state veterans' cemeteries funded under the grant program. This provision would authorize the Secretary to grant up to 100 percent of the cost of improvements to the land to be purchased and up to 100 percent of the initial equipment costs. For existing cemeteries, the Secretary would be authorized to grant up to 100 percent of the cost of the improvements made to any additional land purchased for expansion or 100 percent of the cost of improvements to existing cemetery land. Compromise agreement

The compromise bill contains no provision relating this subject.

**Notice**

Incomplete record of House proceedings. Except for concluding business which follows, today's House proceedings will be continued in the next issue of the Record.

CONFERENCE REPORT ON S. 830, FOOD AND DRUG ADMINISTRATION MODERNIZATION ACT OF 1997

Mr. BLILEY submitted the following conference report and statement on the Senate 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:

CONFERENCE REPORT (H. REPT. 105-399)

The Committee of conference on the disagreeing votes of the two Houses on the amendments of the House 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, having met, after full and free conference, have agreed to recommend and do recommend to their respective Houses as follows:

That the Senate recede from its disagreement to the amendment of the House to the text of the bill and agree to the same with an amendment to the amendment of the House to the Senate bill (S. 830) to amend the Federal Food, Drug, and Cosmetic Act to improve the regulation of food, drugs, devices, and biological products, and for other purposes:

In lieu of the matter proposed to be inserted by the House amendment, insert the following:

**SECTION 1. SHORT TITLE; REFERENCES; TABLE OF CONTENTS.**

(a) SHORT TITLE.—This Act may be cited as the ``Food and Drug Administration Modernization Act of 1997''.

(b) REFERENCES.—Except as otherwise specified, whenever in this Act an amendment or repeal is expressed in terms of an amendment to or repeal of a section or other provision, the reference shall be considered to be made to that section or other provision of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 301 et seq.).

(c) TABLE OF CONTENTS.—The table of contents for this Act is as follows:

1. Short title; references; table of contents.
2. Definitions.
3. Title I—Improving Regulation of Drugs
   Subtitle A—Fees Relating to Drugs
   Sec. 101. Findings.
   Sec. 102. Definitions.
   Sec. 103. Authority to assess and use drug fees.
   Sec. 104. Annual reports.
   Sec. 105. Savings.
   Sec. 106. Effective date.
   Sec. 107. Termination of effectiveness.
   Subtitle B—Other Improvements
   Sec. 111. Pediatric studies of drugs.
   Sec. 112. Expedited study and approval of fast track drugs.
   Sec. 113. Information program on clinical trials for serious or life-threatening diseases.
   Sec. 114. Health care economic information.
   Sec. 115. Clinical investigations.
   Sec. 116. Monitoring changes for drugs.
   Sec. 117. Streamlining clinical research on drugs.
   Sec. 118. Data requirements for drugs and biologicals.
   Sec. 119. Content and review of applications.
   Sec. 120. Scientific advisory panels.
   Sec. 121. Positron emission tomography.
   Sec. 122. Requirements for radiopharmaceuticals.
   Sec. 123. Modernization of regulation.
   Sec. 124. Pilot and small scale manufacture.
   Sec. 125. Insulin and antibiotics.
   Sec. 126. Elimination of certain labeling requirements.
   Sec. 127. Application of Federal law to practice of pharmacy compounding.
   Sec. 128. Reauthorization of clinical pharmacology program.
   Sec. 129. Regulations for sunscreen products.
   Sec. 130. Reports of postmarketing approval studies.
   Sec. 131. Notification of discontinuance of a life saving product.
   Subtitle C—Improving Regulation of Devices
   Sec. 201. Investigational device exemptions.
   Sec. 202. Special review for certain devices.
   Sec. 203. Expanding humanitarian use of devices.
   Sec. 204. Device standards.
   Sec. 205. Scientific advisory; collaborative determinations of device data requirements.
   Sec. 206. Premarket notification.
   Sec. 207. Evaluation of automatic class III designation.
   Sec. 208. Classification panels.
   Sec. 209. Certainty of review timeframes; collaborative review process.
   Sec. 211. Device tracking.
   Sec. 212. Postmarket surveillance.
   Sec. 213. Reports.
   Sec. 214. Practice of medicine.
   Sec. 215. Noninvasive blood glucose meter.
   Sec. 216. Use of human and disease.
   Sec. 217. Clarification of the number of required clinical investigations for approval.
   Subtitle D—Improving Regulation of Food
   Sec. 301. Flexibility for regulations regarding claims.
   Sec. 302. Petitions for claims.
   Sec. 303. Health claims for food products.
   Sec. 304. Nutrient content claims.
   Sec. 305. Referral statements.
   Sec. 306. Disclosure of irradiation.
   Sec. 307. Irradiation petition.
   Sec. 308. Glass and ceramic ware.
   Sec. 309. Food contact substances.
   Subtitle E—General Provisions
   Sec. 400. Registration of foreign establishments.
   Sec. 401. Disposition of information on new uses.
   Sec. 402. Expanded access to investigational therapies and diagnostics.
   Sec. 403. Approval of supplemental applications for approved products.
   Sec. 404. Dispute resolution.
   Sec. 405. Informal agency statements.
   Sec. 406. Food and Drug Administration mission and annual report.
   Sec. 407. Information system.
   Sec. 408. Education and training.
   Sec. 409. Centers for education and research on therapeutics.
   Sec. 410. Mutual recognition agreements and global harmonization.
   Sec. 411. Environmental impact review.
   Sec. 412. National uniformity for nonprescription drugs.
   Sec. 413. Food and Drug Administration study of mercury compounds in drugs and food.
   Sec. 414. Intergency collaboration.
   Sec. 415. Contracts for expert review.
   Sec. 416. Product classification.
   Sec. 417. Registration of foreign establishments.
   Sec. 418. Clarification of seizure authority.
   Sec. 419. Interstate commerce.
   Sec. 420. Safety report disclaimers.
   Sec. 421. Labeling and advertising regarding compliance with statutory requirements.
   Sec. 422. Rule of construction.
   Subtitle V—Effective Date
   Sec. 501. Effective date.

**SECTION 2. DEFINITIONS.**

In this Act, the terms ``drug'', ``device'', ``food'', and ``dietary supplement'' have the meaning given such terms in section 201 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 321).

**TITLE I—IMPROVING REGULATION OF DRUGS**

**Subtitle A—Fees Relating to Drugs**

**SEC. 101. FINDINGS.**

Congress finds that—

(1) prompt approval of safe and effective new drugs and other therapies is critical to the improvement of the public health so that patients may enjoy the benefits provided by these therapies to treat and prevent illness and disease;

(2) the public health will be served by making additional funds available for the purpose of augmenting the resources of the Food and Drug Administration that are devoted to the process for review of human drug applications;

(3) the provisions added by the Prescription Drug User Fee Act of 1992 have been successful in substantially reducing review times for human drug applications and should be—

(A) reauthorized for an additional 5 years, with certain technical improvements; and

(B) carried out by the Food and Drug Administration with new commitments to implement more ambitious and comprehensive improvements in regulatory processes of the Food and Drug Administration; and

(4) the fees authorized by amendments made in this subtitle will be dedicated toward expediting the drug development process and the review of human drug applications as set forth in the paragraph 2 of subchapter C of chapter VII of the Federal Food, Drug, and Cosmetic Act, in the letters from the Secretary of Health and Human Services to the chairman of the Committee on Commerce of the House of Representatives and the chairman of
the Committee on Labor and Human Resources of the Senate, as set forth in the Congressional Record.

