

the report, shall make the report available to the public.

"(4) AUTHORIZATION OF APPROPRIATION.—There are authorized to be appropriated such sums as are necessary to carry out this subsection.

**"SEC. 772. ESTABLISHMENT OF LIST OF ARTICLES AND TEXTBOOKS DISSEMINATED AND LIST OF PROVIDERS THAT RECEIVED ARTICLES AND REFERENCE TEXTBOOKS.**

"(a) IN GENERAL.—A manufacturer that disseminates information in the form of articles or reference textbooks under section 771 shall prepare and submit to the Secretary bi-annually—

"(1) a list containing the titles of the articles and reference textbooks relating to the new use of drugs, biological products, and devices that were disseminated by the manufacturer to a person described in section 771(a)(1) for the 6-month period preceding the date on which the manufacturer submits the list to the Secretary; and

"(2) a list that identifies the categories of providers (as described in section 771(a)(1)) that received the articles and reference textbooks for the 6-month period described in paragraph (1).

"(b) RECORDS.—A manufacturer that disseminates information under section 771 shall keep records that identify the recipients of articles and textbooks provided pursuant to section 771. Such records are to be used by the manufacturer when, pursuant to section 771(a)(6), such manufacturer is required to take corrective action and shall be made available to the Secretary, upon request, for purposes of ensuring or taking corrective action pursuant to paragraph (3), (5), or (6) of section 771(a).

**"SEC. 773. CONSTRUCTION.**

"(a) DISSEMINATION OF INFORMATION ON DRUGS OR DEVICES NOT EVIDENCE OF INTENDED USE.—Notwithstanding subsection (a), (f), or (o) of section 502, or any other provision of law, the dissemination of information relating to a new use of a drug or device, in accordance with section 771, shall not be construed by the Secretary as evidence of a new intended use of the drug or device that is different from the intended use of the drug or device set forth in the official labeling of the drug or device. Such dissemination shall not be considered by the Secretary as labeling, adulteration, or misbranding of the drug or device.

"(b) PATENT PROTECTION.—Nothing in section 771 shall affect patent rights in any manner.

"(c) AUTHORIZATION FOR DISSEMINATION OF ARTICLES AND FEES FOR REPRINTS OF ARTICLES.—Nothing in section 771 shall be construed as prohibiting an entity that publishes a scientific journal (as defined in section 771(c)(5)) from requiring authorization from the entity to disseminate an article published by such entity and from charging fees for the purchase of reprints of published articles from such entity."

(b) PROHIBITED ACT.—Section 301 (21 U.S.C. 331), as amended by section 205(b), is further amended by adding at the end the following:

"(y) The dissemination of information pursuant to section 771 by a manufacturer who fails to comply with the requirements of such section."

(c) REGULATIONS.—Not later than 1 year after the date of enactment of this Act, the Secretary of Health and Human Services shall promulgate regulations to implement the amendments made by this section.

(d) EFFECTIVE DATE.—The amendments made by this section shall take effect 1 year after the date of enactment of this Act, or upon the Secretary's issuance of final regulations pursuant to subsection (c), whichever is sooner.

(e) TERMINATION OF EFFECTIVENESS.—The amendments made by this section cease to be effective September 30, 2006, or 7 years after the date on which the Secretary promulgates the regulations described in subsection (c), whichever is later.

**SEC. 812. REAUTHORIZATION OF CLINICAL PHARMACOLOGY PROGRAM.**

Section 2 of Public Law 102-222 (105 Stat. 1677) is amended—

(1) in subsection (a), by striking "a grant" and all that follows through "Such grant" and inserting the following: "grants for a pilot program for the training of individuals in clinical pharmacology at appropriate medical schools. Such grants"; and

(2) in subsection (b), by striking "to carry out this section" and inserting ", and for fiscal years 1998 through 2002 \$3,000,000 for each fiscal year, to carry out this section".

**SEC. 813. MONOGRAPH FOR SUNBURN PRODUCTS.**

Not later than 18 months after the date of enactment of this Act, the Secretary of Health and Human Services shall issue a final monograph for over-the-counter sunburn products for prevention or treatment of sunburn.

