Huron Cemetery for the purposes specified in paragraph (2) on the condition that if space is available in the Huron Cemetery, no member of the Wyandotte Tribe of Oklahoma may be denied the right to be buried in that cemetery.

(4) The description of the lands of the Huron Cemetery is as follows:

The tract of land in the NW ¼ of sec. 10, T. 11 S., R. 25 E., of the sixth principal meridian, in Wyandotte County, Kansas (as surveyed and marked on the ground on August 15, 1888, by William Millor, Civil Engineer and Surveyor), described as follows:

''Commencing on the Northwest corner of the Northwest Quarter of the Northwest Quarter of said Section 10;

''Thence South 28 poles to the 'true point of beginning';

''Thence South 71 degrees East 10 poles and 18 links;

''Thence South 18 degrees and 30 minutes West 28 poles;

''Thence West 11 and one-half poles;

''Thence North 19 degrees 15 minutes East 31 poles and 15 feet to the 'true point of beginning', containing 2 acres or more.''.

THE FOOD AND DRUG ADMINISTRATION MODERNIZATION AND ACCOUNTABILITY ACT OF 1997 PRESCRIPTION DRUG USERS FEE REAUTHORIZATION ACT OF 1997

FEINSTEIN AMENDMENTS NOS. 1179–1181

(Ordered to lie on the table.)

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

AMENDMENT NO. 1179

In section 761 of the Federal Food, Drug, and Cosmetic Act, as added by section 807(a), add the following new subsection:

''(g) REGULATIONS.—

''(1) REQUIREMENT.—Not later than 2 years after the date of enactment of the Food and Drug Administration Modernization and Accountability Act of 1997, the Secretary shall promulgate final regulations (after notice and comment) that establish the criteria and conditions under which a State may apply for and receive an exemption under subsection (b).

''(2) EFFECTIVE DATE.—No exemption may be provided under subsection (b) until the date on which the Secretary has promulgated the regulations referred to in paragraph (1).''.

AMENDMENT NO. 1180

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

SEC. . RULE OF CONSTRUCTION REGARDING STATE LAWS.

Chapter IX (21 U.S.C. 391 et seq.), as amended by section 804, is further amended by adding at the end thereof the following:

''SEC. 908, RULE OF CONSTRUCTION REGARDING STATE LAWS.

''Nothing in this Act shall be construed to prohibit any State or political subdivision from imposing any requirements that are more stringent than those imposed by this Act, including, but not limited to, requirements relating to embargoing products, the licensing and inspection of manufacturers' facilities, advertising, labeling, packaging, the regulation of the quality and nature of ingredients, and the provision of warnings or other communications to protect the public health.''.

AMENDMENT NO. 1181

On page 141, after line 24, add the following:

''(8) CONSIDERATION OF INFORMATION AS PUBLIC INFORMATION.—The certification, summary of the proposed protocol, and the schedule for the proposed protocol under this subsection, excluding proprietary information, shall be considered to be public information.

HATCH AMENDMENTS NOS. 1182–1183

(Ordered to lie on the table.)

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

AMENDMENT NO. 1182

Beginning on page 4, strike line 11 and all that follows through page 5, line 6, and insert the following:

''(1) IN GENERAL.—The Secretary, acting through the Commissioner, in consultation with experts in science, medicine, and public health, and in cooperation with consumers, users, manufacturers, importers, packers, distributors, and retailers of regulated products, shall protect the public health by taking actions that help ensure that

''(A) foods are safe, wholesome, sanitary, and properly labeled;

''(B) human and veterinary drugs, including biologic, are safe and effective;

''(C) there is reasonable assurance of safety and effectiveness of devices intended for human use;

''(D) cosmetics are safe; and

''(E) public health and safety are protected from electronic product radiation.

''(2) SPECIAL RULES.—The Secretary, acting through the Commissioner, shall promptly and efficiently review clinical research and take appropriate action on the marketing of regulated products in a manner that does not unduly impede innovation or product availability. The Secretary, acting through the Commissioner, shall participate with other countries to reduce the burden of regulation, to harmonize regulatory requirements, and to achieve appropriate reciprocal arrangements with other countries.''.

AMENDMENT NO. 1183

At the appropriate place, insert the following:

SEC. . SAFETY REPORT DISCLAIMERS.

Chapter IX (21 U.S.C. 391 et seq.), as amended by section 804, is further amended by adding at the end the following:

''SEC. 908. SAFETY REPORT DISCLAIMERS.

''With respect to any entity that submits or is required to submit a safety report or other information in connection with the safety of a product (including a product which is a food, drug, new drug, device, dietary supplement, or cosmetic) under this Act (and any release by the Secretary of that report of information), such report or information shall not be construed to necessarily reflect a conclusion by the entity or the Secretary that the report or information constitutes an admission that the product involved caused or contributed to an adverse experience, or otherwise caused or contributed to a death, serious injury, serious illness, or malfunction. Such an entity need not admit, and may deny, that the report or information submitted by the entity constitutes an admission that the product involved caused or contributed to an adverse experience or caused or contributed to a death, serious injury, serious illness, or malfunction.''.