SEC. 102. DEFINITIONS.
Section 735 (21 U.S.C. 379g) is amended—
(1) in the second sentence of paragraph (1)—
(A) by striking "Service Act," and inserting "Service Act,"; and
(B) by striking "September 1, 1992," and inserting the following: "September 1, 1992, does not include an application for a license of a biological product for further manufacturing use only, or does not include an application or supplement submitted by a State or Federal Government entity for a drug that is not distributed commercially. Such term does include an application or supplement, as described in subparagraph (D), of a large volume biological product intended for single dose injection for intravenous use or infusion.;" (2) in the second sentence of paragraph (3)—
(A) by striking "Service Act," and inserting "Service Act,"; and
(B) by striking "September 1, 1992," and inserting the following: "September 1, 1992, does not include a biological product that is licensed for further manufacturing use only, and does not include a drug that is not distributed commercially. Such term does include a large volume biological product intended for single dose intravenous use or infusion. (D) in paragraph (4), by striking "without" and inserting "without substantial"; and
(4) by amending the first sentence of paragraph (5) to read as follows:
"(5) The term 'prescription drug establishment' means a foreign or domestic place of business which is at one general physical location consisting of one or more buildings all of which are within five miles of each other and at which one or more prescription drug products are manufactured in final dosage form.;"
(5) in paragraph (6)—
(A) by striking "employees under contract," and all that follows through "Administration," the second time it occurs and inserting "contractors of the Food and Drug Administration," and
(B) by striking "and committees," and inserting "and committees and contractors with such contractors of each year;" (6) in paragraph (8)—
(A) in subparagraph (A)—
(i) by striking "August of," and inserting "April of;
(ii) by striking "August 1992" and inserting "April 1997;" and
(B) in subparagraph (B)—
(i) by striking "section 254(d)" and inserting "section 254(c);" (ii) by striking "1992" and inserting "1997;" and
(iii) by striking "102d Congress, 2d Session" and inserting "109th Congress, 1st Session;" and
(7) by adding at the end the following: "(9) The term 'affiliate' means a business entity that has a relationship with a second business entity if, directly or indirectly—
(A) one business entity controls, or has the power to control, the other business entity; or
(B) a third party controls, or has power to control, both of the business entities.";

SEC. 103. AUTHORITY TO ASSESS AND USE FEE REVENUES.
(a) TYPES OF FEES.—Section 736(a) (21 U.S.C. 379h(a)) is amended—
(1) by striking "Beginning in fiscal year 1993 and inserting "Beginning in fiscal year 1998;"
(2) in paragraph (A)—
(A) by striking subparagraph (B) and inserting the following: "(B) PAYMENT.—The fee required by subparagraph (A) shall be due upon submission of the application or supplement;";
(B) in subparagraph (D)—
(i) in the subparagraph heading, by striking "NOT ACCEPTED" and inserting "REFUSED;"
(ii) by striking "50 percent" and inserting "75 percent;"
(iii) by striking subparagraph (B)(ii) and inserting subparagraph (B); and
(iv) by striking "not accepted" and inserting "refused;" and
(C) by adding at the end the following: "(E) EXCEPTION FOR DESIGNATED ORPHAN DRUG OR INDICATION.—A human drug application for an orphan drug that has been designated as a drug for a rare disease or condition pursuant to section 526 shall not be subject to a fee under subparagraph (A), unless the application includes an indication for other than a rare disease or condition. A supplement proposing to include a new indication for a rare disease or condition in a human drug application shall not be subject to a fee under subparagraph (A), if the drug has been designated pursuant to section 526 as a drug for a rare disease or condition with regard to the indication proposed in such supplement."
(F) EXCEPTION FOR SUPPLIES FOR PEDIATRIC INDICATIONS.—A supplement to a human drug application proposing to include a new indication for use in pediatric populations shall not be assessed a fee under subparagraph (A)."
(G) REFUND OF FEE IF APPLICATION WITHDRAWN.—If an application or supplement is withdrawn after the application or supplement was filed, the Secretary may refund the fee or a portion of the fee if no substantial work was performed on the application or supplement after the application or supplement was filed. The Secretary shall have the sole discretion to refund a fee or a portion of the fee under this subparagraph. A determination by the Secretary concerning a refund under this paragraph shall not be reviewable.;" (3) by striking paragraph (2) and inserting the following:
"(2) PRESCRIPTION DRUG ESTABLISHMENT FEE.—(A) IN GENERAL.—Except as provided in subparagraph (B), each person that—
(i) is named as the applicant in a human drug application; and
(ii) after September 1, 1992, had pending before the Secretary a human drug application or supplement, shall be assessed an annual fee established in subsection (b) for each prescription drug establishment listed in its approved human drug application as an establishment that manufactures the prescription drug product named in the application. The annual establishment fee shall be assessed each time the prescription drug product named in the application is assessed a fee under paragraph (3) unless the prescription drug establishment listed in the application does not engage in the manufacture of the prescription drug product during the fiscal year. The establishment fee shall be payable on or before January 31 of each year. Each such establishment shall be assessed only one fee per establishment, notwithstanding the number of prescription drug products manufactured at the establishment. In the event an establishment is listed in the establishment database for more than one applicant, the establishment fee for the fiscal year shall be divided equally and assessed among the applicants whose prescription drug products were manufactured by the establishment during the fiscal year and assessed product fees under paragraph (3)."
(B) EXCEPTION FOR SUPPLEMENTS FOR PEDIATRIC INDICATIONS.—If a supplement is submitted for a drug that has been designated as a drug for a rare disease or condition pursuant to section 526 as a drug for a rare disease or condition with regard to the indication proposed in such supplement, the applicant will not be assessed a share of the establishment fee for the fiscal year in which the manufacture of the product began.;" and
(4) in paragraph (3)—
(A) in subparagraph (A)—
(i) in clause (i), by striking "is listed" and inserting "has been listed for listing;" and
(ii) by striking "Such fee shall be payable" and all that follows through "section 510." and inserting the following: "Such fee shall be payable for the fiscal year in which the product is first submitted for listing under section 510, or is submitted for relisting under section 510 if the product has been withdrawn from listing and relisted. After such fee is paid for the fiscal year, such fee shall be payable on or before January 31 of each year. Such fee shall be paid only once for each product for a fiscal year in which the fee is payable.;" and
(B) in subparagraph (B), by striking "505(i)(6)" and inserting the following: "505(i), under an abbreviated application filed under section 507 (as in effect on the day before the date of enactment of the Food and Drug Administration Modernization Act of 1997), or under an abbreviated new drug application pursuant to regulations in effect prior to the implementation of the Amendments to the Federal Food, Drug, and Cosmetic Act by the Prescription Drug User Fee Act of 1992.;"
(b) FEE AMOUNTS.—Section 736(b) (21 U.S.C. 379h(b)) is amended to read as follows:
"(b) FEE AMOUNTS.—Except as provided in subsections (c), (d), and (e), and (2) the fees required under subsection (a) shall be determined and assessed as follows:
"(1) APPLICATION AND SUPPLEMENT FEES.—
(A) FULL FEES.—The application fee under subsection (a)(1)(A) shall be $35,600,000 in fiscal year 1999, $36,400,000 in each of fiscal years 2000, 2001, and 2002, $37,000,000 in each of fiscal years 2003 through 2005, $37,300,000 in fiscal year 2006, $37,600,000 in fiscal year 2007, and $38,000,000 in fiscal year 2008.
(C) TOTAL FEE REVENUES FOR ESTABLISHMENT FEES.—The total fee revenues to be collected in establishment fees under subsection (a)(2) shall be $35,600,000 in fiscal year 1998, $36,400,000 in each of fiscal years 1999 and 2000, $38,000,000 in fiscal year 2001, and $36,700,000 in fiscal year 2002.
(D) TOTAL FEE REVENUES FOR PRODUCT FEES.—The total fee revenues collected in product fees under subsection (a)(3) in a fiscal year shall be equal to the total fee revenues collected in establishment fees under subsection (a)(2) in that fiscal year.
(E) INCREASES AND ADJUSTMENTS.—Section 736(c) (21 U.S.C. 379c) is amended—
(1) in the subsection heading, by striking "INCREASES AND:";
(2) in paragraph (1)—
(A) by striking "INCREASE" and all that follows through "increased by the Secretary" and inserting the following: "(1) INFLATION ADJUSTMENT.—The fees and total fee revenues established in subsection (b) shall be adjusted by the Secretary.;"
(B) in subparagraph (A), by striking "increase" and inserting "change;"
(C) in subparagraph (B), by striking "increase" and inserting "change;" and
(D) by striking at the end the following flush sentence: "The adjustment made each fiscal year by this subsection will be added on a compounded basis to the sum of all adjustments made each fiscal year after fiscal year 1997 under this subsection.;" (3) in paragraph (2), by striking "October 1, 1992," and all that follows through "such
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SEC. 105. SAVINGS.

The amendments made by section 105(b) of the Prescription Drug User Fee Act of 1992 shall continue to include an affiliate thereof.

SEC. 106. EFFECTIVE DATE.

This title shall take effect on October 1, 1998.

SEC. 107. TERMINATION OF EFFECTIVENESS.

This title shall cease to be effective October 1, 1998.

Subtitle B—Other Improvements

SEC. 111. PEDIATRIC STUDIES OF DRUGS.

Chapter V (21 U.S.C. 351 et seq.) is amended by inserting after section 505 the following:

"SEC. 505A. PEDIATRIC STUDIES OF DRUGS.

"(a) Market Exclusivity for New Drugs.—If, prior to approval of an application that is submitted under section 505(b)(1), the Secretary determines that the use of a new drug in the pediatric population may produce health benefits in that population, the Secretary makes a written request for pediatric studies which shall include any reasonable schedule for completing such studies, and such studies are completed within any such timeframe and the reports thereof submitted in accordance with subsection (d)(2) or accepted in accordance with subsection (d)(3)."

Subtitle C—Other Amendments

SEC. 104. ANNUAL REPORTS.

