

of Senate Joint Resolution 6, a joint resolution proposing an amendment to the Constitution of the United States to protect the rights of crime victims.

## SENATE CONCURRENT RESOLUTION 7

At the request of Mr. SARBANES, the name of the Senator from South Carolina [Mr. HOLLINGS] was added as a cosponsor of Senate Concurrent Resolution 7, a concurrent resolution expressing the sense of Congress that Federal retirement cost-of-living adjustments should not be delayed.

## SENATE CONCURRENT RESOLUTION 30

At the request of Mr. HELMS, the name of the Senator from Pennsylvania [Mr. SANTORUM] was added as a cosponsor of Senate Concurrent Resolution 30, a concurrent resolution expressing the sense of the Congress that the Republic of China should be admitted to multilateral economic institutions, including the International Monetary Fund and the International Bank for Reconstruction and Development.

## SENATE CONCURRENT RESOLUTION 38

At the request of Mr. ROTH, the name of the Senator from Michigan [Mr. ABRAHAM] was added as a cosponsor of Senate Concurrent Resolution 38, a concurrent resolution to state the sense of the Congress regarding the obligations of the People's Republic of China under the Joint Declaration and the Basic Law to ensure that Hong Kong remains autonomous, the human rights of the people of Hong Kong remain protected, and the government of the Hong Kong SAR is elected democratically.

## SENATE RESOLUTION 119

At the request of Mr. FEINGOLD, the names of the Senator from Massachusetts [Mr. KENNEDY] and the Senator from Vermont [Mr. LEAHY] were added as cosponsors of Senate Resolution 119, a resolution to express the sense of the Senate that the Secretary of Agriculture should establish a temporary emergency minimum milk price that is equitable to all producers nationwide and that provides price relief to economically distressed milk producers.

## SENATE RESOLUTION 122—DECLARING SEPTEMBER 26, 1997 AS AUSTRIAN-AMERICAN DAY

Mr. ENZI submitted the following resolution; which was referred to the Committee on the Judiciary:

## S. RES. 122

Whereas 1997 marks the 50th anniversary of General George C. Marshall's plan for assisting the free countries of Europe in their post-World War II rebuilding process;

Whereas on September 26, 1945, upon the insistence of the United States, a conference was held in Vienna by the Allies and the 9 Austrian Federal State Governors, that laid the foundation for the first post-war Austrian government recognized by the United States and the other Allied Forces;

Whereas this treaty saved Austria from being divided into an East and West, as in Germany;

Whereas Austrians are thankful for the generosity demonstrated by the citizens and

the Government of the United States after World War II;

Whereas Austrian-Americans have made important contributions to the American way of life as well as in industry, education, culture, and the arts and sciences; and

Whereas Austrian born Americans, or Americans of Austrian descent, have brought prestige and recognition to the United States as Nobel laureates in medicine, economics, and the sciences: Now, therefore, be it

*Resolved*, That the Senate—

(1) declares September 26, 1997, as "Austrian-American Day"; and

(2) authorizes and requests the President to commend this observance to the citizens of the United States in honor of this momentous occasion.

Mr. ENZI. Mr. President, I rise to join my friend, the Honorable Senator from Indiana, RICHARD LUGAR, in the submission of a resolution declaring September 26, 1997, Austrian-American Day. We are also joined by many distinguished colleagues from both sides of the aisle in support of this measure to commemorate and celebrate the strong ties that bind the Government of Austria and the United States and our people. This resolution has deep meaning to me because of my Austrian roots and heritage.

The year 1997 has special significance in the history of Austrian-American relations for it marks the 50th anniversary of what became known as the Marshall plan. It was 1947 when Gen. George C. Marshall outlined his vision of a program to rebuild war-torn Europe through a policy of reconciliation and compassion. The Marshall plan that was eventually implemented by the United States is remembered fondly by the free nations of Europe for its monumental and generous aid that gave the people of these nations hope after the most costly war in the history of the world—hope for freedom and lasting peace. Without the incredible vision of General Marshall the democracies of Europe might have floundered in their rebuilding efforts, creating an avenue for the expansion of communism in the midst of the cold war. Marshall's foresight and the willingness of the people and the Government of the United States to assist all of free Europe, especially Austria, resulted in the growth of stable governments in these countries.

Austrians have not forgotten the efforts of the United States to maintain the unity of their country after World War II. The United States was instrumental in calling for a conference to be held in Vienna to debate the future of Austria. On September 26, 1945, this conference was convened between the Allies and the representatives of the nine Austrian Federal States, during which a treaty was signed that rescued Austria from a fate similar to that of the Soviet-occupied European countries and a divided Germany.

The resolution I propose today, commemorates the sacrifices Americans made for Austria after World War II, as well as contributions that Austrian immigrants and Americans and Austrian

decent have made to the American way of life in industry, education, government, culture, and the arts. Austrian-Americans that have earned the Nobel Prize include Victor Franz Hess in physics, Karl Landsteiner in medicine, and Friedrich von Hayek in economics. Austria has produced the likes of United States Supreme Court Justices Felix Frankfurter and Earl Warren; the originator of the Pulitzer Prize, Joseph Pulitzer; John David Hertz, the founder of today's Hertz-Rent-A-Car and the well-known Yellow Cab system; Estee Lauder, maker of leading cosmetics; and Raoul Fleischman, cofounder of the New Yorker magazine and member of the Fleischman yeast family.

Through the years, Americans have also enjoyed the work of those Americans of Austrian descent or origin, such as Fred Astaire, Billy Wilder, and of course "The Terminator," Arnold Schwarzenegger. This is but a small sample of the names to be found on a list of famous Austrian-Americans who have made heartfelt contributions to the legacy of the America they love.

Austria and the United States have shared these common ideals and interests, not just in the past 50 years, but for nearly two centuries. It is for these reasons that I feel it is altogether appropriate that we recognize not only the proud people of Austria, but the warm and cordial relations that exist between our two countries at this historic time that holds such deep meaning for both our nations.

## AMENDMENTS SUBMITTED

THE FOOD AND DRUG ADMINISTRATION MODERNIZATION AND ACCOUNTABILITY ACT OF 1997  
PRESCRIPTION DRUG USERS FEE  
REAUTHORIZATION ACT OF 1997HARKIN (AND OTHERS)  
AMENDMENT NO. 1137

(Ordered to lie on the table.)

Mr. HARKIN (for himself, Mr. HATCH, Mr. DASCHLE, and Ms. MIKULSKI) submitted an amendment intended to be proposed by them to the bill (S. 830) to amend the Federal Food, Drug, and Cosmetic Act and the Public Health Service Act to improve the regulation of food, drugs, devices, and biological products, and for other purposes; as follows:

At the appropriate place, insert the following new section:

## SEC. \_\_\_\_ . ESTABLISHMENT OF NATIONAL CENTER FOR COMPLEMENTARY AND ALTERNATIVE MEDICINE.

(a) IN GENERAL.—Title IV of the Public Health Service Act (42 U.S.C. 281 et seq.) is amended—

(1) by striking section 404E; and  
(2) in part E, by amending subpart 4 to read as follows:

“Subpart 4—National Center for Complementary and Alternative Medicine  
“SEC. 485C. PURPOSE OF CENTER.

“(a) IN GENERAL.—The general purposes of the National Center for Complementary and

Alternative Medicine (in this subpart referred to as the 'Center') are—

“(1) the conduct and support of basic and applied research (including both intramural and extramural research), research training, the dissemination of health information, and other programs, including prevention programs, with respect to identifying, investigating, and validating complementary and alternative treatment, prevention, and diagnostic systems, modalities, and disciplines; and

“(2) carrying out the functions specified in sections 485D (relating to dietary supplements).

The Center shall be headed by a director, who shall be appointed by the Secretary. The Director of the Center shall report directly to the Director of NIH.

“(b) ADVISORY COUNCIL.—The Secretary shall establish an advisory council for the Center in accordance with section 406, except that the members of the advisory council who are not ex officio members shall include one or more practitioners from each of the disciplines and systems with which the Center is concerned, and at least 3 individuals representing the interests of individual consumers of complementary and alternative medicine.

“(c) COMPLEMENT TO CONVENTIONAL MEDICINE.—In carrying out subsection (a), the Director of the Center shall, as appropriate, study the integration of alternative medical treatment and diagnostic systems, modalities, and disciplines into the practice of conventional medicine as a complement to such medicine and into health care delivery systems in the United States.

