''(B) the applicant demonstrates that reasonable attempts to produce a pediatric formulation necessary for that subpopulation have failed.

''(3) LABELING REQUIREMENT.—If the Secretary grants a full or partial waiver because there is evidence that a drug or biological product would be ineffective or unsafe in pediatric populations, the information shall be included in the labeling for the drug or biological product.

''(e) MEETINGS.—The Secretary shall meet at appropriate times in the investigational new drug process with the sponsor to discuss background information that the sponsor shall submit on plans and timelines for pediatric studies, or any planned request for waiver or deferral of pediatric studies.''.

(b) CONFORMING AMENDMENTS.—

(1) Section 505(b)(1) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 355(b)(1)) is amended in the second sentence—

(A) by striking ''and (F)'' and inserting ''(F)''; and

(B) by striking the period at the end and inserting '', and (G) any assessments required under section 505B.''.

(2) Section 505A(h) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 355a(h)) is amended—

(A) in the subsection heading, by striking ''REGULATIONS'' and inserting ''PEDIATRIC STUDY REQUIREMENTS''; and

(B) by striking ''pursuant to regulations promulgated by the Secretary'' and inserting ''by a provision of law (including a regulation) other than this section''.

(3) Section 351(a)(2) of the Public Health Service Act (42 U.S.C. 262(a)(2)) is amended—

(A) by redesignating subparagraph (B) as subparagraph (C); and

(B) by inserting after subparagraph (A) the following:

''(B) PEDIATRIC STUDIES.—A person that submits an application for a license under this paragraph shall submit to the Secretary as part of the application any assessments required under section 505B of the Federal Food, Drug, and Cosmetic Act.''.

(c) FINAL RULE.—Except to the extent that the final rule is inconsistent with the amendment made by subsection (a), the final rule promulgating regulations requiring manufacturers to assess the safety and effectiveness of new drugs and biological products in pediatric patients (63 Fed. Reg. 66632 (December 2, 1998)), shall be considered to implement the amendment made by subsection (a).

(d) NO EFFECT ON AUTHORITY.—Section 505B of the Federal Food, Drug, and Cosmetic Act (as added by subsection (a)) does not affect whatever existing authority the Secretary of Health and Human Services has to require pediatric assessments regarding the safety and efficacy of drugs and biological products in addition to the assessments required under that section. The authority, if any, of the Secretary of Health and Human Services regarding specific populations other than the pediatric population shall be exercised in accordance with the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 301 et seq.) as in effect on the day before the date of enactment of this Act.

SA 4318. Mrs. CLINTON 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 appropriate place, insert the following:

TITLE ____—ETHICAL PRESCRIPTION DRUG MARKETING ACT OF 2002

SEC. ___1. SHORT TITLE.

This title may be cited as the ''Ethical Prescription Drug Marketing Act of 2002''.

SEC. ___2. PROHIBITION ON OFFERING OR PROVIDING ITEMS OR SERVICES FROM DRUG MANUFACTURERS TO HEALTH CARE PROFESSIONALS.

Section 503 of the Federal Food, Drug, and Cosmetics Act (21 U.S.C. 353) is amended by adding at the end the following:

''(h)(1) A drug manufacturer shall not offer or provide any item or service to a health care professional in a manner or on a condition that would interfere with the independence of the health care professional's prescribing practices.

''(2)(A) A drug manufacturer shall not offer or provide any money (including cash or a cash equivalent) to a health care professional, except as compensation under an arrangement for bona fide services, such as services as a consultant, as a participant in speaker training meetings, or as a researcher.

''(B) A drug manufacturer shall not offer or provide any non-monetary item or service to a health care professional intended primarily for the personal benefit of the health care professional.

''(C) A drug manufacturer shall not offer or provide any non-monetary item or service, of substantial value, to a health care professional, except that a drug manufacturer may distribute a drug sample in compliance with subsection (d).

''(3) Each drug manufacturer shall be subject to a civil monetary penalty of not more than $10,000 for each violation of this subsection. Each unlawful offer or provision shall constitute a separate violation. The provisions of paragraphs (3), (4), and (5) of section 303(g) shall apply to such a violation in the same manner as such provisions apply to a violation of a requirement of this Act that relates to devices.

''(4)(A) For purposes of this subsection, an arrangement between a drug manufacturer and a health care professional for the services of the health care professional shall be considered to be an arrangement for bona fide services if, of the factors described in subparagraph (B), the factors that are relevant to the arrangement are present.