"(a) Annual Reports.—The Secretary shall submit an annual report to the Committees on Appropriations of the Senate and the House of Representatives for each fiscal year, beginning with fiscal year 1998, and for each fiscal year thereafter, describing the administrative operations of the Food and Drug Administration during that fiscal year and the use, by the Food and Drug Administration, of the fees collected during that fiscal year for which the report is made.

SEC. 105. SAVINGS.

The amendments made by this title shall take effect on October 1, 1998.

SEC. 106. EFFECTIVE DATE.

This title shall cease to be effective October 1, 2002, and section 106 ceases to be effective 120 days after such date.
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"(b) SECRETARY TO DEVELOP LIST OF DRUGS FOR WHICH ADDITIONAL PEDIATRIC INFORMATION MAY BE BENEFICIAL.—Not later than 180 days after the date of enactment of the Food and Drug Administration Modernization Act of 1997, the Secretary, after consultation with experts in pediatric research shall develop, prioritize, and publish an initial list of approved drugs for which additional pediatric information may produce health benefits in the pediatric population. The Secretary shall annually update the list.

(c) THE EVENT EXCLUSION FOR ALREADY-MARKETED DRUGS.—If the Secretary makes a written request to the holder of an approved application under section 505(b)(1) for pediatric studies, and the sponsor agrees to conduct a timeframe for completing such studies concerning a drug identified in the list described in subsection (b), the holder agrees to the request, the studies are completed within any such timeframe, and the reports thereof are submitted in accordance with subsection (d)(2) or accepted in accordance with subsection (d)(3),

(1) the period referred to in subsection (c)(3)(D)(iii) of section 505, and in subsection (j)(4)(D)(ii) of such section, is deemed to be five years rather than three years; and

(2) the references in subsections (c)(3)(D)(ii) and (j)(4)(D)(ii) of such section to four, to forty-eight months, and to seven and one-half years, respectively, are deemed to be seven and one-half months, fifty-four months, and eight years, respectively; or

(3) the period referred to in clauses (ii) and (iv) of subsection (c)(3)(D) of such section to is deemed to be three years and six months rather than three years; and

(4) if the drug is designated under section 526 for a rare disease or condition, the period referred to in section 527(a) is deemed to be seven years and six months rather than seven years; and

(5) (A) if the drug is the subject of—

(i) a listed patent for which a certification has been made by the Secretary under subsection (b)(2)(A)(ii) or (j)(2)(A)(viii)(II) of section 505, and for which pediatric studies were submitted prior to the expiration of the patent (including any patent extensions); or

(ii) a listed patent for which a certification has been submitted under subsection (b)(2)(A)(ii) or (j)(2)(A)(viii)(II) of section 505, and in the patent infringement litigation resulting from the certification the court determines that the patent is valid and would be infringed, the period during which such litigation may not be extended under section 505(c)(3) or section 505(j)(4)(B) shall be extended by a period of six months after the date the patent expires (including any patent extensions); or

(B) if the drug is the subject of a listed patent for which a certification has been submitted under subsection (b)(2)(A)(ii) or (j)(2)(A)(viii)(II) of section 505, and in the patent infringement litigation resulting from the certification the court determines that the patent is valid and would be infringed, the period during which such litigation may not be extended under section 505(c)(3) or section 505(j)(4)(B) shall be extended by a period of six months after the date the patent expires (including any patent extensions); or

(c) the period referred to in section 505(b)(1) is submitted on or before January 1, 2002.

SEC. 112. EXPEDITING STUDY AND APPROVAL OF FAST TRACK DRUGS.

(a) IN GENERAL.—Chapter V of title 21 U.S.C. 351 et seq., as amended by section 125, is amended by inserting before section 358 the following:

"SEC. 506. FAST TRACK PRODUCTS.

"(a) DESIGNATION OF DRUG AS A FAST TRACK PRODUCT.—

"(1) IN GENERAL.—The Secretary shall, at the request of the sponsor of a new drug, facilitate the development and expedite the review of such drug if it is intended for the treatment of a serious or life-threatening condition and it demonstrates the potential to address unmet medical needs for such a condition. In such circumstance, such drug is referred to as a "fast track product." (2) REQUEST FOR DESIGNATION.—The sponsor of a new drug may request the Secretary to designate the drug as a fast track product. A request for the designation may be made concurrently, or at any time, after any previously submitted application for the investigation of the drug under section 505(1) or section 351(a)(3) of the Public Health Service Act.

(b) APPROVAL OF APPLICATION FOR A FAST TRACK PRODUCT.—

"(1) IN GENERAL.—The Secretary may approve an application for a fast track product under section 505(c) or section 351 of the Public Health Service Act upon a determination that the drug meets the criteria, the drug that is the subject of the request meets the criteria prescribed in section 505(b)(1), if the Secretary finds that the drug meets the criteria, the Secretary shall designate the drug as a fast track product and shall take such actions as are appropriate to expedite the development and review of the application for approval of such product.

"(2) APPLICATION FOR A FAST TRACK PRODUCT.—

"(1) IN GENERAL.—The Secretary may approve an application for a fast track product under section 505(c) or section 351 of the Public Health Service Act upon a determination that the drug has an effect on a clinical endpoint or on a surrogate endpoint that is reasonably likely to predict clinical benefit.

"(2) LIMITATION.—Approval of a fast track product under this subsection may be subject to the requirements—

(A) that the sponsor conduct appropriate pediatric studies to evaluate the drug for the clinical endpoint or on a surrogate endpoint or otherwise confirm the effect on the clinical endpoint; and

(B) that the sponsor submit copies of all pediatric data and materials relating to the fast track product during the preapproval review period and, following approval and for such period
thereafter as the Secretary determines to be appropriate, at least 30 days prior to dissemination of the materials.

(3) EXPEDITED WITHDRAWAL OF APPROVAL.—The Secretary may withdraw approval of a fast track product using expedited procedures (as prescribed by the Secretary in regulations which shall include an opportunity for an informal hearing—

(a) the sponsor fails to conduct any required post-approval study of the fast track drug with due diligence;

(b) a post-approval study of the fast track product fails to verify clinical benefit of the product;

(c) other evidence demonstrates that the fast track product is not safe or effective under the conditions of use; or

(d) the sponsor disseminates false or misleading promotional materials with respect to the product.

(c) REVIEW OF INCOMPLETE APPLICATIONS FOR APPROVAL OF A FAST TRACK PRODUCT.—

(1) IN GENERAL.—If the Secretary determines, after preliminary evaluation of clinical data submitted by the sponsor, that a fast track product may not meet the requirements of section 402(k) for filing, and may commence review of portions of, an application for the approval of the product before the sponsor submits a complete application, the Secretary shall commence such review only if the applicant—

(A) provides a schedule for submission of information necessary to make the application complete; and

(B) pays any fee that may be required under section 736.

(2) EXCEPTION.—Any time period for review of human drug applications that has been agreed to by the Secretary and that has been set forth in goals identified in letters of the Secretary (relating to the use of fees collected under section 736 to expedite the drug development process and the review of human drug applications) shall not apply to an application submitted under paragraph (1) until the date on which the application is complete.

(d) AWARENESS EFFORTS.—The Secretary shall—

(1) develop and disseminate to physicians, patient organizations, pharmaceutical and biotechnology companies, and other appropriate persons a description of the provisions of this section applicable to fast track products; and

(2) establish a program to encourage the development of surrogate endpoints that are reasonable in light of clinical benefit, serious or life-threatening conditions for which there exist significant unmet medical needs.

(b) GUIDANCE.—Within 1 year after the date of enactment of this Act, the Secretary shall disseminate guidance, as appropriate, on the inclusion of women and minorities in clinical trials.

SEC. 113. INFORMATION PROGRAM ON CLINICAL TRIALS FOR SERIOUS OR LIFE-THREATENING DISEASES.

(a) IN GENERAL.—Section 402 of the Public Health Service Act (42 U.S.C. 282) is amended—

(1) by inserting in the first sentence of subsections (j) and (k) as subsections (k) and (l), respectively, and

(2) by inserting after subsection (i) the following—

"(i) The Secretary, acting through the Director of NIH, shall establish, maintain, and operate a data bank of information on clinical trials for serious or life-threatening diseases and conditions (in this subsection referred to as the ‘data bank’). The activities of the data bank shall be integrated and coordinated with the activities of other agencies of the Department of Health and Human Services, and to the extent practicable, coordinated with other data banks containing similar information.

(3) The Secretary shall establish the data bank after consultation with the Commissioner of Food and Drugs, the directors of the appropriate agencies of the National Institutes of Health (including the National Library of Medicine), and the Director of the Centers for Disease Control and Prevention.