“(d) APPROPRIATE SCIENTIFIC EXPERTISE.—The Director of the Center, after consultation with the advisory council for the Center and the division of research grants, shall ensure that scientists with appropriate expertise in research on complementary and alternative medicine are incorporated into the review, oversight, and management processes of all research projects and other activities funded by the Center. In carrying out this subsection, the Director of the Center, as necessary, may establish review groups with appropriate scientific expertise.

“(e) EVALUATION OF VARIOUS DISCIPLINES AND SYSTEMS.—In carrying out subsection (a), the Director of the Center shall identify and evaluate alternative medical treatment and diagnostic modalities in each of the disciplines and systems with which the Center is concerned, including each discipline and system in which accreditation, national certification, or a State license is available.

“(f) ENSURING HIGH QUALITY, RIGOROUS SCIENTIFIC REVIEW.—In order to ensure high quality, rigorous scientific review of complementary and alternative medical and diagnostic systems, modalities, and disciplines, the Director of the Center shall conduct or support the following activities:

- “(1) Outcomes research and investigations.
- “(2) Epidemiological studies.
- “(3) Health services research.
- “(4) Basic science research.
- “(5) Clinical trials.
- “(6) Other appropriate research and investigational activities.

“(g) DATA SYSTEM; INFORMATION CLEARINGHOUSE.—

“(1) DATA SYSTEM.—The Director of the Center shall establish a bibliographic system for the collection, storage, and retrieval of worldwide research relating to complementary and alternative medical treatment and diagnostic systems, modalities, and disciplines. Such a system shall be regularly updated and publicly accessible.

“(2) CLEARINGHOUSE.—The Director of the Center shall establish an information clear-

inghouse to facilitate and enhance, through the effective dissemination of information, knowledge and understanding of alternative medical treatment and diagnostic systems and disciplines by health professionals, patients, industry, and the public.

“(h) RESEARCH CENTERS.—

“(1) IN GENERAL.—The Director of the Center, after consultation with the advisory council for the Center, shall provide support for the development and operation of multi-purpose centers to conduct research and other activities described in subsection (a)(1) with respect to complementary and alternative medical treatment and diagnostic systems, modalities, and disciplines.

“(2) REQUIREMENTS.—Each center assisted under paragraph (1) shall use the facilities of a single entity, or be formed from a consortium of cooperating entities, and shall meet such requirements as may be established by the Director of the Center. Each such center shall—

“(A) be established as an independent entity; or

“(B) be established within or in affiliation with an entity that conducts research or training described in subsection (a)(1).

“(3) DURATION OF SUPPORT.—Support of a center under paragraph (1) may be for a period not exceeding 5 years. Such period may be extended for one or more additional periods not exceeding 5 years if the operations of such center have been reviewed by an appropriate technical and scientific peer review group established by the Director of the Center and if such group has recommended to the Director that such period should be extended.

“(i) BIENNIAL REPORT.—The Director of the Center shall prepare biennial reports on the activities carried out or to be carried out by the Center, and shall submit each such report to the Director of NIH for inclusion in the biennial report under section 403.

“(j) AVAILABILITY OF RESOURCES.—After consultation with the Director of the Center, the Director of NIH shall ensure that resources of the National Institutes of Health, including laboratory and clinical facilities, fellowships (including research training fellowship and junior and senior clinical fellowships), and other resources are sufficiently available to enable the Center to appropriately and effectively carry out its duties as described in subsection (a).

“(k) AUTHORIZATION OF APPROPRIATIONS.—For the purpose of carrying out this subpart, there are authorized to be appropriated such sums as may be necessary for each of the fiscal years 1998 through 2002. Amounts appropriated under this subsection for fiscal year 1998 are available for obligation through September 30, 2000. Amounts appropriated under this subsection for fiscal year 1999 are available for obligation through September 30, 2000.

“SEC. 485D. OFFICE OF DIETARY SUPPLEMENTS.

“(a) IN GENERAL.—There is established within the Center an office to be known as the Office of Dietary Supplements (in this section referred to as the 'Office'). The Office shall be headed by a director, who shall be appointed by the Director of the Center. The Director of the Center shall carry out the functions specified in this section acting through the Director of the Office.

“(b) DUTIES.—

“(1) IN GENERAL.—The Director of the Office shall—

“(A) expand the activities of the national research institutes with respect to the potential role of dietary supplements as a significant part of the efforts of the United States to improve health care; and

“(B) promote scientific study of the benefits of dietary supplements in maintaining

health and preventing chronic disease and other health-related conditions.

“(2) CERTAIN DUTIES.—The Director of the Office shall—

“(A) conduct and coordinate scientific research within the National Institutes of Health relating to dietary supplements and the extent to which the use of dietary supplements can limit or reduce the risk of diseases such as heart disease, cancer, birth defects, osteoporosis, cataracts, or prostatism;

“(B) collect and compile the results of scientific research relating to dietary supplements, including scientific data from foreign sources or other offices of the Center;

“(C) serve as the principal advisor to the Secretary and to the Assistant Secretary for Health and provide advice to the Director of NIH, the Director of the Centers for Disease Control and Prevention, and the Commissioner of Food and Drugs on issues relating to dietary supplements including—

“(i) dietary intake regulations;

“(ii) the safety of dietary supplements;

“(iii) claims characterizing the relationship between dietary supplements and the prevention of disease or other health-related conditions;

“(iv) claims characterizing the relationship between dietary supplements and the maintenance of health; and

“(v) scientific issues arising in connection with the labeling and composition of dietary supplements;

“(D) compile a database of scientific research on dietary supplements and individual nutrients; and

“(E) coordinate funding relating to dietary supplements for the National Institutes of Health.

“(c) BIENNIAL REPORT.—The Director of the Office shall prepare biennial reports on the activities carried out or to be carried out by the Office, and shall submit each such report to the Director of the Center for inclusion in the biennial report under section 485C(i).

“(d) DEFINITION.—For purposes of this section, the term 'dietary supplement' has the meaning given such term in section 201(ff) of the Federal Food, Drug, and Cosmetic Act.”.

(b) SAVINGS PROVISIONS.—

(1) NATIONAL CENTER FOR COMPLEMENTARY AND ALTERNATIVE MEDICINE.—All officers and employees employed in the Office of Alternative Medicine on the day before the date of the enactment of this Act (pursuant to section 404E of the Public Health Service Act, as in effect on such day) are transferred to the National Center for Complementary and Alternative Medicine. Such transfer does not affect the status of any such officer or employee (except to the extent that the amendments made by subsection (a) affect the authority to make appointments to employment positions). All funds available on such day for such Office are transferred to such Center, and the transfer does not affect the availability of funds for the purposes for which the funds were appropriated (except that such purposes shall apply with respect to the Center to the same extent and in the same manner as the purposes applied with respect to the Office). All other legal rights and duties with respect to the Office are transferred to the Center, and continue in effect in accordance with their terms.

(2) OFFICE OF DIETARY SUPPLEMENTS.—With respect to the Office of Dietary Supplements established in section 485D of the Public Health Service Act (as added by subsection (a)), such establishment shall be construed to constitute a transfer of such Office to the National Center for Complementary and Alternative Medicine from the Office of the Director of the National Institutes of Health (in which the Office of Dietary Supplements was located pursuant to section 485C of the Public Health Service Act, as such section

was in effect on the day before the date of the enactment of this Act). Such transfer does not affect the status of any individual as an officer or employee in the Office of Dietary Supplements (except to the extent that the amendments made by subsection (a) affect the authority to make appointments to employment positions), does not affect the availability of funds of the Office for the purposes for which the funds were appropriated, and does not affect any other rights or duties with respect to the Office.

(c) TECHNICAL AND CONFORMING AMENDMENTS.—Part A of title IV of the Public Health Service Act (42 U.S.C. 281 et seq.), as amended by subsection (a), is amended—

(1) in section 401(b)(2), by amending subparagraph (E) to read as follows:

“(E) The National Center for Complementary and Alternative Medicine.”; and

(2) in section 402, by redesignating subsections (g) through (k) as subsections (f) through (j), respectively.