**SNOWE (AND OTHERS)  
AMENDMENT NO. 1131**

(Ordered to lie on the table.)

Ms. SNOWE (for herself, Mrs. MURRAY, Mr. D'AMATO, Ms. MOSELEY-BRAUN, Mr. FAIRCLOTH, and Ms. MIKULSKI) submitted an amendment intended to be proposed by them to the bill, S. 830, supra; as follows:

At the appropriate place, insert the following:

**SEC. . OFFICE OF WOMEN'S HEALTH.**

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. OFFICE OF WOMEN'S HEALTH.**

"(a) ESTABLISHMENT.—There is established within the Office of the Commissioner of the Food and Drug Administration an office to be known as the Office of Women's Health (hereafter referred to in this section as the 'Office'). The Office shall be headed by a Director who shall be appointed by the Commissioner of the Agency.

"(b) PURPOSE.—The Office shall—

"(1) monitor current levels of activity regarding women's participation in clinical trials and the study of gender differences in the testing of drugs, medical devices, and biological products;

"(2) advise the agency in providing guidance or criteria for drug and device manufacturers to use in determining the extent and sufficiency of female representation in clinical trials;

"(3) consult with women's health advocacy organizations, health professionals with expertise in women's issues, consumer organizations, and pharmaceutical manufacturers on Commission policy with regard to women's health.

"(4) make annual estimates of funds needed to monitor clinical trials in accordance with needs that are identified; and

"(5) coordinate women's health activities throughout the Food and Drug Administration.

"(c) COORDINATING COMMITTEE.—

"(1) ESTABLISHMENT.—In carrying out subsection (b), the Director of the Office shall establish a committee to be known as the Coordinating Committee on Women's Health (hereafter referred to in this subsection as the 'Coordinating Committee').

"(2) COMPOSITION.—The Coordinating Committee shall be composed of the Directors of

the Food and Drug Administration Centers or their representatives.

"(3) CHAIRPERSON.—The Director of the Office shall serve as the Chairperson of the Coordinating Committee.

"(4) DUTIES.—With respect to advancing women's health within the mission of the Food and Drug Administration, the Coordinating Committee shall assist the Director of the Office in—

"(A) identifying the need for further studies in specific areas of women's health that fall within the mission of the agency, and developing strategies to foster such studies;

"(B) advising and expediting the intramural research funding process;

"(C) identifying needs regarding the coordination of agency activities; and

"(D) maintaining the agency's focus in ensuring that all agency actions are conducive to women's health.

"(d) REPORTS.—Not later than January 31, 1998, and January 31 of each second year thereafter, the Director shall prepare and submit to the Commissioner of the Food and Drug Administration, a report describing the activities carried out under this section during the preceding 2 fiscal years.

"(e) AUTHORIZATION OF APPROPRIATIONS.—There is authorized to be appropriated such sums as may be necessary to carry out this section."

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

**GREGG AMENDMENT NO. 1132**

Mr. GORTON (for Mr. GREGG) proposed an amendment 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:

On page 126, line 16, insert after "government" the following "that lies in whole or in part within the White Mountain National Forest and is"

On page 126, line 19, strike "recreational user fee" and insert in lieu thereof: "Demonstration Program Fee (parking permit or passport)"

On page 126, line 21-22, strike "White Mountain National" and "that lies, in whole or in part, within those boundaries."

**RESOLUTION ON THE BOMBING IN  
JERUSALEM**

**HUTCHINSON (AND BREAUX)  
AMENDMENT NO. 1133**

Mr. GORTON (for Mr. HUTCHINSON, for himself and Mr. BREAUX) proposed an amendment to the concurrent resolution (S. Con. Res. 50) condemning in the strongest possible terms the bombing in Jerusalem on September 4, 1997; as follows:

On page 3, beginning on line 6, strike out "should provide" and all that follows through "it has fulfilled" and insert in lieu thereof "will only provide monetary or other assistance to the Palestinian Authority once it has fulfilled".

On page 3, strike out lines 16 and 17.

On page 3, line 18, strike out "(E)" and insert in lieu thereof "(D)".

On page 3, line 21, strike out "(F)" and insert in lieu thereof "(E)".