(4) The data bank shall include the following—

(a) A registry of clinical trials (whether federally or privately funded) of experimental treatments for serious or life-threatening diseases and conditions (in this subsection referred to as the ‘data bank’). The activities of the data bank shall be integrated and coordinated with related activities of other agencies of the Department of Health and Human Services, and to the extent practicable, coordinated with other data banks containing similar information.

(b) A report—

(i) describing the provisions of this section relating to an investigation if the sponsor

(ii) as a Group C cancer drug (as defined by the National Cancer Institute).

(c) The data bank shall include the following—

(1) A registry of clinical trials (whether federally or privately funded) of experimental treatments for serious or life-threatening diseases and conditions under regulations promulgated pursuant to section 505(i) of the Federal Food, Drug, and Cosmetic Act, which provides a description of the purpose of each experimental drug, either with the consent of the protocol sponsor, or when a trial to test effectiveness begins. Information provided shall consist of eligibility criteria in the clinical trials, a description of the location of trial sites, and a point of contact for those wanting to enroll in the trial, and shall be in a form that can be readily understood by members of the public. Such information shall be forwarded to the data bank by the sponsor of the trial not later than 21 days after the approval of the protocol.

(2) Information pertaining to experimental treatments for serious or life-threatening diseases and conditions that may be available—

(A) under a treatment investigational new drug application submitted to the Secretary under section 561(c) of the Federal Food, Drug, and Cosmetic Act; or

(B) as a Group C cancer drug (as defined by the National Cancer Institute).

(d) The data bank may also include information pertaining to the results of clinical trials of such treatments, with the consent of the sponsor, including information concerning potential toxicities or adverse effects associated with the use or administration of such experimental treatments.

(e) The data bank shall not include information relating to an investigation if the sponsor has provided a detailed certification to the Secretary that such clinical trial would not substantially interfere with the timely enrollment of subjects in the investigation, unless the Secretary, after the receipt of the certification, provides a written determination that such disclosure would not substantially interfere with such enrollment.

(f) For the purpose of carrying out this subsection, there are authorized to be appropriated such sums as may be necessary. Fees collected under section 736 of the Federal Food, Drug, and Cosmetic Act shall not be used in carrying out this subsection.

(g) COLLABORATION AND REPORT.—

(1) IN GENERAL.—The Secretary of Health and Human Services, the Director of the National Institutes of Health, the Commissioner of Food and Drugs shall collaborate to determine the feasibility of including device investigations within the scope of the data bank under section 402(k) of the Public Health Service Act.

(2) REPORT.—Not later than 2 years after the date of enactment of this Act, the Secretary shall—

(a) prepare and submit to the Committee on Labor and Human Resources of the Senate and the Committee on Commerce of the House of Representa
tives a report—

(A) of the public health need, if any, for inclusion of device investigations within the scope of the data bank under section 402(k) of the Public Health Service Act; and

(B) on the adverse impact, if any, on device innovation and research in the United States if information relating to such device investigations is required to be publicly disclosed; and

(c) on such other issues relating to such section 402(j) as the Secretary determines to be appropriate.

SEC. 114. 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:

"(l) The data bank shall include the following—

(1) A registry of clinical trials (whether federally or privately funded) of experimental treatments for serious or life-threatening diseases and conditions that may be effective, the Secretary shall evaluate and consider the feasibility of including device investigations within the data bank under section 402(k) of the Public Health Service Act for such drug and is based on competent and reliable scientific evidence. The requirements set forth in section 505(a) or in section 531(a) of the Public Health Service Act 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.

(b) STUDY AND REPORT.—The Comptroller General of the United States shall conduct a study of the implementation of the provisions of this section relating to 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.

SEC. 115. CLINICAL INVESTIGATIONS.

(a) CLARIFICATION OF THE NUMBER OF REQUIRED CLINICAL INVESTIGATIONS FOR APPROVAL.—Section 505(d) (21 U.S.C. 355(d)) is amended by adding at the end the following:

"(e) The Secretary shall, in consultation with the Director of the National Institutes of Health and with representatives of the drug manufacturing industry, review and develop guidance, as appropriate, on the inclusion of women and minorities in clinical trials required by clause (A)."

SEC. 116. MANUFACTURING CHANGES FOR DRUGS.

(a) IN GENERAL.—Chapter V, as amended by section 112, is amended by inserting after section 506 the following section:

"SEC. 506A. MANUFACTURING CHANGES.

(a) IN GENERAL.—With respect to a drug for which a license under section 505 or 512 or a license under section 351 of the Public Health Service Act, a change from the manufacturing process approved pursuant to such license may be made, and the drug as made with the change may be distributed, if—

(1) the holder of the approved application or license (as referred to in this section, a ‘holder’) has validated the effects of the change in accordance with subsection (b); and
Changes.—For purposes of subsection (a)(2)(A), subparagraph (A) applies and categories to changes.

(b) Validation of Effects of Changes.—For purposes of subsection (a)(1), a drug made with a manufacturing change (whether a major manufacturing change or otherwise) may be distributed only if, before the distribution of the drug as so made, the holder involved submits to the Secretary a supplemental application for such change and the Secretary approves the application. The application shall contain such information as the Secretary determines to be appropriate, and shall include the information developed under subsection (b) by the holder in validating the effects of the change.

(c) Major Manufacturing Changes.—

(1) Requirement of Supplemental Application.—For purposes of subsection (a)(2)(A), a drug made with a major manufacturing change may be distributed only if, before the distribution of the drug as so made, the holder involved submits to the Secretary a supplemental application for such change and the Secretary approves the application. The application shall contain such information as the Secretary determines to be appropriate, and shall include the information developed under subsection (b) by the holder in validating the effects of the change.

(2) Transition Rule.—The amendment made by paragraph (1) shall apply to all drug applications submitted on or after the date of the enactment of this Act, whichever occurs first.

(d) Other Manufacturing Changes.—

(1) In General.—For purposes of subsection (a)(2)(A), a major manufacturing change is a manufacturing change that is determined by the Secretary to have the potential to adversely affect the identity, strength, quality, purity, or potency of the drug as they may relate to the safety or effectiveness of the drug. Such a change includes the change—

(A) in the qualitative or quantitative formulation of the drug involved or in the specifications in the approved application or license referred to in paragraph (1) for the drug (unless exempted by the Secretary by regulation or guidance from the requirements of this subsection);

(B) in the definition of the drug involved or in the information for the drug involved which is intended to be used as a basis for the distribution of the drug involved; or

(C) any other change determined by the Secretary to have the potential to adversely affect the safety or effectiveness of the drug.

(2) Other Manufacturing Changes.—

(a) Section 505(b).—Section 505(b) (21 U.S.C. 355(i)) is amended—

(1) by redesigning paragraphs (1) through (3) as subparagraphs (A) through (C), respectively;

(2) by inserting "(i)" after "(ii)";

(3) by striking the last two sentences; and

(4) by inserting (1) (as designated by paragraph (2) of this section) the following new paragraphs:

Subject to paragraph (3), a clinical investigation of a new drug may begin 30 days after the Secretary receives from the manufacturer or sponsor of the investigation a submission containing such information about the drug and the clinical investigation, including—

(1) information on design of the investigation and adequate reports of basic information, certified by the applicant to be accurate reports, necessary to assess the safety of the drug for use in clinical investigation; and

(2) adequate information on the chemistry and manufacturing controls, including controls available for the drug, and primary data tabulations from animal or human studies.

(3) Any time, the Secretary may prohibit the clinical investigation from being conducted if the Secretary is not convinced as to the adequacy of the submission described by paragraph (1), and shall require such demonstrations of the adequacy as the Secretary determines to be appropriate.

(b) The Secretary shall meet with a sponsor of an investigation or an applicant for approval for a drug under this subsection or section 351 of the Public Health Service Act (42 U.S.C. 262) for certain types of studies. Such guidance shall describe the kinds of studies for which abbreviated reports may be submitted, in lieu of full reports, with a new drug application under section 505(b) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 355(b)) and with a biologics license application under section 351 of the Public Health Service Act (42 U.S.C. 262) for certain types of studies. Such guidance shall describe the kinds of studies for which abbreviated reports may be submitted, in lieu of full reports, with a new drug application under section 505(b) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 355(b)) and with a biologics license application under section 351 of the Public Health Service Act (42 U.S.C. 262) for certain types of studies. Such guidance shall describe the kinds of studies for which abbreviated reports may be submitted, in lieu of full reports, with a new drug application under section 505(b) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 355(b)) and with a biologics license application under section 351 of the Public Health Service Act (42 U.S.C. 262) for certain types of studies. Such guidance shall describe the kinds of studies for which abbreviated reports may be submitted, in lieu of full reports, with a new drug application under section 505(b) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 355(b)) and with a biologics license application under section 351 of the Public Health Service Act (42 U.S.C. 262) for certain types of studies.
shall be reduced to writing and made part of the administrative record by the Secretary. Such agreement shall not be changed after the testing begins, except—

"(iii) pursuant to a decision, made in accordance with subparagraph (D) by the director of the reviewing division if that decision is based on a substantial scientific or medical matter, chemistry, manufactured, and controls)"

(2) CONFORMING AMENDMENTS.—Section 505(j) (21 U.S.C. 355)(j), as amended by paragraph (1), is further amended—

"(A) in paragraph (2)(A)(i), by striking ``(6)'' and inserting ``(7)'';

"(B) in paragraph (4) (as redesignated in paragraph (3)), by striking ``(4)'' and inserting ``(5)'';

"(C) in paragraph (4)(I) (as redesignated in paragraph (3)), by striking ``(5)'' and inserting ``(6)'';

"(D) in paragraph (7)(C) (as redesignated in paragraph (1)), by striking ``(5)'' and inserting ``(6)'';

"(E) The written decisions of the reviewing division shall be binding upon, and may not directly or indirectly be changed by, the field or compliance office personnel unless such field or compliance office personnel demonstrate to the reviewing division why such decision should be modified.