#### DURBIN AMENDMENTS NOS. 1138–1141

(Ordered to lie on the table.)

Mr. DURBIN submitted four amendments intended to be proposed by him to the bill, S. 830, supra; as follows:

##### AMENDMENT NO. 1138

Strike subsection (c) of section 404 and insert the following:

(c) RULE OF CONSTRUCTION.—Nothing in this Act or any amendment made by this Act shall be construed to alter any authority of the Secretary of Health and Human Services to regulate any tobacco product, or any additive or ingredient of a tobacco product.

##### AMENDMENT NO. 1139

Strike sections 605 and 606.

##### AMENDMENT NO. 1140

In section 523 of the Federal Food, Drug, and Cosmetic Act, as added by section 204, strike subsection (b) and insert the following:

“(b) ACCREDITATION.—

“(1) IN GENERAL.—Within 180 days after the date of enactment of this section, the Secretary shall adopt methods of accreditation that ensure that entities or individuals who conduct reviews and make recommendations under this section are qualified, properly trained, knowledgeable about handling confidential documents and information, and free of conflicts of interest.

“(2) STANDARDS.—In adopting the methods of accreditation, the Secretary shall ensure that the entities and individuals—

“(A) are subject to—

“(i) the conflict of interest standards applicable to employees of the Food and Drug Administration under subparts E, H, and I of part 73 of title 45, Code of Federal Regulations (as in effect on January 1, 1996); or

“(ii) if the standards described in clause (i) would be inappropriate for the entities and individuals, conflict of interest standards developed by the Secretary that are—

“(I) based on the standards described in clause (i); and

“(II) modified, as appropriate, to apply to the entities and individuals; and

“(B) are not subject to the conflict of interest standards under subpart J of such part.

“(3) PUBLICATION.—The Secretary shall publish the methods of accreditation in the Federal Register on the adoption of the methods.”.

##### AMENDMENT NO. 1141

At the end of title VIII, add the following:

#### SEC. \_\_\_\_ NOTIFICATION OF DISCONTINUANCE OF A LIFE SAVING PRODUCT.

Chapter VII (21 U.S.C. 371 et seq.), as amended by section 811, is further amended by adding at the end the following:

#### “Subchapter H—Notification of the Discontinuance of a Life Saving Product “SEC. 781. DISCONTINUANCE OF A LIFE SAVING PRODUCT.

“(a) IN GENERAL.—A manufacturer that is the sole manufacturer of a drug (including a biological product) or device—

“(1) that is—

“(A) life supporting;

“(B) life sustaining; or

“(C) intended for use in the prevention of a debilitating disease or condition; and

“(2) for which an application has been approved under section 505(b), 505(j), or 515(d), shall notify the Secretary of a discontinuance of the manufacture of the drug or device at least 6 months prior to the date of the discontinuance.

“(b) REDUCTION IN NOTIFICATION PERIOD.—On application of a manufacturer, the Secretary may reduce the notification period required under subsection (a) for the manufacturer if good cause exists for the reduction, such as a situation in which—

“(1) a public health problem may result from continuation of the manufacturing for the 6-month period;

“(2) a biomaterials shortage prevents the continuation of the manufacturing for the 6-month period;

“(3) a liability problem may exist for the manufacturer if the manufacturing is continued for the 6-month period;

“(4) continuation of the manufacturing for the 6-month period may cause substantial economic hardship for the manufacturer; or

“(5) the manufacturer has filed for bankruptcy under chapter 7 or 11 of title 11, United States Code.

“(c) DISTRIBUTION.—To the maximum extent practicable, the Secretary shall distribute information on the discontinuation of the drugs and devices described in subsection (a) to appropriate physician and patient organizations.”.

#### KENNEDY AMENDMENTS NOS. 1142–1155

(Ordered to lie on the table.)

Mr. KENNEDY submitted 14 amendments intended to be proposed by him in the bill, S. 830, supra; as follows:

##### AMENDMENT NO. 1142

Strike section 404.

##### AMENDMENT NO. 1143

On age 30, strike lines 1 through 16, and insert the following:

(b) PREMARKET NOTIFICATION.—Section 513(i)(1) (21 U.S.C. 360c(i)(1)) is amended by adding at the end the following:

“(C) Whenever the Secretary requests information to demonstrate that the devices with differing technological characteristics are substantially equivalent, the Secretary shall only request information that is necessary to make a substantial equivalence determination. In making such a request, the Secretary shall consider the least burdensome means of demonstrating substantial equivalence and shall request information accordingly.

“(D) The determination of the Secretary under this subsection and section 513(f)(1) with respect to the intended use of a device shall be based on the intended use included in the proposed labeling of the device submitted in a report under section 510(k), except that nothing in this subparagraph may be construed to limit what the Secretary

may consider in determining whether a device is substantially equivalent to a predicate device under subparagraph (A)(ii).”.

##### AMENDMENT NO. 1144

On page 30, line 16, after the first period, insert the following: “Nothing in the preceding sentence shall be construed to prohibit the Secretary from determining that a new device is not substantially equivalent to a predicate device because changes in the technological characteristics of the new device demonstrate that the device is intended for a different use than the use stated in the labeling of the device.”.

##### AMENDMENT NO. 1145

On page 30, line 16, insert before the first period the following: “If the proposed labeling is neither false nor misleading”.

##### AMENDMENT NO. 1146

Strike section 406.

##### AMENDMENT NO. 1147

Amend section 406 to read as follows:

#### SEC. 406. LIMITATIONS ON INITIAL CLASSIFICATION DETERMINATIONS.

Section 510(21 U.S.C. 360) is amended by adding at the end the following:

“(m) The Secretary may not withhold a determination of the initial classification of a device under section 513(f)(1) because of a failure to comply with any provision of this Act that is unrelated to a substantial equivalence decision, including a failure to comply with the requirements relating to good manufacturing practices under section 520(f), if such failure is unrelated to a substantial equivalence decision.”.

##### AMENDMENT NO. 1148

Amend section 406 to read as follows:

#### SEC. 406. LIMITATIONS ON INITIAL CLASSIFICATION DETERMINATIONS.

Section 510 (21 U.S.C. 360) is amended by adding at the end the following:

“(m) The Secretary may not withhold a determination of the initial classification of a device under section 513(f)(1) because of a failure to comply with any provision of this Act that is unrelated to a substantial equivalence decision, including a failure to comply with the requirements relating to good manufacturing practices under section 520(f), unless such failure could result in harm to human health.”.

##### AMENDMENT NO. 1149

Strike section 602.

##### AMENDMENT NO. 1150

Strike section 602 and insert the following:

#### SEC. 602. ENVIRONMENTAL IMPACT REVIEW.

Chapter VII (21 U.S.C. 371 et seq.), as amended by section 402, is further amended by adding at the end the following:

#### “SEC. 742. ENVIRONMENTAL IMPACT REVIEW.

“Notwithstanding any other provision of law, an environmental impact statement prepared in accordance with the regulations published in part 25 of title 21, Code of Federal Regulations (as in effect on August 31, 1997) in connection with an action carried out under (or a recommendation or report relating to) this Act, shall be considered to meet the requirements for a detailed statement under section 102(2)(C) of the National Environmental Policy Act of 1969 (42 U.S.C. 4332(2)(C)).”.

##### AMENDMENT NO. 1151

On page 26, line 9, strike “1999” and insert “2000”.

##### AMENDMENT NO. 1152

On page 24, line 19, strike “is” and insert “could be”.

## AMENDMENT NO. 1153

On page 31, strike lines 13 through 15 and insert the following: "a major amendment to an application."

## AMENDMENT NO. 1154

On page 38, line 12, strike "120" and insert "240".

## AMENDMENT NO. 1155

On page 43, line 12, strike "30" and insert "180".

WELLSTONE AMENDMENTS NOS.  
1156-1159

(Ordered to lie on the table.)