HUTCHINSON AMENDMENT NO. 1184

(Ordered to lie on the table.)

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

Strike section 809 and insert the following:

SEC. 809. APPLICATION OF FEDERAL LAW TO THE PRACTICE OF PHARMACY COMPOUNDING.

Section 503 (21 U.S.C. 353) is amended by adding at the end the following:

''(h)(1) Sections 501(a)(2)(B), 502(f)(1), 502(l), 505, and 507 shall not apply to a drug product if—

''(A) the drug product is compounded for an identified individual patient, based on a medical need for a compounded product—

''(i) by a licensed pharmacist in a State licensed pharmacy or a Federal facility, or a licensed physician, or the prescription order of a licensed physician or other licensed practitioner authorized by State law to prescribe drugs; or

''(ii) by a licensed pharmacist or licensed physician in limited quantities, prior to the receipt of a valid prescription order for the identified individual patient, and is compounded based on a history of the licensed pharmacist or licensed physician receiving valid prescription orders for the compounding of the drug product that have been generated solely within an established relationship between the licensed pharmacist, or licensed physician, and—

''(I) the individual patient for whom the prescription order will be provided; or

''(II) the physician or other licensed practitioner who will write such prescription order; and

''(B) the licensed pharmacist or licensed physician—

''(i) compounds the drug product using bulk drug substances—

''(I) that—

''(aa) comply with the standards of an applicable United States Pharmacopeia or National Formulary monograph; or

''(bb) in a case in which such a monograph does not exist, are drug substances that are covered by regulations issued by the Secretary under paragraph (3);

''(II) that are manufactured by an establishment that is registered under section 510 (including a foreign establishment that is registered under section 510(i)); and

''(III) that are accompanied by valid certificates of analysis for each bulk drug substance;

''(ii) compounds the drug product using ingredients (other than bulk drug substances) that comply with the standards of an applicable United States Pharmacopeia or National Formulary monograph and the United States Pharmacopeia chapter on pharmacy compounding;

''(iii) only advertises or promotes the compounding service provided by the licensed pharmacist or licensed physician and does not advertise or promote the compounding of any particular drug, class of drug, or type of drug;

''(iv) does not compound a drug product that appears on a list published by the Secretary in the Federal Register of drug products that have been withdrawn or removed from the market because such drug products or components of such drug products have been found to be unsafe or not effective;

''(iv) does not compound a drug product that is identified by the Secretary in regulation as presenting demonstrable difficulties for compounding that reasonably demonstrate an adverse effect on the safety or effectiveness of that drug product; and

''(vi) does not distribute compounded drugs outside of the State in which the drugs are compounded, unless the principal State agency of jurisdiction that regulates the

practice of pharmacy in such State has entered into a memorandum of understanding with the Secretary regarding the regulation of drugs that are compounded in the State and are distributed outside of the State, that provides for appropriate investigation by the State agency of complaints relating to compounded products distributed outside of the State.

''(2)(A) The Secretary shall, after consultation with the National Association of Boards of Pharmacy, develop a standard memorandum of understanding for use by States in complying with paragraph (1)(B)(vi).

''(B) Paragraph (1)(B)(vi) shall not apply to a licensed pharmacist or licensed physician, who does not distribute inordinate amounts of compounded products outside of the State, until—

''(i) the date that is 180 days after the development of the standard memorandum of understanding; or

''(ii) the date on which the State agency enters into a memorandum of understanding under paragraph (1)(B)(vi),

whichever occurs first.

''(3) The Secretary, after consultation with the United States Pharmacopeia Convention Incorporated, shall promulgate regulations limiting compounding under paragraph (1)(B)(i)(I)(bb) to drug substances that are components of drug products approved by the Secretary and to other drug substances as the Secretary may identify.

''(4) The provisions of paragraph (1) shall not apply—

''(A) to compounded positron emission tomography drugs as defined in section 201(ii); or

''(B) to radiopharmaceuticals.

''(5) In this subsection, the term 'compound' does not include to mix, reconstitute, or perform another similar act, in accordance with directions contained in approved drug labeling provided by a drug manufacturer.''.

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

BROWNBACK AMENDMENT NO. 1185

(Ordered to lie on the table.)

Mr. BROWNBACK submitted an amendment intended to be proposed by him to the bill, H.R. 2107, supra; 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 Wyandotte 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.

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 Huron Cemetery for the purposes specified in paragraph (2) on the condition that if space is available in the Huron Cemetery, no member of the Wyandotte Tribe of Oklahoma may be denied the right to be buried in that cemetery.