"(F) No action by the reviewing division may be delayed because of the unavailability of information from or action by field personnel unless the reviewing division determines that a delay is necessary to assure the marketing of a safe and effective drug.

"(G) For purposes of this paragraph, the reviewing division is the division responsible for the review of an application for approval of a drug under this subsection (including scientific matters, chemistry, manufacturing, and controls)."

2. SEC. 320. SCIENTIFIC ADVISORY PANELS.

Section 505 (21 U.S.C. 355) is amended by adding at the end the following:

``(n) For the purpose of providing expert scientific advice and recommendations to the Secretary regarding a clinical investigation of a drug or the approval for marketing of a drug under section 505 or section 351 of the Public Health Service Act, the Secretary shall establish panels of experts or use panels of experts established before the date of enactment of the Food and Drug Administration Modernization Act of 1997, or both.

``(2) The Secretary may delegate the appointment and oversight authority granted under section 904(a) to a director of a center or successor entity within the Food and Drug Administration.

``(3) The Secretary shall make appointments to each panel established under paragraph (1) so that each panel shall consist of—

``(A) members who are qualified by training and experience to evaluate the safety and effectiveness of the drugs to be referred to the panel and who, to the extent feasible, possess skill and experience in bioequivalence studies and bioavailability and bioequivalence studies needed for approval of such application. The sponsor or applicant shall provide information necessary for discussion and agreement on the design and size of such studies. Minutes of any such meeting shall be prepared by the Secretary and made available to the sponsor or applicant.

``(B) The Secretary shall meet with a sponsor of an investigation or an applicant for approval for a drug under this subsection if the sponsor or applicant is unable to make written comments at a meeting for the purpose of reaching agreement on the design and size of bioavailability and bioequivalence studies needed for approval of such application. The sponsor or applicant shall provide information necessary for discussion and agreement on the design and size of such studies.

``(C) Any agreement regarding the parameters of design and size of bioavailability and bioequivalence studies of a drug under this paragraph that is reached between the Secretary and a sponsor or applicant shall be reduced to writing and made part of the administrative record by the Secretary. Such agreement shall not be changed after the testing begins, except—

``(i) with the written agreement of the sponsor or applicant;

``(ii) pursuant to a decision, made in accordance with subparagraph (D) by the director of the reviewing division, that a substantial scientific or medical issue involved.

``(D) A decision under subparagraph (C)(iii) by the director of the reviewing division is the division responsible for the review of a drug under this subsection (including scientific matters, chemistry, manufacturing, and controls)."

3. SEC. 321. POSITRON EMISSION TOMOGRAPHY.

(a) REGULATION OF COMPOUNDED POSITRON EMISSION TOMOGRAPHY DRUGS.—Section 201 (21 U.S.C. 321) is amended by adding at the end the following:

``(l) The term 'compounded positron emission tomography drug'—

``(1) means a drug that—

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

``(2) 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 paragraph (l)(1), and is compounded in accordance with that State's law, for a patient or for research, teaching, or quality control; and

``(3) 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) (21 U.S.C. 351)(a) is amended by striking 'or' and inserting 'or' in the following: '--(3) if it is a compounded positron emission tomography drug and the methods used in, or the facilities and controls used for, its compounding, processing, packaging, 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 Pharmacopoeia to assure that such drug meets the requirements of this Act as to safety and has the identity, strength, and purity of the drug as shown by the methods of standardization known to exist at the time that it purports or is represented to possess; or (3) such drug is compounded by a pharmacist for the patient.

(2) SUNSET.—Section 501(a)(2)(C) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 351(a)(2)(C)) shall not apply 4 years after the date of enactment of this Act or 2 years after the date on 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 DRUGS.

(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 publish in the Federal Register final regulations governing the approval of radiopharmaceuticals. The regulations shall provide that the determination of the safety and effectiveness of such a radiopharmaceutical under section 505 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 355) or section 351 of the Public Health Service Act (42 U.S.C. 262) shall include consideration of the proposed use of the radiopharmaceutical in the practice of medicine, the pharmacological and toxicological activity of the radiopharmaceutical (including any carrier or ligand component of the radiopharmaceutical), and the estimated absorbed radiation dose of the radiopharmaceutical.

(B) FORMAL CONSIDERATION.—In establishing the procedures and requirements required by subparagraph (A), the Secretary of Health and Human Services shall consult with patient advocacy groups, professional associations, manufacturers, 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.—Except as provided in subparagraph (B), 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 section 3(j)(2)); or

(B) EXCEPTION.—Nothing in this Act shall prohibit the voluntary submission of such applications or the review of such applications 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 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 355).

(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 this section.


(e) DEFINITION.—As used in this section, the term “compounded positron emission tomography drug” means—

(i) the biological product that is the subject of the application is safe, pure, and potent; and

(ii) the facility in which the biological product is manufactured, processed, packed, or held is registered with the Secretary of Health and Human Services to assure that the biological product continues to be safe, pure, and potent; and

that in the event of death, injury, or illness to any person who consents to the use of the biological product for which a license has been approved under this section, the death, injury, or illness shall be deemed to have been caused by the biological product under investigation shall be exempt from the requirements of paragraph (1).

(f) ELIMINATION OF EXISTING LICENSE REQUIREMENT.—Section 351(d) of the Public Health Service Act (42 U.S.C. 262(d)) is amended—

(A) by striking “(d)(1)” and all that follows through “of this section”;

(B) in paragraph (2)—

(i) by striking “(2)(A)” and inserting “(2)(A) Upon” and “(d)(1)” and “(d)(1)”;

(ii) by redesignating subparagraph (B) as paragraph (2); and

(C) in paragraph (2) (as so redesignated by subparagraph (B))—

(i) by striking “(paragraph)” and “and inserting “(paragraph)”; and

(ii) by striking “(paragraph)” and “and inserting “(paragraph)”.

(g) APPLICATION OF FEDERAL FOOD, DRUG, AND COSMETIC ACT.—Section 351 of the Public Health Service Act (42 U.S.C. 262) is amended to read as follows:

(h) EXAMINATIONS AND PROCEDURES.—Paragra

(h) EXAMINATIONS AND PROCEDURES.—The examinations and procedures identified in paragraph (2) are laboratory examinations and procedures that have been approved by the Food and Drug Administration for home use or that, as determined by the Secretary, are simple laboratory examinations and procedures that have an insignificant risk of an erroneous result, including: "

(1) the term 'antibiotic drug' means any drug (except for use in animals other than humans) composed wholly or partly of any kind of penicillin, streptomycin, chloramphenicol, bacitracin, or any other drug or substance, or a chemically synthesized equivalent of any such substance) and any derivative thereof.''.

SEC. 126. ELIMINATION OF CERTAIN LABELING REQUIREMENTS.

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A drug that is subject to paragraph (1) shall be deemed to be misbranded if at any time prior to dispensing the label of the drug fails to bear, at a minimum, the symbol 'Rx only' or the symbol 'caution' that is the subject of the application contains a certification of the drug under section 507, or by striking subparagraph (B), and by redesignating subparagraph (C) as subparagraph (B)."
“(2)(A) is by a licensed pharmacist or licensed physician in limited quantities before the receipt of a valid prescription order for such individual patient; and

(B) is based on a history of the licensed pharmacist or licensed physician receiving valid prescription orders for the compounding of the drug product, which orders have been generated solely within an established relationship between—

(i) the licensed pharmacist or licensed physician; and

(ii) such individual patient for whom the prescription order will be provided; or

(ii) the physician or other licensed practitioner who will write such prescription order.