Mr. WELLSTONE submitted four amendments intended to be proposed by him to the bill, S. 830, supra; as follows:

## AMENDMENT NO. 1156

Strike section 612 and insert the following:  
**SEC. 612. HEALTH CARE ECONOMIC INFORMATION.**

(a) IN GENERAL.—Section 502(a) (21 U.S.C. 352(a)) is amended by adding at the end the following: "Health care economic information provided to a formulary committee, or other similar entity, in the course of the committee or the entity carrying out its responsibilities for the selection of drugs for managed care or other similar organizations, shall not be considered to be false or misleading if the health care economic information directly relates to an indication approved under section 505 or 507 or section 351(a) of the Public Health Service Act (42 U.S.C. 262(a)) for such drug and is based on competent and reliable scientific evidence. The requirements set forth in section 505(a), 507, or section 351(a) of the Public Health Service Act (42 U.S.C. 262(a)) shall not apply to health care economic information provided to such a committee or entity in accordance with this paragraph. Information that is relevant to the substantiation of the health care economic information presented pursuant to this paragraph shall be made available to the Secretary upon request. In this paragraph, the term 'health care economic information' means any analysis that identifies, measures, or compares the economic consequences, including the costs of the represented health outcomes, of the use of a drug to the use of another drug, to another health care intervention, or to no intervention."

(b) STUDY AND REPORT.—The Comptroller General of the United States shall conduct a study of the implementation of the provisions added by the amendment made by subsection (a). Not later than 4 years and 6 months after the date of enactment of this Act, the Comptroller General of the United States shall prepare and submit to Congress a report containing the findings of the study.

## AMENDMENT NO. 1157

Strike section 602.

## AMENDMENT NO. 1158

At the appropriate place, insert the following:

**SEC. . PARKINSON'S DISEASE RESEARCH.**

(a) SHORT TITLE.—This section may be cited as the "Morris K. Udall Parkinson's Research Act of 1997".

(b) FINDINGS AND PURPOSE.—

(1) FINDING.—Congress finds that to take full advantage of the tremendous potential for finding a cure or effective treatment, the Federal investment in Parkinson's must be expanded, as well as the coordination strengthened among the National Institutes of Health research institutes.

(2) PURPOSE.—It is the purpose of this Section to provide for the expansion and coordination of research regarding Parkinson's, and to improve care and assistance for afflicted individuals and their family caregivers.

(c) PARKINSON'S RESEARCH.—Part B of title IV of the public Health Service Act (42 U.S.C. 284 et seq.) is amended by adding at the end the following:

**"PARKINSON'S DISEASE**

"Sec. 409B. (a) IN GENERAL.—The Director of NIH shall establish a program for the conduct and support of research and training with respect to Parkinson's disease with funding for such program allocated to the extent authorized.

"(b) INTER-INSTITUTE COORDINATION.—

"(1) IN GENERAL.—The Director of NIH shall provide for the coordination of the program established under subsection (a) among all of the national research institutes conducting Parkinson's research.

"(2) CONFERENCE.—Coordination under paragraph (1) shall include the convening of a research planning conference not less frequently than once every 2 years. Each such conference shall prepare and submit to the Committee on Appropriations and the Committee on Labor and Human Resources of the Senate and the Committee on Appropriations and the Committee on Commerce of the House of Representatives a report concerning the conference.

"(c) MORRIS K. UDALL RESEARCH CENTERS.—

"(1) IN GENERAL.—The Director of NIH shall award Core Center Grants to encourage the development of innovative multidisciplinary research and provide training concerning Parkinson's. The Director shall award not more than 10 Core Center Grants and designate each center funded under such grants as a Morris K. Udall Center for Research on Parkinson's Disease.

"(2) REQUIREMENTS.—

"(A) IN GENERAL.—With respect to Parkinson's, each center assisted under this subsection shall—

"(i) use the facilities of a single institution or a consortium of cooperating institutions, and meet such qualifications as may be prescribed by the Director of the NIH; and

"(ii) conduct basic and clinical research.

"(B) DISCRETIONARY REQUIREMENTS.—With respect to Parkinson's, each center assisted under this subsection may—

"(i) conduct training programs for scientists and health professionals;

"(ii) conduct programs to provide information and continuing education to health professionals;

"(iii) conduct programs for the dissemination of information to the public;

"(iv) develop and maintain, where appropriate, a bank to collect specimens related to the research and treatment of Parkinson's;

"(v) separately or in collaboration with other centers, establish a nationwide data system derived from patient populations with Parkinson's, and where possible, comparing relevant data involving general populations;

"(vi) separately or in collaboration with other centers, establish a Parkinson's Disease Information Clearinghouse to facilitate and enhance knowledge and understanding of Parkinson's disease; and

"(vii) separately or in collaboration with other centers, establish a national education program that fosters a national focus on Parkinson's and the care of those with Parkinson's.

"(3) STIPENDS REGARDING TRAINING PROGRAMS.—A center may use funds provided under paragraph (1) to provide stipends for

scientists and health professionals enrolled in training programs under paragraph (2)(B).

"(4) DURATION OF SUPPORT.—Support of a center under this subsection may be for a period not exceeding five years. Such period may be extended by the Director of NIH for one or more additional periods of not more than five years if the operations of such center have been reviewed by an appropriate technical and scientific peer review group established by the Director and if such group has recommended to the Director that such period should be extended.

"(d) MORRIS K. UDALL AWARDS FOR EXCELLENCE IN PARKINSON'S DISEASE RESEARCH.—The Director of NIH shall establish a grant program to support investigators with a proven record of excellence and innovation in Parkinson's research and who demonstrate potential for significant future breakthroughs in the understanding of the pathogenesis, diagnosis, and treatment of Parkinson's. Grants under this subsection shall be available for a period of not to exceed 5 years.

"(e) AUTHORIZATION OF APPROPRIATIONS.—For the purpose of carrying out this section, there are authorized to be appropriated \$100,000,000 for fiscal year 1998, and such sums as may be necessary for each of the fiscal years 1999 and 2000."

## AMENDMENT NO. 1159

In section 613, strike subsection (b) and insert the following:

(b) CIVIL MONEY PENALTIES.—Section 303(g)(1) (21 U.S.C. 333(g)(1)) is amended—

(1) in subparagraph (A), by inserting "or a requirement of section 561 that relates to conducting post-approval studies for fast track drugs" after "devices"; and

(2) by adding at the end the following:

"(C) The Secretary may waive the application of subparagraph (A) to a person who fails to conduct post-approval studies for fast track drugs, as required in section 561, if the Secretary determines that the failure was due to circumstances beyond the control of the person, or for other good cause."

(c) GUIDANCE.—Within 1 year after the date of enactment of this Act, the Secretary of Health and Human Services shall issue guidance for fast track drugs that describes the policies and procedures that pertain to section 561 of the Federal Food, Drug, and Cosmetic Act.

MURRAY AMENDMENTS NOS. 1160-  
1161

(Ordered to lie on the table.)

Mrs. MURRAY submitted two amendments intended to be proposed by her to the bill, S. 830, supra; as follows:

## AMENDMENT NO. 1160

On page 118, strike lines 6 through 10, and insert the following:

"(2) would not cause any drug to be in violation of any applicable requirement or prohibition under Federal law;

"(3) would not unduly burden interstate commerce; or

"(4) provides that the label or labeling of a drug shall include written information, or a symbol, to warn or educate children and the parents of the children with respect to any harm that may result from the use of the drug by the children."

## AMENDMENT NO. 1161

Beginning on page 117, strike line 24 and all that follows through page 118, line 10, and insert the following:

"(b) EXEMPTION.—

"(1) IN GENERAL.—Upon application of a State or political subdivision thereof, the

Secretary may by regulation, after notice and opportunity for written and oral presentation of views, exempt from subsection (a), under such conditions as may be prescribed in such regulation, a State or political subdivision requirement that—

“(A) protects an important public interest that would otherwise be unprotected, including the health and safety of children;

“(B) would not cause any drug to be in violation of any applicable requirement or prohibition under Federal law; and

“(C) would not unduly burden interstate commerce.

“(2) **TIMELY ACTION.**—The Secretary shall make a decision on the exemption of a State or political subdivision requirement under paragraph (1) not later than 120 days after receiving the application of the State or political subdivision under paragraph (1).”

#### BIDEN AMENDMENTS NOS. 1162–1167

(Ordered to lie on the table.)