''(B) The factors referred to in subparagraph (A) are—

''(i) a legitimate need for the services, identified in advance of requesting the services and entering into the arrangement;

''(ii) a written contract specifying the nature of the services and the basis for payment for those services;

''(iii) selection of the health care professional to provide the services, based on criteria directly related to the identified need, and conducted by a person with the expertise necessary to evaluate whether health care professionals meet the criteria;

''(iv) a number of health care professionals retained under the arrangement that is not greater than the number reasonably necessary to address the identified need;

''(v) maintenance of appropriate records concerning, and appropriate use of the services of, the health care professional; and

''(vi) a venue and circumstances for any meeting that is conducive to providing the services, with any social or entertainment events at the meeting clearly subordinate to the provision of the services.

''(5) In this subsection:

''(A) The term 'drug manufacturer' means—

''(i) a person who manufactures a prescription drug approved under section 505 or a biological product licensed under section 351 of the Public Health Service Act (42 U.S.C. 262); or

''(ii) a person who is licensed by a person described in clause (i) to distribute or market such a drug or biological product.

''(B) The term 'health care professional' means a physician, or other individual who is a provider of health care, who is licensed under the law of a State to prescribe drugs.

''(C) The term 'substantial value' means $100 or more.''.

AUTHORITY FOR COMMITTEES TO MEET

COMMITTEE ON ENERGY AND NATURAL RESOURCES

Mr. SCHUMER. Mr. President, I ask unanimous consent that the Committee on Energy and Natural Resources be authorized to hold a Hearing during the session of the Senate on Wednesday, July 24, 2002, at 3 p.m. in SD–366.

The purpose of the hearing is to examine issues related to the need for and barriers to development of electricity infrastructure. The hearing will focus on DOE'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 2001.

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

COMMITTEE ON ENVIRONMENT AND PUBLIC WORKS COMMITTEE ON FOREIGN RELATION

Mr. SCHUMER. Mr. President, I ask unanimous consent that the Committee on Environment and Public Works be authorized to meet jointly with the Committee on Foreign Relations on Wednesday, July 24, 2002, at 10:30 a.m. to conduct a hearing to review environmental treaties implementation. The hearing will be held in SD–406.

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

COMMITTEE ON FOREIGN RELATIONS

Mr. SCHUMER. Mr. President, I ask unanimous consent that the Committee on Foreign Relations be authorized to meet during the session of the Senate on Wednesday, July 24 2002 at 10:30 a.m. to hold a hearing on Environmental Treaties.

Agenda

Witnesses

Panel I: Mr. John F. Turner, Assistant Secretary for the Bureau of Oceans and International Environment and Scientific Affairs, U.S. Department of State, Washington, DC; Mr. James Connaughton, Chair, White House Council on Environmental Quality, Washington, D.C.

Panel II: Mr. Maurice Strong, Chairman, Earth Council Institute Canada, Toronto, Ontario, Canada; Professor John C. Dernbach, Widener University Law School, Harrisburg, PA; Mr. Christopher C. Horner, Counsel, Competitive Enterprise Institute, Washington, D.C.

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

COMMITTEE ON FOREIGN RELATIONS

Mr. SCHUMER. Mr. President, I ask unanimous consent that the Committee on Foreign Relations be authorized to meet during the session of the Senate on Wednesday, July 24, 2002, at 2:30 p.m. to hold a nomination hearing.

Agenda

Nominees:

Ms. Kristie A. Kenney, of Maryland, to be Ambassador to the Republic of Ecuador.

Mr. Larry L. Palmer, of Georgia, to be Ambassador to the Republic of Honduras.

Mrs. Barbara C. Moore, of Maryland, to be Ambassador to the Republic of Nicaragua.

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

COMMITTEE ON GOVERNMENTAL AFFAIRS

Mr. SCHUMER. Mr. President, I ask unanimous consent that the Committee on Governmental Affairs be authorized to meet on Wednesday, July 24, 2002, at 9:30 a.m. for a business meeting to consider pending business.

Agenda

1. To authorize withdrawal of the Committee amendments and offering of a floor amendment in the nature of a substitute to the National Homeland Security and Combating Terrorism Act of 2002 (S. 2452) which the Committee ordered reported on May 22, 2002.

2. Nominations:

(a) James ''Jeb'' E. Boasberg to be an Associate Judge of the Superior Court of the District of Columbia.

(b) Michael D. Brown to be Deputy Director of the Federal Emergency Management Agency.

(c) The Honorable 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 INDIAN AFFAIRS

Mr. SCHUMER. Mr. President, I ask unanimous consent that the Committee on Indian Affairs be authorized to meet on Wednesday, July 24, 2002, at 10 a.m. in Room 485 of the Russell Senate Office Building to conduct a hearing on S. 1344, a bill to Encourage Training to Native Americans Interested in Commercial Vehicle Driving Careers.