(b) COMPOUNDED DRUG.—

(1) LICENSED PHARMACIST AND LICENSED PHYSICIAN.—A drug product may be compounded under subsection (a) if the licensed pharmacist or licensed physician—

(A) compounds the drug product using bulk drug substances, as defined in regulations of the Secretary published at section 207.3(a)(4) of title 21 of the Code of Federal Regulations—

(i) comply with the standards of an applicable United States Pharmacopeia or National Formulary monograph, if a monograph exists, and, in the absence of a monograph, the United States Pharmacopeia chapter on pharmacy compounding;

(ii) if such a monograph does not exist, are drug substances that are components of drugs approved by the Secretary;

(iii) if such a monograph does not exist and the drug substance is not a component of a drug approved by the Secretary, that appear on a list developed by the Secretary through regulations issued by the Secretary under subsection (d);

(ii) that are manufactured by an establishment that is registered under section 510(c); and

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

(B) compounded drug product using ingredients (other than bulk drug substances) that comply with the standards of an applicable United States Pharmacopeia or National Formulary monograph, if a monograph exists, and the United States Pharmacopeia chapter on pharmacy compounding;

(C) 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 of an unacceptable safety risk or because of components of drug products have been found to be unsafe or not effective; and

(D) does not compound regularly or in inordinate amounts (as defined by the Secretary) any drug products that are essentially copies of a commercially available drug product.

(2) DEFINITION.—For purposes of paragraph (1)(D), the term ‘essentially a copy of a commercially available drug product’ does not include a drug product in which there is a change, made for an identified individual patient, which produces for that patient a significant difference, as determined by the prescribing practitioner, between the compounded drug and the commercially available drug product.

(3) DRUG PRODUCT.—A drug product may be compounded under subsection (a) only if—

(A) such drug product is not a drug product identified by the Secretary by regulation as a drug product that presents demonstrable difficulties for compounding that reasonably demonstrate an adverse effect on the safety or effectiveness of that drug product; and

(B) such drug product is compounded in a State that has entered into a memorandum of understanding with the Secretary which addresses the distribution of inordinate amounts of compounded drug products interstate and provides such other investigation and ethics agency of complaints relating to compounded drug products distributed outside such State; or

(iii) that has not entered into the memorandum of understanding described in clause (i) and the licensed pharmacist, licensed physician, or licensed physician distributes (or causes to be distributed) protected information sets, or prescription order sets, for a State in which they are compounded in quantities that do not exceed 5 percent of the total prescription orders dispensed or distributed by such pharmacy

The Secretary shall, in consultation with the National Association of Boards of Pharmacy, develop a standard memorandum of understanding for use by the States in complying with subparagraph (B).

(4) ADVERTISING AND PROMOTION.—A drug may be compounded under subsection (a) only if—

(A) the licensed pharmacist or licensed physician does not advertise or promote the compounding of any particular drug, class of drug, or type of drug. The pharmacy, licensed pharmacist, or licensed physician may advertise and promote the compounding service provided by the licensed pharmacist or licensed physician;

(B) REGULATIONS.—

(i) in GENERAL.—The Secretary shall issue regulations to implement this section. Before issuing regulations to implement subsections (b)(1)(A)(i)(III), (b)(1)(C), or (b)(3)(A), the Secretary shall convene and consult an advisory committee on compounding unless the Secretary determines that the issuance of such regulations before consultation is necessary to protect the public health. The advisory committee shall include representatives from the National Association of Boards of Pharmacy, the United States Pharmacopeia, the American Medical Association, the American Pharmaceutical Association, consumer organizations, and other experts selected by the Secretary.

(ii) LIMITING COMPOUNDING.—The Secretary, in consultation with the United States Pharmacopeia Convention, Incorporated, shall promulgate regulations identifying drug substances that may be compounded under subsection (a)(I) or (a)(II), for which a monograph does not exist or which are not components of drugs approved by the Secretary. The Secretary shall include in the regulation the criteria for such substances, which shall include historical use, reports in peer reviewed medical literature, or other criteria the Secretary may identify.

(iii) APPLICATION.—This section shall not apply to—

(C) a recombinant product, a biological product, or a drug product proved under section 505(b) or 505(j); and

(iv) DEFINITION.—As used in this section, the term ‘compounding’ does not include mixing, reconstituting, or other such acts that are performed in accordance with approved labeling provided by the product manufacturer and other manufacturer directions consistent with that labeling.

(B) EFFECTIVE DATE.—Section 503A of the Federal Food, Drug, and Cosmetic Act, added by subsection (a), shall take effect upon the expiration of the 1-year period beginning on the date of the enactment of this Act.

SEC. 128. 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 grants” and inserting the following: “grants for a pilot program for the training of individuals in clinical pharmacology at appropriate medical schools. Such grants”;

(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. 129. REGULATIONS FOR SUNSCREEN PRODUCTS.

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

SEC. 130. REPORTS OF POSTMARKETING APPROVAL STUDIES.

(a) IN GENERAL.—Chapter V, as amended by section 116, is further amended by inserting after section 506A the following:

SEC. 506B. REPORTS OF POSTMARKETING STUDIES.

(a) SUBMISSION.—

(1) IN GENERAL.—A sponsor of a drug that has entered into an agreement with the Secretary to conduct a postmarketing study of a drug shall submit to the Secretary, within 1 year after the approval of such drug and annually thereafter until the study is completed or terminated, a report of the progress of the study or the reasons for the failure of the sponsor to conduct the study. The report shall be submitted in such form as is prescribed by the Secretary in regulations issued by the Secretary.

(b) AGREEMENTS PRIOR TO EFFECTIVE DATE.—Any agreement entered into between the Secretary and a sponsor of a drug, prior to the date of enactment of the Food and Drug Administration Modernization Act of 1997, to conduct a postmarketing study of a drug shall be subject to the requirements of this section. An initial report for such an agreement shall be submitted within 6 months after the date of the issuance of the regulations under paragraph (1).

SEC. 506C. DISCONTINUANCE OF A LIFE SAVING PRODUCT.

(a) IN GENERAL.—A manufacturer that is the holder of an approval, license, or registration under section 505, 506, 506A, or 506B of the Federal Food, Drug, and Cosmetic Act;

(b) EFFECTIVE DATE.—Section 303A of the Federal Food, Drug, and Cosmetic Act, added by subsection (a), shall take effect upon the expiration of the 1-year period beginning on the date of the enactment of this Act.

SEC. 129. REGULATIONS FOR SUNSCREEN PRODUCTS.

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

SEC. 130. REPORTS OF POSTMARKETING APPROVAL STUDIES.

(a) IN GENERAL.—Chapter V, as amended by section 116, is further amended by inserting after section 506A the following:

SEC. 506B. REPORTS OF POSTMARKETING STUDIES.

(a) SUBMISSION.—

(1) IN GENERAL.—A sponsor of a drug that has entered into an agreement with the Secretary to conduct a postmarketing study of a drug shall submit to the Secretary, within 1 year after the approval of such drug and annually thereafter until the study is completed or terminated, a report of the progress of the study or the reasons for the failure of the sponsor to conduct the study. The report shall be submitted in such form as is prescribed by the Secretary in regulations issued by the Secretary.

(b) AGREEMENTS PRIOR TO EFFECTIVE DATE.—Any agreement entered into between the Secretary and a sponsor of a drug, prior to the date of enactment of the Food and Drug Administration Modernization Act of 1997, to conduct a postmarketing study of a drug shall be subject to the requirements of this section. An initial report for such an agreement shall be submitted within 6 months after the date of the issuance of the regulations under paragraph (1).

(c) STATUS OF STUDIES AND REPORTS.—The Secretary shall annually develop and publish in the Federal Register a report that provides information with respect to the conduct of postmarketing studies described in section 506B of the Federal Food, Drug, and Cosmetic Act;

(d) EVALUATION.—

(A) the performance of the sponsors referred to in such section in fulfilling the agreements with respect to the conduct of postmarketing studies described in such section of such Act;

(B) the timeliness of the Secretary’s review of the postmarketing studies; and

(C) any legislative recommendations respecting the postmarketing studies.

SEC. 131. NOTIFICATION OF DISCONTINUANCE OF A LIFE SAVING PRODUCT.

(a) IN GENERAL.—Chapter V, as amended by section 130, is further amended by inserting after section 506B the following:

SEC. 506C. DISCONTINUANCE OF A LIFE SAVING PRODUCT.

(a) IN GENERAL.—A manufacturer that is the holder of an approval, license, or registration under section 505, 506, 506A, or 506B of the Federal Food, Drug, and Cosmetic Act;

(b) EFFECTIVE DATE.—Section 303A of the Federal Food, Drug, and Cosmetic Act, added by subsection (a), shall take effect upon the expiration of the 1-year period beginning on the date of the enactment of this Act.
shall notify the Secretary of a discontinuance of the manufacture of the drug at least 6 months prior to the date of the discontinuance.