Mr. BIDEN submitted six amendments intended to be proposed by him to the bill, S. 830, supra; as follows:

##### AMENDMENT NO. 1162

At the appropriate place in title VIII, insert the following:

#### SEC. . REAUTHORIZATION FOR MEDICATION DEVELOPMENT PROGRAM.

Section 464P(e) of the Public Health Service Act (42 U.S.C. 2850–4(e)) is amended to read as follows:

“(e) **AUTHORIZATION OF APPROPRIATIONS.**—There is authorized to be appropriated to carry out this section such sums as may be necessary for each of the fiscal years 1998 through 2002 of which the following amount may be appropriated from the Violent Crime Reduction Trust Fund:

“(1) \$100,000,000 for fiscal year 2001; and

“(2) \$100,000,000 for fiscal year 2002.”.

##### AMENDMENT NO. 1163

At the appropriate place insert the following:

#### TITLE —PATENT PROTECTIONS FOR PHARMACOTHERAPIES

#### SEC. 01. RECOMMENDATION FOR INVESTIGATION OF DRUGS.

Section 525(a) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 360aa(a)) is amended—

(1) by striking “States” each place it appears and inserting “States, or for treatment of an addiction to illegal drugs”; and

(2) by striking “such disease or condition” each place it appears and inserting “such disease, condition, or treatment of such addiction”.

#### SEC. 02. DESIGNATION OF DRUGS.

Section 526(a) of the Federal, Food, Drug, and Cosmetic Act (21 U.S.C. 360bb(a)) is amended—

(1) in paragraph (1)—

(A) by inserting before the period in the first sentence the following: “or for treatment of an addiction to illegal drugs”;

(B) in the third sentence, by striking “rare disease or condition” and inserting “rare disease or condition, or for treatment of an addiction to illegal drugs.”; and

(C) by striking “such disease or condition” each place it appears and inserting “such disease, condition, or treatment of such addiction”;

(2) in paragraph (2)—

(A) by striking “(2) For” and inserting “(2)(A) For”;

(B) by striking “(A) affects” and inserting “(i) affects”;

(C) by striking “(B) affects” and inserting “(ii) affects”;

(D) by adding at the end the following:

“(B) **TREATMENT OF AN ADDICTION TO ILLEGAL DRUGS.**—The term ‘treatment of an addiction to illegal drugs’ means any pharmacological agent or medication that—

“(i) reduces the craving for an illegal drug for an individual who—

“(I) habitually uses the illegal drug in a manner that endangers the public health, safety, or welfare; or

“(II) is so addicted to the use of the illegal drug that the individual is not able to control the addiction through the exercise of self-control;

“(ii) blocks the behavioral and physiological effects of an illegal drug for an individual described in clause (i);

“(iii) safely serves as a replacement therapy for the treatment of drug abuse for an individual described in clause (i);

“(iv) moderates or eliminates the process of withdrawal for an individual described in clause (i);

“(v) blocks or reverses the toxic effect of an illegal drug on an individual described in clause (i); or

“(vi) prevents, where possible, the initiation of drug abuse in individuals at high risk.

“(C) **ILLEGAL DRUG.**—The term ‘illegal drug’ means a controlled substance identified under schedules I, II, III, IV, and V in section 202(c) of the Controlled Substance Act (21 U.S.C. 812(c)).”.

#### SEC. 03. PROTECTION FOR DRUGS.

Section 527 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 360cc) is amended—

(1) by striking “rare disease or condition” each place it appears and inserting “rare disease or condition or for treatment of an addiction to illegal drugs”;

(2) by striking “such disease or condition” each place it appears and inserting “such disease, condition, or treatment of the addiction”;

(3) in subsection (b)(1), by striking “the disease or condition” and inserting “the disease, condition, or addiction”.

#### SEC. 04. OPEN PROTOCOLS FOR INVESTIGATIONS OF DRUGS.

Section 528 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 360dd) is amended—

(1) by striking “rare disease or condition” and inserting “rare disease or condition or for treatment of an addiction to illegal drugs”; and

(2) by striking “the disease or condition” each place it appears and inserting “the disease, condition, or addiction”.

##### AMENDMENT NO. 1164

At the appropriate place in title VIII, insert the following:

#### SEC. . DEVELOPMENT, MANUFACTURE, AND PROCUREMENT OF DRUGS FOR THE TREATMENT OF ADDICTION TO ILLEGAL DRUGS.

Chapter V (21 U.S.C. 351 et seq.), as amended by sections 102 and 613(a), is further amended by adding at the end the following:

#### “Subchapter F—Drugs for Cocaine and Heroin Addictions

#### “SEC. 571. CRITERIA FOR AN ACCEPTABLE DRUG TREATMENT FOR COCAINE AND HEROIN ADDICTIONS.

“(a) **IN GENERAL.**—Subject to subsections (b) and (c), the Secretary shall, through the Institute of Medicine of the National Academy of Sciences, establish criteria for an acceptable drug for the treatment of an addiction to cocaine and for an acceptable drug for the treatment of an addiction to heroin. The criteria shall be used by the Secretary in making a contract, or entering into a licensing agreement, under section 572.

“(b) **REQUIREMENTS.**—The criteria established under subsection (a) for a drug shall include requirements—

“(1) that the application to use the drug for the treatment of addiction to cocaine or heroin was filed and approved by the Secretary under this Act after the date of enactment of this section;

“(2) that a performance based test on the drug—

“(A) has been conducted through the use of a randomly selected test group that received the drug as a treatment and a randomly selected control group that received a placebo; and

“(B) has compared the long term differences in the addiction levels of control group participants and test group participants;

“(3) that the performance based test conducted under paragraph (2) demonstrates that the drug is effective through evidence that—

“(A) a significant number of the participants in the test who have an addiction to cocaine or heroin are willing to take the drug for the addiction;

“(B) a significant number of the participants in the test who have an addiction to cocaine or heroin and who were provided the drug for the addiction during the test are willing to continue taking the drug as long as necessary for the treatment of the addiction; and

“(C) a significant number of the participants in the test who were provided the drug for the period of time required for the treatment of the addiction refrained from the use of cocaine or heroin for a period of 3 years after the date of the initial administration of the drug on the participants; and

“(4) that the drug shall have a reasonable cost of production.

“(c) **REVIEW AND PUBLICATION OF CRITERIA.**—The criteria established under subsection (a) shall, prior to the publication and application of such criteria, be submitted for review to the Committee on the Judiciary and the Committee on Economic and Educational Opportunities of the House of Representatives, and the Committee on the Judiciary and the Committee on Labor and Human Resources of the Senate. Not later than 90 days after notifying each of the committees, the Secretary shall publish the criteria in the Federal Register.

#### “SEC. 572. PURCHASE OF PATENT RIGHTS FOR DRUG DEVELOPMENT.

“(a) **APPLICATION.**—

“(1) **IN GENERAL.**—The patent owner of a drug to treat an addiction to cocaine or heroin, may submit an application to the Secretary—

“(A) to enter into a contract with the Secretary to sell to the Secretary the patent rights of the owner relating to the drug; or

“(B) in the case in which the drug is approved by the Secretary for more than 1 indication, to enter into an exclusive licensing agreement with the Secretary for the manufacture and distribution of the drug to treat an addiction to cocaine or heroin.

“(2) **REQUIREMENTS.**—An application described in paragraph (1) shall be submitted at such time and in such manner, and accompanied by such information, as the Secretary may require.

“(b) **CONTRACT AND LICENSING AGREEMENTS.**—

“(1) **REQUIREMENTS.**—The Secretary may enter into a contract or a licensing agreement with a patent owner who has submitted an application in accordance with (a) if the drug covered under the contract or licensing agreement meets the criteria established by the Secretary under section 571(a).

“(2) **SPECIAL RULE.**—The Secretary may enter into—

“(A) not more than 1 contract or exclusive licensing agreement relating to a drug for

the treatment of an addiction to cocaine; and

“(B) not more than 1 contract or licensing agreement relating to a drug for the treatment of an addiction to heroin.

“(3) COVERAGE.—A contract or licensing agreement described in subparagraph (A) or (B) of paragraph (2) shall cover not more than 1 drug.

“(4) PURCHASE AMOUNT.—Subject to amounts provided in advance in appropriations Acts—

“(A) the amount to be paid to a patent owner who has entered into a contract or licensing agreement under this subsection relating to a drug to treat an addiction to cocaine shall not exceed \$100,000,000; and

“(B) the amount to be paid to a patent owner who has entered into a contract or licensing agreement under this subsection relating to a drug to treat an addiction to heroin shall not exceed \$50,000,000.

