## AMENDMENTS SUBMITTED

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

### KENNEDY AMENDMENT NO. 1190

(Ordered to lie on the table.)

Mr. KENNEDY submitted an amendment intended to be proposed by him 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:

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 from such device.''.

### HATCH AMENDMENTS NOS. 1191–1192

(Ordered to lie on the table.)

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

AMENDMENT NO. 1191

At the end of the matter proposed to be inserted, 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 or 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.''.

AMENDMENT NO. 1192

At the end of the matter proposed to be inserted, insert the following:

(d) MISSION STATEMENT.—Section 903(b), as amended by section 101(2), is further amended by striking paragraphs (1) and (2) and inserting 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 biologics, 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.''.

### HARKIN (AND OTHERS) AMENDMENT NO. 1193

(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 an amendment intended to be proposed to the bill, S. 830, supra; as follows:

At the end of the amendment, 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 clearinghouse 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 multipurpose 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.

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

### DeWINE AMENDMENT NO. 1194

(Ordered to lie on the table.)

Mr. DEWINE submitted an amendment intended to be proposed by him to amendment No. 1186 intended to be proposed by Mrs. HUTCHISON 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 end, insert the following:

(g)(1) In awarding or expending grant funds under this section, the Chairperson of the National Endowment for the Arts, the Secretary, and each State, territory, group, or institution that receives funds under this section shall ensure that priority is given to supporting projects, productions, workshops, or programs that serve underserved populations or children.

(2) In this section:

(A) The term ''child'' means an individual under the age of 19.

(B) The term ''underserved population'' means a population of individuals who have historically been outside the purview of arts and humanities programs due to a high incidence of income below the poverty line or to geographic isolation.

(C) The term ''poverty line'' means the poverty line (as defined by the Office of Management and Budget, and revised annually in accordance with section 673(2) of the Community Services Block Grant Act (42 U.S.C. 9902(2))) applicable to a family of the size involved.

### HUTCHINSON AMENDMENT NO. 1195

(Ordered to lie on the table.)

Mr. HUTCHINSON submitted an amendment intended to be proposed by him to the bill, H.R. 2107, supra; as follows:

On page 127, between lines 15 and 16, insert the following:

**SEC. . MAN AND THE BIOSPHERE PROGRAM.**

None of the funds appropriated or otherwise made available by this Act shall be made available for the United States Man and the Biosphere program or any related project.

### HUTCHINSON AMENDMENT NO. 1196

Mr. HUTCHINSON proposed an amendment to the bill, H.R. 2107, supra; as follows:

On page 152, between lines 13 and 14, insert the following:

TITLE VII—AMERICAN HERITAGE RIVERS INITIATIVE

**SEC. 701. AMERICAN HERITAGE RIVERS INITIATIVE.**

(a) IN GENERAL.—During fiscal year 1998 and each fiscal year thereafter, the President and other officers of the executive branch may implement the American Heritage Rivers Initiative under Executive Order 13061 (62 Fed. Reg. 48445) only in accordance with this section.

(b) DESIGNATION BY CONGRESS.—

(1) NOMINATIONS.—The President, acting through the Chair of the Council on Environmental Quality shall submit to Congress nominations of the 10 rivers that are proposed for designation as American Heritage Rivers.