(b) Reduction in Notification Period.—
The notification period required under subsection (a) for a manufacturer may be reduced if the manufacturer certifies to the Secretary that 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 materials 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;

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

(6) the manufacturer can continue the distribution of the drug involved for 6 months.

(c) Distribution.—To the maximum extent practicable, the Secretary shall distribute information on the notification of the discontinuance prescribed in subsection (a) to appropriate physician and patient organizations.

TITLE II—IMPROVING REGULATION OF INVESTIGATIONAL DEVICES

SEC. 201. INVESTIGATIONAL DEVICE EXEMPTIONS.

(a) In General.—Section 520(g) (21 U.S.C. 360g) is amended by adding at the end the following:

"(6) Not later than 1 year after the date of enactment of this Act, the Secretary shall, by rule and without regard to section 520(f)(1) of this title, require the sponsor or applicant to provide a written request to the Secretary of an investigational plan (including a clinical protocol) that is reached between the Secretary and the sponsor or applicant for the purpose of reaching agreement regarding the investigational plan (including a clinical protocol) that is about to be submitted to the Secretary, for review, an investigational plan (including a clinical protocol) for determining whether there is a reasonable assurance of effectiveness and, if available, information regarding the expected performance of the device.

(b) Any agreement regarding the parameters of an investigational plan (including a clinical protocol) that is reached between the Secretary and the sponsor or applicant shall be reduced to writing and made part of the administrative record by the Secretary if such agreement shall not be changed, except—

(1) with the written agreement of the sponsor or applicant;

(2) pursuant to a decision, made in accordance with subparagraph (C) by the director of the office in which the device involved is reviewed, that a substantial scientific issue essential to determining the safety or effectiveness of the device involved has been identified.

"(C) A decision under subsection (B)(ii) by the director shall be in writing, and may be made only if the device has been provided to the sponsor or applicant an opportunity for a meeting at which the director and the sponsor or applicant are present and at which the director will discuss the data or information relied on by the person making the declaration of conformity to the Secretary.

"(d) Action on Application.—Section 513(d)(1)(B) (21 U.S.C. 360e(d)(1)(B)) is amended by adding at the end the following:

"(ii) pursuant to a decision, made in accordance with subparagraph (C) by the director of the office in which the device involved is reviewed, that a substantial scientific issue essential to determining the safety or effectiveness of the device involved has been identified.

SEC. 202. SPECIAL REVIEW FOR CERTAIN DEVICES.

Section 515(d) (21 U.S.C. 360d) is amended—

(1) by redesignating paragraph (3) as paragraph (4); and

(2) by adding at the end the following:

"(5) In order to provide for more effective treatment or diagnosis of life-threatening or irreversibly debilitating human diseases or conditions, the Secretary shall provide review priority for devices—

"(A) representing breakthrough technologies;

"(B) for which no approved alternatives exist, or

"(C) which offer significant advantages over existing approved alternatives; or

"(D) the availability of which is in the best interest of the patients.

SEC. 203. EXISTING HUMANITARIAN USE OF DEVICES.

Section 520(m) (21 U.S.C. 360(m)) is amended—

(1) in paragraph (2), by adding after and below subparagraph (C) the following sentences:

"The request shall be in the form of an application submitted to the Secretary. Not later than 30 days after the date of the receipt of the application, the Secretary shall issue an order approving or denying the application.";

(2) in paragraph (4)—

(A) in subparagraph (B), by inserting after "(2)" the following: "", unless a physician determines in an emergency situation that approval from a local institutional review committee would result in serious harm or death to a patient;"; and

(B) by adding after and below subparagraph (B) the following:

"(2) the Secretary shall, by rule and without regard to section 520(f)(1) of this title, require the sponsor or applicant to provide a written request to the Secretary of an investigational plan (including a clinical protocol) that is about to be submitted to the Secretary, for review, an investigational plan (including a clinical protocol) for determining whether there is a reasonable assurance of effectiveness and, if available, information regarding the expected performance of the device.

(b) Any agreement regarding the parameters of an investigational plan (including a clinical protocol) that is reached between the Secretary and the sponsor or applicant shall be reduced to writing and made part of the administrative record by the Secretary if such agreement shall not be changed, except—

(1) with the written agreement of the sponsor or applicant;

(2) pursuant to a decision, made in accordance with subparagraph (C) by the director of the office in which the device involved is reviewed, that a substantial scientific issue essential to determining the safety or effectiveness of the device involved has been identified.

"(C) A decision under subsection (B)(ii) by the director shall be in writing, and may be made only if the device has been provided to the sponsor or applicant an opportunity for a meeting at which the director and the sponsor or applicant are present and at which the director will discuss the data or information relied on by the person making the declaration of conformity to the Secretary.

"(d) Action on Application.—Section 513(d)(1)(B) (21 U.S.C. 360e(d)(1)(B)) is amended by adding at the end the following:

"(ii) pursuant to a decision, made in accordance with subparagraph (C) by the director of the office in which the device involved is reviewed, that a substantial scientific issue essential to determining the safety or effectiveness of the device involved has been identified.

SEC. 204. DEVICE STANDARDS.

(a) Alternative Procedure.—Section 514 (21 U.S.C. 360d) is amended by adding at the end the following:

"Recognition of a Standard

"(C)(1) In addition to establishing a performance standard under this section, the Secretary shall, by publication in the Federal Register, recognize all or part of an appropriate standard established by a nationally or internationally recognized standard development organization for a device only if following notice and an opportunity for an informal hearing.

"(3) Not later than 3 years after the date of enactment of this Act, the Secretary shall publish in the Federal Register a list of recognized standards for devices that are appropriate for meeting the requirements of this section.

SEC. 205. PERIODIC REVIEW OF DEVICES.

SEC. 206. PROHIBITION ON DEVICES SUBJECT TO UNDERWRITING.

SEC. 207. INVESTIGATIONAL DEVICES.
and information demonstrating conformity of the device to the standard for a period of two years after the date of the classification or approval of the device by the Secretary or a period equal to the time necessary to achieve the intended design life of the device, whichever is longer.

(b) Section 301. Section 301 (21 U.S.C. 331) is amended by adding at the end the following: "(x) A declares the determination of the Secretary that a device is in conformity with such standard."

(c) Section 501. Section 501 (21 U.S.C. 351) is amended— (1) by striking "(e)(1);" and (2) by inserting at the end the following: "(f) Any device that is in conformity with any standard recognized under section 514(c) unless such device is in all respects in conformity with such standard." 

(d) Conforming Amendments. Section 514(a) (21 U.S.C. 360(a)) is amended— (1) in paragraph (1), by striking "under this section" and inserting "under subsection (b);" (2) in paragraph (2), in the matter preceding subparagraph (A), by striking "under this section" and inserting "under subsection (b);" (3) in paragraph (3), by striking "under this section" and inserting "under subsection (b);" and (4) in paragraph (4), in the matter preceding subparagraph (A), by striking "this section" and inserting "this subsection and subsection (b)."

Sec. 205. Scope of Review; Collaborative Determinations of Device Data Requirements.

(a) Section 513(a). Section 513(a)(3) (21 U.S.C. 360(a)(3)) is amended by adding at the end the following: "(C) In making a determination of a reasonable assurance of the effectiveness of a device for which an application under section 515 has been submitted, the Secretary shall consider whether the extent of data that otherwise would be required for approval of the application with respect to effectiveness can be reduced through reliance on postmarket controls.

"(D)(i) The Secretary, upon the written request of any person, or in its own discretion, may issue a report under section 515, as the Secretary shall meet with such person to determine the type of valid scientific evidence (within the meaning of subparagraphs (A) and (B)) that will be necessary for demonstrating purposes of approval of an application the effectiveness of a device for the conditions of use proposed by such person. The written request shall include a detailed description of the device, a detailed description of the proposed conditions of use of the device, a proposed plan for determining whether there is a reasonable assurance of effectiveness, and, if available, information regarding the expected performance from the device. Within 30 days after such meeting, the Secretary shall specify in writing the type of valid scientific evidence (within the meaning of subparagraphs (A) and (B)) that will provide a reasonable assurance that a device is effective under the conditions of use proposed by such person.

"(iii) Any clinical data, including one or more well-controlled investigations, specified in writing by the Secretary for demonstrating a reasonable assurance of device effectiveness shall be specified as result of a determination by the Secretary that such data are necessary to establish device effectiveness. The Secretary shall consider, in consultation with the applicant, the least burdensome, appropriate means of evaluating device effectiveness that would have a reasonable likelihood of resulting in approval.

"(iii) The determination of the Secretary with respect to an appropriate means of evaluation of valid scientific evidence under clauses (i) and (ii) shall be binding upon the Secretary, unless such determination by the Secretary could be contrary to the public health."