“(c) TRANSFER OF RIGHTS UNDER CONTRACTS AND LICENSING AGREEMENT.—

“(1) CONTRACTS.—A contract under subsection (b)(1) to purchase the patent rights relating to a drug to treat cocaine or heroin addiction shall transfer to the Secretary—

“(A) the exclusive right to make, use, or sell the patented drug within the United States for the term of the patent;

“(B) any foreign patent rights held by the patent owner;

“(C) any patent rights relating to the process of manufacturing the drug; and

“(D) any trade secret or confidential business information relating to the development of the drug, process for manufacturing the drug, and therapeutic effects of the drug.

“(2) LICENSING AGREEMENTS.—A licensing agreement under subsection (b)(1) to purchase an exclusive license relating to manufacture and distribution of a drug to treat an addiction to cocaine or heroin shall transfer to the Secretary—

“(A) the exclusive right to make, use, or sell the patented drug for the purpose of treating an addiction to cocaine or heroin within the United States for the term of the patent;

“(B) the right to use any patented processes relating to manufacturing the drug; and

“(C) any trade secret or confidential business information relating to the development of the drug, process for manufacturing the drug, and therapeutic effects of the drug relating to use of the drug to treat an addiction to cocaine or heroin.

“**SEC. 573. PLAN FOR MANUFACTURE AND DEVELOPMENT.**

“(a) IN GENERAL.—Not later than 90 days after the date on which the Secretary purchases the patent rights of a patent owner, or enters into a licensing agreement with a patent owner, relating to a drug under section 571, the Secretary shall develop a plan for the manufacture and distribution of the drug.

“(b) PLAN REQUIREMENTS.—The plan shall set forth—

“(1) procedures for the Secretary to enter into licensing agreements with private entities for the manufacture and the distribution of the drug;

“(2) procedures for making the drug available to nonprofit entities and private entities to use in the treatment of a cocaine or heroin addiction;

“(3) a system to establish the sale price for the drug; and

“(4) policies and procedures with respect to the use of Federal funds by State and local governments or nonprofit entities to purchase the drug from the Secretary.

“(c) APPLICABILITY OF PROCUREMENT AND LICENSING LAWS.—The procurement and licensing laws of the United States shall be

applicable to procurements and licenses covered under the plan described in subsection (a).

“(d) REVIEW OF PLAN.—

“(1) IN GENERAL.—Upon completion of the plan under subsection (a), the Secretary shall notify the Committee on the Judiciary and the Committee on Economic and Educational Opportunities of the House of Representatives, and the Committee on the Judiciary and the Committee on Labor and Human Resources of the Senate, of the development of the plan and publish the plan in the Federal Register. The Secretary shall provide an opportunity for public comment on the plan for a period of not more than 30 days after the date of the publication of the plan in the Federal Register.

“(2) FINAL PLAN.—Not later than 60 days after the date of the expiration of the comment period described in paragraph (1), the Secretary shall publish in the Federal Register a final plan. The implementation of the plan shall begin on the date of the final publication of the plan.

“(e) CONSTRUCTION.—The development, publication, or implementation of the plan, or any other agency action with respect to the plan, shall not be considered agency action subject to judicial review.

“(f) REGULATIONS.—The Secretary may promulgate regulations to carry out this section.

“**SEC. 574. AUTHORIZATION OF APPROPRIATIONS.**

“There is authorized to be appropriated to carry out this subchapter, such sums as may be necessary in each of the fiscal years 1998 through 2000.”

#### AMENDMENT No. 1165

At the end of title VIII, add the following:

**SEC. 8 . AUTHORITY TO RESCHEDULE CERTAIN CONTROLLED SUBSTANCES POSING IMMINENT HAZARD TO PUBLIC SAFETY.**

Section 201(h) of the Controlled Substances Act (21 U.S.C. 811(h)) is amended—

(1) in paragraph (1)—

(A) by inserting “, or the rescheduling of a scheduled substance,” after “the scheduling of a substance”; and

(B) by striking “if the substance is not listed in any other schedule in section 202 or”; and

(2) in paragraph (2), by inserting “or rescheduling” after “scheduling” each place that term appears.

#### AMENDMENT No. 1166

At the end of title VIII, add the following:

**SEC. 8 . CLASSIFICATION OF KETAMINE HYDROCHLORIDE.**

Notwithstanding section 201 or subsection (a) or (b) of section 202 of the Controlled Substances Act (21 U.S.C. 811, 812(a), 812(b)) respecting the scheduling of controlled substances, the Attorney General shall, by order, add ketamine hydrochloride to schedule III of such Act.

#### AMENDMENT No. 1167

At the end of title VIII, add the following:

**SEC. 8 . RESCHEDULING OF ROHPYNOL.**

Notwithstanding section 201 or subsection (a) or (b) of section 202 of the Controlled Substances Act (21 U.S.C. 811, 812(a), 812(b)) respecting the scheduling of controlled substances, the Attorney General shall, by order, transfer flunitrazepam from schedule IV of such Act to schedule I of such Act.

#### BREAUX AMENDMENT No. 1168

(Ordered to lie on the table.)

Mr. BREAUX submitted an amendment intended to be proposed by him to the bill, S. 830, supra; as follows:

At the appropriate place, add the following:

#### TITLE —COMMISSION

##### SEC. 1. ESTABLISHMENT OF COMMISSION.

(a) IN GENERAL.—There is established a Drug and Device Review Advisory Commission (referred to in this title as the “Commission”), to conduct a study and prepare recommendations concerning the determinations and administrative processes of the Food and Drug Administration.

(b) MEMBERSHIP.—

(1) COMPOSITION.—The Commission shall be composed of 11 members, including—

(A) 5 individuals appointed by the President;

(B) 3 individuals appointed jointly by the President pro tempore of the Senate and the majority and minority leaders of the Senate; and

(C) 3 individuals appointed jointly by the Speaker of the House of Representatives and the majority and minority leaders of the House of Representatives.

(2) QUALIFICATIONS.—

(A) DRUG AND DEVICE MANUFACTURERS.—Two of the members appointed under paragraph (1)(A), one of the members appointed under paragraph (1)(B), and one of the members appointed under paragraph (1)(C), shall be manufacturers of drugs or devices (as such terms are defined in section 201 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 321)).

(B) MEDICAL PROFESSIONALS.—Two of the members appointed under paragraph (1)(A), one of the members appointed under paragraph (1)(B), and one of the members appointed under paragraph (1)(C), shall be health personnel described in section 792(a) of the Public Health Service Act (42 U.S.C. 295k(a)).

(C) GENERAL PUBLIC.—One of the members appointed under paragraph (1)(A), one of the members appointed under paragraph (1)(B), and one of the members appointed under paragraph (1)(C), shall be members of the general public.

(3) APPOINTMENT.—The members of the Commission shall be appointed not later than 60 days after the date of enactment of this Act.

(c) CHAIRPERSON.—The Commission shall select a Chairperson from among its members.

(d) TERM OF OFFICE.—

(1) IN GENERAL.—Except as otherwise provided in this subsection, a member of the Commission shall be appointed for a term of 5 years.

(2) INITIAL MEMBERS.—Of the members first appointed—

(A) 2 shall be appointed for terms of 1 year;

(B) 2 shall be appointed for terms of 2 years;

(C) 2 shall be appointed for terms of 3 years;

(D) 2 shall be appointed for terms of 4 years; and

(E) 3 shall be appointed for terms of 5 years.

(3) SCHEDULE.—The appointing individuals described in subsection (b)(1) shall jointly determine a schedule for the appointment of members of the Commission that ensures that, in any year—

(A) no appointing individual appoints more than 1 member; and

(B) the appointing individuals appoint not more than 1 member from any class of persons described in subparagraph (A), (B), or (C) of subsection (b)(2).

(e) VACANCIES.—Any vacancy occurring in the membership of the Commission shall be filled in the same manner as the original appointment for the position being vacated. The vacancy shall not affect the power of the

remaining members to execute the duties of the Commission.

(f) **COMPENSATION AND EXPENSES.**—

(1) **COMPENSATION.**—Each member of the Commission who is not an employee of the Federal Government shall receive compensation at the daily equivalent of the rate specified for level V of the Executive Schedule under section 5316 of title 5, United States Code, for each day the member is engaged in the performance of duties for the Commission, including attendance at meetings and conferences of the Commission, and travel to conduct the duties of the Commission.

