AFFORDABLE PHARMACEUTICALS

### SEC. 101. SHORT TITLE.

This title may be cited as the "Greater Access to Affordable Pharmaceuticals Act of 2002".

### SEC. 102. FINDINGS; PURPOSES.

(a) FINDINGS.—Congress finds that—

(1) prescription drug costs are increasing at an alarming rate and are a major worry of American families and senior citizens;

(2) enhancing competition between generic drug manufacturers and brand-name manufacturers can significantly reduce prescription drug costs for American families;

(3) the pharmaceutical market has become increasingly competitive during the last decade because of the increasing availability and accessibility of generic pharmaceuticals, but competition must be further stimulated and strengthened;

(4) the Federal Trade Commission has discovered that there are increasing opportunities for drug companies owning patents on brand-name drugs and generic drug companies to enter into private financial deals in a manner that could restrain trade and greatly reduce competition and increase prescription drug costs for consumers;

(5) generic pharmaceuticals are approved by the Food and Drug Administration on the basis of scientific testing and other information establishing that pharmaceuticals are therapeutically equivalent to brand-name pharmaceuticals, ensuring consumers a safe, efficacious, and cost-effective alternative to brand-name innovator pharmaceuticals;

(6) the Congressional Budget Office estimates that—

(A) the use of generic pharmaceuticals for brand-name pharmaceuticals could save purchasers of pharmaceuticals between \$8,000,000,000 and \$10,000,000,000 each year; and

(B) generic pharmaceuticals cost between 25 percent and 60 percent less than brand-name pharmaceuticals, resulting in an estimated average savings of \$15 to \$30 on each prescription;

(7) generic pharmaceuticals are widely accepted by consumers and the medical profession, as the market share held by generic pharmaceuticals compared to brand-name pharmaceuticals has more than doubled during the last decade, from approximately 19 percent to 43 percent, according to the Congressional Budget Office;

(8) expanding access to generic pharmaceuticals can help consumers, especially senior citizens and the uninsured, have access to more affordable prescription drugs;

(9) Congress should ensure that measures are taken to effectuate the amendments made by the Drug Price Competition and

Patent Term Restoration Act of 1984 (98 Stat. 1585) (referred to in this section as the "Hatch-Waxman Act") to make generic drugs more accessible, and thus reduce health care costs; and

(10) it would be in the public interest if patents on drugs for which applications are approved under section 505(c) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 355(c)) were extended only through the patent extension procedure provided under the Hatch-Waxman Act rather than through the attachment of riders to bills in Congress.

(b) PURPOSES.—The purposes of this title are—

(1) to increase competition, thereby helping all Americans, especially seniors and the uninsured, to have access to more affordable medication; and

(2) to ensure fair marketplace practices and deter pharmaceutical companies (including generic companies) from engaging in anticompetitive action or actions that tend to unfairly restrain trade.

### SEC. 103. FILING OF PATENT INFORMATION WITH THE FOOD AND DRUG ADMINISTRATION.

(a) FILING AFTER APPROVAL OF AN APPLICATION.—

(1) IN GENERAL.—Section 505 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 355) (as amended by section 9(a)(2)(B)(ii)) is amended in subsection (c) by striking paragraph (2) and inserting the following:

"(2) PATENT INFORMATION.—

"(A) IN GENERAL.—Not later than the date that is 30 days after the date of an order approving an application under subsection (b) (unless the Secretary extends the date because of extraordinary or unusual circumstances), the holder of the application shall file with the Secretary the patent information described in subparagraph (C) with respect to any patent—

"(i) (I) that claims the drug for which the application was approved; or

"(II) that claims an approved method of using the drug; and

"(ii) with respect to which a claim of patent infringement could reasonably be asserted if a person not licensed by the owner engaged in the manufacture, use, or sale of the drug.

"(B) SUBSEQUENTLY ISSUED PATENTS.—In a case in which a patent described in subparagraph (A) is issued after the date of an order approving an application under subsection (b), the holder of the application shall file with the Secretary the patent information described in subparagraph (C) not later than the date that is 30 days after the date on which the patent is issued (unless the Secretary extends the date because of extraordinary or unusual circumstances).

"(C) PATENT INFORMATION.—The patent information required to be filed under subparagraph (A) or (B) includes—

"(i) the patent number;

"(ii) the expiration date of the patent;

"(iii) with respect to each claim of the patent—

"(I) whether the patent claims the drug or claims a method of using the drug; and

"(II) whether the claim covers—

"(aa) a drug substance;

"(bb) a drug formulation;

"(cc) a drug composition; or

"(dd) a method of use;

"(iv) if the patent claims a method of use, the approved use covered by the claim;

"(v) the identity of the owner of the patent (including the identity of any agent of the patent owner); and

"(vi) a declaration that the applicant, as of the date of the filing, has provided complete and accurate patent information for all patents described in subparagraph (A).

"(D) PUBLICATION.—On filing of patent information required under subparagraph (A) or (B), the Secretary shall—

"(i) immediately publish the information described in clauses (i) through (iv) of subparagraph (C); and

"(ii) make the information described in clauses (v) and (vi) of subparagraph (C) available to the public on request.

"(E) CIVIL ACTION FOR CORRECTION OR DELETION OF PATENT INFORMATION.—

"(i) IN GENERAL.—A person that has filed an application under subsection (b)(2) or (j) for a drug may bring a civil action against the holder of the approved application for the drug seeking an order requiring that the holder of the application amend the application—

"(I) to correct patent information filed under subparagraph (A); or

"(II) to delete the patent information in its entirety for the reason that—

"(aa) the patent does not claim the drug for which the application was approved; or

"(bb) the patent does not claim an approved method of using the drug.

"(ii) LIMITATIONS.—Clause (i) does not authorize—

"(I) a civil action to correct patent information filed under subparagraph (B); or

"(II) an award of damages in a civil action under clause (i).

"(F) NO CLAIM FOR PATENT INFRINGEMENT.—An owner of a patent with respect to which a holder of an application fails to file information on or before the date required under subparagraph (A) or (B) shall be barred from bringing a civil action for infringement of the patent against a person that—

"(i) has filed an application under subsection (b)(2) or (j); or

"(ii) manufactures, uses, offers to sell, or sells a drug approved under an application under subsection (b)(2) or (j)."

(2) TRANSITION PROVISION.—

(A) FILING OF PATENT INFORMATION.—Each holder of an application for approval of a new drug under section 505(b) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 355(b)) that has been approved before the date of enactment of this Act shall amend the application to include the patent information required under the amendment made by paragraph (1) not later than the date that is 30 days after the date of enactment of this Act (unless the Secretary of Health and Human Services extends the date because of extraordinary or unusual circumstances).

(B) NO CLAIM FOR PATENT INFRINGEMENT.—An owner of a patent with respect to which a holder of an application under subsection (b) of section 505 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 355) fails to file information on or before the date required under subparagraph (A) shall be barred from bringing a civil action for infringement of the patent against a person that—

(i) has filed an application under subsection (b)(2) or (j) of that section; or

(ii) manufactures, uses, offers to sell, or sells a drug approved under an application under subsection (b)(2) or (j) of that section.

(b) FILING WITH AN APPLICATION.—Section 505 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 355) is amended—

(1) in subsection (b)(2)—

(A) in subparagraph (A), by striking "and" at the end;

(B) in subparagraph (B), by striking the period at the end and inserting "; and"; and

(C) by adding at the end the following:

"(C) with respect to a patent that claims both the drug and a method of using the drug or claims more than 1 method of using the drug for which the application is filed—

"(i) a certification under subparagraph (A)(iv) on a claim-by-claim basis; and