(4) The description of the lands of the Huron Cemetery is as follows:

The tract of land in the NW ¼ of sec. 10, T. 11 S., R. 25 E., of the sixth principal meridian, in Wyandotte County, Kansas (as surveyed and marked on the ground on August 15, 1888, by William Millor, Civil Engineer and Surveyor), described as follows:

''Commencing on the Northwest corner of the Northwest Quarter of the Northwest Quarter of said Section 10;

''Thence South 28 poles to the 'true point of beginning';

''Thence South 71 degrees East 10 poles and 18 links;

''Thence South 18 degrees and 30 minutes West 28 poles;

''Thence West 11 and one-half poles;

''Thence North 19 degrees 15 minutes East 31 poles and 15 feet to the 'true point of beginning', containing 2 acres or more.''.

(c) Nothing is this section is intended to modify or supersede the agreement that the United States entered into on March 20, 1918, with the City of Kansas City, Kansas, for the maintenance of the Huron Cemetery.

HUTCHISON AMENDMENT NO. 1186

(Ordered to lie on the table.)

Mrs. HUTCHISON submitted an amendment intended to be proposed by her to the bill, H.R. 2107, supra; as follows:

Beginning on page 96, strike line 14 and all that follows through line 8 on page 97, and insert the following:

(a) FUNDING.—For necessary expenses of the National Endowment for the Arts, $100,060,000 to be used in accordance with this section.

(b) USE OF FUNDS.—

(1) IN GENERAL.—Of the amount appropriated under subsection (a), the Chairman of the National Endowment for the Arts shall use—

(A) not less than 75 percent of such amount to make block grants to State under subsection (c);

(B) not less than 20 percent of such amount to make grants to national groups or institutions under subsection (d); and

(C) not more than 5 percent for the administrative costs of carrying out this section, including any costs associated with the reduction in the operations of the National Endowment for the Arts.

(2) LIMITATION ON ADMINISTRATIVE COSTS.—With respect to the budget authority provided for in this section, not more than $1,525,915 shall be available for obligation with respect to the administrative costs described in paragraph (1)(C) prior to September 30, 1998.

(c) BLOCK GRANTS TO STATES OR TERRITORIES.—

(1) In general.—The Secretary shall award block grants to States under this subsection to support the arts.

(2) ELIGIBILITY.—To be eligible to receive a grant under this subsection, a State or Territory shall prepare and submit to the Chairman an application, at such time, in such manner, and containing such information as the Chairman may require, including an assurance that no funds received under the grant will be used to fund programs that are determined to be obscene.

(3) AMOUNT OF GRANT.—

(A) IN GENERAL.—Of the amount available for grants under this subsection, the Chairman shall allot to each State (including the District of Columbia) or Territory an amount equal to—

(i) with respect to a State, the amount under subparagraph (B); and

(ii) with respect to a territory, the amount determined under subparagraph (C).

(B) FORMULA.—The amount determined under this subparagraph with respect to a State (or the District of Columbia) shall be equal to—

(i) subject to subparagraph (D), the aggregate of the amounts provided by the National Endowment for the Arts to the State (or District), and the groups and institutions in the State (or District), in fiscal year 1997; and

(ii) an amount that bears the same relationship to the amounts remaining available for allotment for the fiscal year involved after the amounts are determined under clause (i), as the percentage of the population of the State (or District) bears to the total population of all States and the District.

(C) TERRITORIES.—The amount determined under this subparagraph with respect to a territory shall be equal to the aggregate of the amounts provided by the National Endowment for the Arts to the territory, and the groups and institutions in the territory, in fiscal year 1997.

(D) LIMITATION.—Notwithstanding the formula described in subparagraph (B), the allotment for a State (or the District of Columbia) under clause (i) of such subparagraph shall not exceed an amount equal to 6.6 percent of the total amount provided by the National Endowment for the Arts to States and the District of Columbia in fiscal year 1997.

(4) LIMITATION ON OBLIGATION OF FUNDS.—With respect to the budget authority provided for in this section, not more than $22,888,725 shall be available for obligation with respect to block grants under this subsection prior to September 30, 1998.

(5) USE OF FUNDS.—

(A) IN GENERAL.—A State or territory shall use funds provided under a grant under this subsection to carry out activities to support the arts in the State or territory.

(B) ENDOWMENT INCENTIVE.—A State or territory may use not to exceed 25 percent of the funds provided under a grant under this subsection to establish a permanent arts endowment in the State or territory. A State or territory that uses funds under this subparagraph to establish a State endowment shall contribute non-Federal funds to such endowment in an amount equal to not less than the amount of Federal funds provided to the endowment.

(C) LIMITATION.—A State (or territory) may not use in excess of 15 percent of the amount received under this section in any fiscal year for administrative purposes.

(d) NATIONAL GRANTS.—

(1) IN GENERAL.—The Secretary shall award grants to nationally prominent groups or institutions under this subsection to support the arts.

(2) ELIGIBILITY.—To be eligible to receive a grant under this subsection, an entity shall