(2) **TRAVEL EXPENSES.**—Each member of the Commission shall receive travel expenses, including per diem in lieu of subsistence, at rates authorized for employees of agencies under subchapter I of chapter 57 of title 5, United States Code, for each day the member is engaged in the performance of duties away from the home or regular place of business of the member.

**SEC. 2. STUDY AND REPORT.**

(a) **STUDY.**—The Commission shall annually conduct a study of the determinations and administrative processes of the Food and Drug Administration.

(b) **REPORT.**—Not later than 15 months after the date of the enactment of this Act, and annually thereafter, the Commission shall prepare and submit to the President and the appropriate committees of Congress a written report containing—

(1) the findings and conclusions of the Commission resulting from the study conducted under subsection (a); and

(2) recommendations, based on the findings and conclusions described in paragraph (1), for improvements in the efficiency and administrative processes of the Food and Drug Administration.

**SEC. 3. POWERS OF THE COMMISSION.**

(a) **IN GENERAL.**—The Commission is authorized to—

(1) hold such hearings and sit and act at such times;

(2) take such testimony;

(3) have such printing and binding done;

(4) enter into such contracts and other arrangements;

(5) make such expenditures; and

(6) take such other actions;

as the Commission may determine to be necessary to carry out the duties of the Commission.

(b) **OBTAINING INFORMATION FROM FEDERAL AGENCIES.**—The Commission may secure directly from any Federal agency such information as the Commission may require to carry out its duties.

(c) **USE OF MAIL.**—The Commission may use the United States mails in the same manner and under the same conditions as Federal agencies.

**SEC. 4. STAFF AND CONSULTANTS.**

(a) **STAFF.**—

(1) **APPOINTMENT AND COMPENSATION.**—The Commission may appoint and determine the compensation of such staff as the Commission determines to be necessary to carry out the duties of the Commission.

(2) **LIMITATIONS.**—The rate of compensation for each staff member shall not exceed the daily equivalent of the rate specified for level V of the Executive Schedule under section 5316 of title 5, United States Code for each day the staff member is engaged in the performance of duties for the Commission. The Commission may otherwise appoint and determine the compensation of staff without regard to the provisions of title 5, United States Code, that govern appointments in the competitive service, and the provisions of chapter 51 and subchapter III of chapter 53 of title 5, United States Code, that relate to classification and General Schedule pay rates.

(b) **EXPERTS AND CONSULTANTS.**—The Chairperson of the Commission may obtain such temporary and intermittent services of experts and consultants and compensate the experts and consultants in accordance with section 3109(b) of title 5, United States Code, as the Commission determines to be necessary to carry out the duties of the Commission.

(c) **DETAIL OF FEDERAL EMPLOYEES.**—On the request of the Chairperson of the Commission, the head of any Federal agency shall detail, without reimbursement, any of the personnel of the agency to the Commission to assist the Commission in carrying out its duties. Any detail shall not interrupt or otherwise affect the civil service status or privileges of the Federal employee.

(d) **TECHNICAL ASSISTANCE.**—On the request of the Chairperson of the Commission, the head of a Federal agency shall provide such technical assistance to the Commission as the Commission determines to be necessary to carry out its duties.

**SEC. 5. AUTHORIZATION OF APPROPRIATIONS.**

There are authorized to be appropriated to the Commission such sums as may be necessary to carry out the provisions of this title. The sums shall remain available until expended, without fiscal year limitation.

**SEC. 6. TERMINATION.**

Section 15 of the Federal Advisory Committee Act (5 U.S.C. App.) shall not apply to the Commission.

**REED AMENDMENTS NOS. 1169-1170**

(Ordered to lie on the table.)

Mr. REED submitted two amendments intended to be proposed by him to the bill, S. 830, supra; as follows:

**AMENDMENT NO. 1169**

Strike section 404.

**AMENDMENT NO. 1170**

On page 30, strike lines 1 through 16, and insert the following:

(b) **PREMARKET NOTIFICATIONS.**—Section 513(i)(1) (21 U.S.C. 360c(i)(1)) is amended by adding at the end the following:

“(C) Whenever the Secretary requests information to demonstrate that the devices with differing technological characteristics are substantially equivalent, the Secretary shall only request information that is necessary to make a substantial equivalence determination. In making such a request, the Secretary shall consider the least burdensome means of demonstrating substantial equivalence and shall request information accordingly.

“(D) The determination of the Secretary under this subsection and section 513(f)(1) with respect to the intended use of a device shall be based on the intended use included in the proposed labeling of the device submitted in a report under section 510(k), except that nothing in this subparagraph may be construed to limit what the Secretary may consider in determining whether a device is substantially equivalent to a predicate device under subparagraph (A)(ii).”

**HARKIN AMENDMENT NO. 1171**

(Ordered to lie on the table.)

Mr. HARKIN submitted an amendment intended to be proposed by him to the bill, S. 830, supra; as follows:

**AMENDMENT NO. 1171**

At the end of title VIII, add the following:

**SEC. . ELECTRONIC PASTEURIZATION.**

(a) **DEFINITION.**—In this section, the term “electronic pasteurization” means exposure

of a food to an electron beam, or to an x-ray produced from an energy source generated by electricity.

(b) **REGULATION.**—

(1) **IN GENERAL.**—Notwithstanding any other provision of this Act, not later than 90 days after the date of enactment of this Act, the Secretary of Health and Human Services shall issue a final rule amending the regulation issued under the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 321 et seq.) relating to labeling requirements applicable to the use of ionizing radiation for the treatment of food.

(2) **PROVISION.**—The amended regulation shall provide that a food that has been treated by electronic pasteurization and has not been irradiated by a radioactive isotope source—

(A) shall not be considered to violate the labeling requirements solely because the labeling and other identifying materials associated with the food fail to identify the food as having been treated with radiation or treated by irradiation; and

(B) shall be considered to comply with the labeling requirements if the labeling and other identifying materials identify the food as electronically pasteurized or having been treated with electronic pasteurization.

**COATS AMENDMENT NO. 1172**

(Ordered to lie on the table.)

Mr. COATS submitted an amendment intended to be proposed by him to the bill, S. 830, supra; as follows:

At the appropriate place, insert the following:

**SEC. . EXAMINATIONS AND PROCEDURES.**—

Paragraph 353(d)(3) of the Public Health Service Act (42 U.S.C. 263a(d)(3)) is amended—

(1) by striking “, including those which” and by inserting in its place “. The following three types of examinations and procedures shall each be deemed to meet the standards in the preceding sentence”;

(2) in subparagraph (A), by inserting at the end thereof “even if FDA places limits on the sale of the devices associated with such examinations or procedures (e.g., prescription status), or”;

(3) in subparagraph (B), by inserting “by the user” before “negligible”.

**JEFFORDS AMENDMENTS NOS.**

1173-1175

(Ordered to lie on the table.)

Mr. JEFFORDS submitted three amendments intended to be proposed by him to the bill, S. 830, supra; as follows:

**AMENDMENT NO. 1173**

Strike section 619 and insert the following:

**SEC. 619. POSITRON EMISSION TOMOGRAPHY.**

(a) **REGULATION OF COMPOUNDED POSITRON EMISSION TOMOGRAPHY DRUGS UNDER THE FEDERAL FOOD, DRUG, AND COSMETIC ACT.**—

(1) **DEFINITION.**—Section 201 (21 U.S.C. 321) is amended by adding at the end the following:

“(ii) The term ‘compounded positron emission tomography drug’—

“(1) means a drug that—

“(A) exhibits spontaneous disintegration of unstable nuclei by the emission of positrons and is used for the purpose of providing dual photon positron emission tomographic diagnostic images; and

“(B) has been compounded by or on the order of a practitioner who is licensed by a State to compound or order compounding for a drug described in subparagraph (A), and is compounded in accordance with that State’s

law, for a patient or for research, teaching, or quality control; and

“(2) includes any nonradioactive reagent, reagent kit, ingredient, nuclide generator, accelerator, target material, electronic synthesizer, or other apparatus or computer program to be used in the preparation of such a drug.”.