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

COMMITTEE ON SMALL BUSINESS AND ENTREPRENEURSHIP

Mr. SCHUMER. Mr. President, I ask unanimous consent that the Committee on Small Business and Entrepreneurship be authorized to meet during the session of the Senate on Wednesday, July 24, 2002, beginning at 9:00 a.m. in room 428A of the Russell Senate Office Building to markup pending legislation.

Agenda

S. 2753 Small and Disadvantaged Business Ombudsman for Procurement;

S. 2335 Office of Native American Affairs at SBA;

S. 2734 Non-Farm Drought Relief;

S. 1994 Small Business Federal Contracts;

HR 2666 Vocational and Technical Entrepreneurship Development Program;

S. 2483 Pilot Program To Provide Regulatory Compliance Assistance To Small Business;

S. 2466 Contract Consolidation Requirements.

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

COMMITTEE ON VETERANS' AFFAIRS

Mr. SCHUMER. Mr. President, I ask unanimous consent that the Committee on Veterans' Affairs be authorized to meet during the session of the Senate on Wednesday, July 24, 2002, for a hearing on ''Mental Health Care: Can VA Still Deliver.''

The hearing will take place in SR–418 of the Russell Senate Office Building at 9:30 a.m.

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

SUBCOMMITTEE ON CRIME AND DRUGS

Mr. SCHUMER. 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 ''Ensuring Corporate Responsibility: Using Criminal Sanctions to Deter Wrongdoing,'' on Wednesday, July 24, 2002, at 2:30 p.m. in SD226.

Tentative Witness List

The Honorable G. William Miller, Former Secretary of the U.S. Treasury, Former Chairman of the Federal Reserve Board, Chairman, G. William Miller & Co.

The Honorable Roderick Hills, Former Chairman of the U.S. Securities and Exchange Commission, Founder, Law Firms of Hills & Stern, Chairman, Hills Enterprises Ltd.

The Honorable J. Carter Beese, Jr., Former Commissioner of the U.S. Securities and Exchange Commission, Senior Advisor and Chairman, International Financial Markets Project of the Center for Strategic and International Studies.

The PRESIDING OFFICER. Without objection it is so ordered.

SUBCOMMITTEE ON HOUSING AND TRANSPORTATION

Mr. SCHUMER. 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 24, 2002, at 2:30 p.m. to conduct an oversight hearing on ''HUD's Management Challenges.''

The PRESIDING OFFICER. Without objection it is so ordered.

SUBCOMMITTEE ON SCIENCE, TECHNOLOGY, AND SPACE

Mr. SCHUMER. Mr. President, I ask unanimous consent that the Subcommittee on Science, Technology and Space of the Committee on Commerce, Science, and Transportation be authorized to meet on Wednesday, July 24, 2002, at 2:30 p.m. on Women in Science and Technology.

The PRESIDING OFFICER. Without objection it is so ordered.

PRIVILEGE OF THE FLOOR

Mr. DAYTON. Madam President, I ask unanimous consent that my staff person, Krystle J. Klema, be able to be on the floor for my colloquy with Senator WELLSTONE.

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

APPOINTMENT

The PRESIDING OFFICER. The Chair, on behalf of the majority leader, pursuant to Public Law 107–171, announces the appointment of the following individuals to serve as members of the Board of Trustees of the Congressional Hunger Fellows Program: the Senator from Iowa (Mr. HARKIN); the Representative from North Carolina (Mrs. CLAYTON).

YANKTON SIOUX TRIBE AND SANTEE SIOUX TRIBE EQUITABLE COMPENSATION ACT

Mr. REID. Mr. President, I ask unanimous consent that the Senate proceed to the consideration of Calendar No. 507, S. 434.

The PRESIDING OFFICER. The clerk will report the bill by title.

The legislative clerk read as follows:

A bill (S. 434) to provide equitable compensation to the Yankton Sioux Tribe of South Dakota and the Santee Sioux Tribe of Nebraska for the loss of value of certain lands.

There being no objection, the Senate proceeded to consider the bill, which had been reported from the Committee on Indian Affairs with amendments, as follows:

[Omit the part in black brackets and insert the part printed in italic.]

S. 434

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 ''Yankton Sioux Tribe and Santee Sioux Tribe Equitable Compensation Act''.

SEC. 2. FINDINGS AND PURPOSES.

(a) FINDINGS.—Congress finds that—

(1) by enacting the Act of December 22, 1944, commonly known as the ''Flood Control Act of 1944'' (58 Stat. 887, chapter 665; 33 U.S.C. 701–1 et seq.) Congress approved the Pick-Sloan Missouri River Basin program (referred to in this section as the ''Pick-Sloan program'')—

(A) to promote the general economic development of the United States;

(B) to provide for irrigation above Sioux City, Iowa;

(C) to protect urban and rural areas from devastating floods of the Missouri River; and

(D) for other purposes;