(b) ADULTERATION.—

(1) IN GENERAL.—Section 501(a)(2) (21 U.S.C. 351(a)(2)) is amended by striking “; or (3)” and inserting the following: “; or (C) if it is a compounded positron emission tomography drug and the methods used in, or the facilities and controls used for, its compounding, processing, packing, or holding do not conform to or are not operated or administered in conformity with the positron emission tomography compounding standards and the official monographs of the United States Pharmacopeia to assure that such drug meets the requirements of this Act as to safety and has the identity and strength, and meets the quality and purity characteristics, that it purports or is represented to possess; or (3)”.

(2) SUNSET.—Sections 201(ii) and 501(a)(2)(C) (21 U.S.C. 321(ii) and 351(a)(2)(C)) shall not apply 4 years after the date of enactment of this Act or 2 years after the date or which the Secretary of Health and Human Services establishes the requirements described in subsection (c)(1)(B), whichever is later.

(c) REQUIREMENTS FOR REVIEW OF APPROVAL PROCEDURES AND CURRENT GOOD MANUFACTURING PRACTICES FOR POSITRON EMISSION TOMOGRAPHY.—

(1) PROCEDURES AND REQUIREMENTS.—

(A) IN GENERAL.—In order to take account of the special characteristics of positron emission tomography drugs and the special techniques and processes required to produce these drugs, not later than 2 years after the date of enactment of this Act, the Secretary of Health and Human Services shall establish—

(i) appropriate procedures for the approval of positron emission tomography drugs pursuant to section 505 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 355); and

(ii) appropriate current good manufacturing practice requirements for such drugs.

(B) CONSIDERATIONS AND CONSULTATION.—In establishing the procedures and requirements required by subparagraph (A), the Secretary of Health and Human Services shall take due account of any relevant differences between not-for-profit institutions that compound the drugs for their patients and commercial manufacturers of the drugs. Prior to establishing the procedures and requirements, the Secretary of Health and Human Services shall consult with patient advocacy groups, professional associations, manufacturers, and physicians and scientists licensed to make or use positron emission tomography drugs.

(2) SUBMISSION OF NEW DRUG APPLICATIONS AND ABBREVIATED NEW DRUG APPLICATIONS.—

(A) IN GENERAL.—The Secretary of Health and Human Services shall not require the submission of new drug applications or abbreviated new drug applications under subsection (b) or (j) of section 505 (21 U.S.C. 355), for compounded positron emission tomography drugs that are not adulterated drugs described in section 501(a)(2)(C) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 351(a)(2)(C)) (as amended by subsection (b)), for a period of 4 years after the date of enactment of this Act, or for 2 years after the date or which the Secretary establishes procedures and requirements under paragraph (1), whichever is later.

(B) CONSTRUCTION.—Nothing in this Act shall prohibit the voluntary submission of such applications or the review of such appli-

cations by the Secretary of Health and Human Services. Nothing in this Act shall constitute an exemption for a positron emission tomography drug from the requirements of regulations issued under section 505(i) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 355(i)) for such drugs.

(d) REVOCATION OF CERTAIN INCONSISTENT DOCUMENTS.—Within 30 days after the date of enactment of this Act, the Secretary of Health and Human Services shall publish in the Federal Register a notice terminating the application of the following notices and rule:

(1) A notice entitled “Regulation of Positron Emission Tomography Radiopharmaceutical Drug Products; Guidance; Public Workshop”, published in the Federal Register on February 27, 1995, 60 Fed. Reg. 10594.

(2) A notice entitled “Draft Guideline on the Manufacture of Positron Emission Tomography Radiopharmaceutical Drug Products; Availability”, published in the Federal Register on February 27, 1995, 60 Fed. Reg. 10593.

(3) A final rule entitled “Current Good Manufacturing Practice for Finished Pharmaceuticals; Positron Emission Tomography”, published in the Federal Register on April 22, 1997, 62 Fed. Reg. 19493 (codified at part 211 of title 21, Code of Federal Regulations).

(e) DEFINITION.—In this section:

(1) COMPOUNDED POSITRON EMISSION TOMOGRAPHY DRUG.—The term “compounded positron emission tomography drug” means a positron emission tomography drug that has been compounded by or on the order of a practitioner who is licensed by a State to compound or order compounding for such a drug, and is compounded in accordance with that State’s law, for a patient or for research, teaching, or quality control.

(2) DRUG.—The term “drug” has the meaning given the term in section 201 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 321 et seq.).

(3) POSITRON EMISSION TOMOGRAPHY DRUG.—The term “positron emission tomography drug” means a drug that—

(A) exhibits spontaneous disintegration of unstable nuclei by the emission of positrons and is used for the purpose of providing dual photon positron emission tomographic diagnostic images; and

(B) includes any nonradioactive reagent, reagent kit, ingredient, nuclide generator, accelerator, target material, electronic synthesizer, or other apparatus or computer program to be used in the preparation of such a drug.

AMENDMENT NO. 1174

On page 30, strike lines 17 through 20, and insert the following:

(c) RULE OF CONSTRUCTION.—Nothing in the amendments made by subsections (a) and (b) shall be construed to alter any authority of the Secretary of Health and Human Services to regulate any tobacco product, or any additive or ingredient of a tobacco product.

AMENDMENT NO. 1175

Strike section 602 and insert the following:

**SEC. 602. ENVIRONMENTAL IMPACT REVIEW.**  
Chapter VII (21 U.S.C. 371 et seq.), as amended by section 402, is further amended by adding at the end the following:

**“SEC. 742. ENVIRONMENTAL IMPACT REVIEW.**

“Notwithstanding any other provision of law, an environmental impact statement prepared in accordance with the regulations published in part 25 of title 21, Code of Federal Regulations (as in effect on August 31, 1997) in connection with an action carried out under (or a recommendation or report re-

lating to) this Act, shall be considered to meet the requirements for a detailed statement under section 102(2)(C) of the National Environmental Policy Act of 1969 (42 U.S.C. 4332(2)(c)).”.

REED AMENDMENTS NOS. 1176–1177

(Ordered to lie on the table.)

Mr. REED submitted two amendments intended to be proposed by him to the bill, S. 830, supra; as follows:

AMENDMENT NO. 1176

On page 30, line 16, after the first period, insert the following: “Nothing in the preceding sentence shall be construed to prohibit the Secretary from determining that a new device is not substantially equivalent to a predicate device because changes in the technological characteristics of the new device demonstrate that the device is intended for a different use than the use stated in the labeling of the device.”.

AMENDMENT NO. 1177

On page 30, line 16, insert before the first period the following: “if the proposed labeling is neither false nor misleading”.

THE DEPARTMENT OF THE INTERIOR AND RELATED AGENCIES APPROPRIATIONS ACT, 1998

BROWNBACK AMENDMENT NO. 1178

Mr. BROWNBACK submitted an amendment intended to be proposed by him to the bill (H.R. 2107) making appropriations for the Department of the Interior and related agencies for the fiscal year ending September 30, 1998, and for other purposes; as follows:

At the appropriate place in title I, insert the following:

“SEC. 1 . (a) In this section—

(1) the term “Huron Cemetery” means the lands that form the cemetery that is popularly known as the Huron Cemetery, located in Kansas City, Kansas, as described in subsection (b)(4);

(2) the term “Secretary” means the Secretary of the Interior; and

(3) the term “Wyandot Nation” means the nation of the Wyandot Indians that consists of the descendants of the Wyandott nation described in the treaty between the United States and the Wyandott Indians, done at Washington on January 31, 1855 (10 Stat. 1159 et seq.), and includes—

(A) the Wyandot Nation of Kansas, Inc.; and

(B) the Wayandotte Tribe of Oklahoma.

(b)(1) Subject to subsection (c), the Secretary shall take such action as may be necessary to ensure that the lands comprising the Huron Cemetery (as described in paragraph (4)) are held in trust for the Wyandot Nation to be used only for a burial ground for the Wyandot Nation in accordance with this subsection.

(2) Subject to subsection (c), the Secretary shall take such action as may be necessary to ensure that the lands of the Huron Cemetery are used only—

(A) for religious and cultural uses of the Wyandot Nation that are compatible with the use of the lands as a cemetery; and

(B) as a burial ground for members of the Wyandot Nation.

(3) In carrying out this subsection, the Secretary shall take such action as may be necessary to ensure that members of the Wyandot Nation of Kansas, Inc. may use the