(b) Section 513(i). Section 513(i)(1) (21 U.S.C. 360(i)(1)) is amended by adding at the end the following: "(f) To facilitate reviews of reports submitted to the Secretary under section 510(k), the Secretary shall consider the extent to which reliance on postmarket controls may expedite the classification of devices under subsection (f)(1) of this section.

"(d) Whenever the Secretary requests information from applications with differing technological characteristics are substantially equivalent, the Secretary shall only request information that is necessary to making substantial equivalence determinations. In making such request, the Secretary shall consider the least burdensome means of demonstrating substantial equivalence and request information accordingly.

"(E)(i) Any determination by the Secretary of the intended use of a device shall be based upon the proposed labeling submitted in a report for the device under section 510(k). However, in determining that a device can be found substantially equivalent to a legally marketed device, the director of the organizational unit responsible for making such determination (referred to as the `Director') may require a statement in labeling that provides appropriate information regarding a use of the device not identified in the proposed labeling if, after providing an opportunity for consultation with the person who submitted such report, the Director determines and states in writing—""(i) that there is a reasonable likelihood that the device will be used for an intended use not identified in the proposed labeling for the device; and

"(ii) that such use could cause harm.

"(iii) Such determination shall—""(i) be provided to the person who submitted the report within 10 days from the date of the notification of the Director's concerns regarding the proposed labeling; and

"(ii) find the device substantially equivalent if the requirements of subparagraph (A) are met and if the labeling for such device conforms to the limitations specified in paragraph (1)(i).

"(B)(i) Subject to clause (ii), in reviewing a report under section 510(k), the Secretary shall consider the reports submitted in a report under subsection (k) to provide reasonable assurance of safety and effectiveness for the changed device.

"(ii) The Secretary may require, when necessary, additional clinical data to evaluate the design modification of the device to provide a reasonable assurance of safety and effectiveness.

Sec. 206. Premarket Notification.

(a) Section 510. Section 510 (21 U.S.C. 360) is amended— (1) in subsection (k), in the matter preceding paragraph (1), by adding after "report to the Secretary" the following: "or person who is accredited under section 351(e)(1)"; and (2) by adding at the end the following subclauses: "(A) A report under subsection (k) is not required for a device intended for human use that is exempted from the requirements of this subsection if no intact use or within a type that has been classified into class I under section 510(i)(3). The exception established in the predecessor does not apply to any device that is intended for use which is of substantial importance in preventing impairment of health, or which presents a potential unreasonable risk of illness or injury.

"(B) Not later than 30 days after the date of the publication of the Federal Register notice under paragraph (1) of this section, the Secretary may exempt a class II device from the requirement to submit a report under subsection (k), upon the Secretary's own initiative or a petition of an interested person, if the Secretary determines that such report is not necessary to assure the safety and effectiveness of the device. The Secretary shall publish in the Federal Register a list of each type of class II device that does not require a report under subsection (k) to provide reasonable assurance of safety and effectiveness. Each type of class II device identified by the Secretary, as not requiring the report shall be exempted from the requirement to provide a report under subsection (k) as of the date of the publication of the list in the Federal Register.

"(2) Beginning on the date that is 1 day after the date of the publication of the Federal Register notice under subsection (b)(1) of this section, the Secretary may exempt a class II device from the requirement to submit a report under subsection (k), upon the Secretary's own initiative or a petition of an interested person, if the Secretary determines that such report is not necessary to assure the safety and effectiveness of the device. The Secretary shall publish in the Federal Register a list of each type of class II device that is exempt from the requirement to exempt the device, or of the petition, and provide a 30-day period for public comment. Within 120 days after the issuance of the notice of final determination, the Secretary shall publish an order in the Federal Register that sets forth the final determination of the Secretary.
regarding the exemption of the device that was the subject of the notice. If the Secretary fails to respond to a petition within 180 days of receiving it, the petition shall be deemed to be granted.

(b) **SECTION 513(f).**—Section 513(f) (21 U.S.C. 360c(f)) is amended by adding at the end the following:

(5) The Secretary may not withhold a determination of the initial classification of a device under paragraph (1) because of a failure to comply with any provision of this Act unrelated to the enactment of the Food and Drug Administration Modernization Act of 1997, the Secretary shall issue guidance specifying the general principles and requirements for classifications of the Secretary under section 520(f) (other than a finding that there is a substantial likelihood that the failure to comply with such regulations will potentially present a serious risk to human health)."

(c) **SECTION 513(h).**—Section 513(h) (21 U.S.C. 360c(h)), as amended by section 205(b), is amended—

(1) in subparagraph (A)(ii)—

(A) in clause (I), by striking "clinical data" and inserting "data and information that is based on clinical or scientific data and by inserting "or a person accredited under section 523" after "Secretary"; and

(B) in clause (II), by striking "efficacy" and inserting "effectiveness"; and

(2) by adding at the end the following:

(F) Not later than 270 days after the date of the enactment of the Food and Drug Administration Modernization Act of 1997, the Secretary shall issue guidance specifying the general principles and requirements for determining when a specific intended use of a device is not reasonably included within a general use for purposes of paragraph (1), and any device classified under this section on the basis of such determination shall be subject to the annual chartering and annual report requirements of the Federal Advisory Committee Act.

SEC. 206. CLASSIFICATION PANELS.

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

(5) Classification panels covering each type of device shall be scheduled to meet at such times as may be appropriate for the Secretary to meet applicable statutory deadlines.

(6)(A) Any person whose device is specifically the subject of review by a classification panel shall—

(i) the same access to data and information submitted to a classification panel (except for data and information that are not available for public disclosure under section 522 of title 5, United States Code) as the Secretary;

(ii) the opportunity to submit, for review by a classification panel, information that is based on data or information provided in the application submitted under section 515 by the person, which information shall be submitted to the Secretary for prompt transmittal to the classification panel; and

(iii) the same opportunity as the Secretary to participate in meetings of the panel.

(B) Any meetings of a classification panel shall provide to the applicant a detailed and open participation by all interested persons.

(7) A classification panel under this subsection shall not be subject to the annual chartering and annual report requirements of the Federal Advisory Committee Act.

(8) A classification panel under this subsection shall not be subject to the annual chartering and annual report requirements of the Federal Advisory Committee Act.

SEC. 207. EVALUATION OF AUTOMATIC CLASS III DESIGNATION.

(a) **SECTION 513(f).**—Section 513(f) (21 U.S.C. 360c(f)), as amended by section 206(b), is amended—

(1) in paragraph (1)—

(A) in subparagraph (B), by striking "paragraph (2)" and inserting "paragraphs (2) and (3)"; and

(B) in the last sentence, by striking "paragraph (2) and (3)" and inserting "paragraph (2) or (3)";

(2) in paragraph (2) as amended by section 206(a)(2) as paragraphs (3) and (4), respectively; and

(3) by inserting after paragraph (1) the following:

(1)(2) A person who submits a report under section 510(k) for a type of device that has not been previously classified under this Act, and that was not previously classified under section 513(b), may request, within 30 days after receiving written notice of such a classification, the Secretary to classify the device under the criteria set forth in subparagraphs (A) through (C) of subsection (a)(1). The person may, in the request, recommend to the Secretary a classification for the device. Any such request shall describe the device and provide detailed information and reasons for the recommended classification.

(2)(i) Not later than 60 days after the date of the submission of the request under subparagraph (A), the Secretary shall by written order classify the device involved. Such classification shall be the initial classification of the device for purposes of paragraph (1) and any device classified under this paragraph shall be a predicate device for determining substantial equivalence under paragraph (1).

(ii) A device that remains in class III under this subparagraph shall be deemed to be adulterated within the meaning of section 501(f)(1)(B) of this Act and shall not be included under section 515 or exempted from such approval under section 520(g).

(C) Within 30 days after the issuance of an order classifying a device under the paragraph, the Secretary shall publish a notice in the Federal Register announcing such classification.

SEC. 208. CERTAINTY OF REVIEW TIMES; COLLABORATIVE REVIEW PROCESS.

(a) **CERTAINTY OF REVIEW TIMES.**—Section 510 (21 U.S.C. 360), as amended by section 206(a)(2), is amended by adding at the end the following:

(2) ACCREDITATION. The Secretary shall establish and publish in the Federal Register announcing such classification.

SEC. 209. CERTAINTY OF REVIEW TIMETRAMES; COLLABORATIVE REVIEW PROCESS.

(a) **CERTAINTY OF REVIEW TIMES.**—Section 510 (21 U.S.C. 360), as amended by section 206(a)(2), is amended by adding at the end the following:

(2) ACCREDITATION. The Secretary shall establish and publish in the Federal Register announcing such classification.

SEC. 210. ACCREDITATION OF PERSONS FOR REVIEW OF PREMARKET NOTIFICATION REPORTS.

(a) **IN GENERAL.**—Subchapter A of chapter V is amended by adding at the end the following:

(1) **SECTION 523 ACCREDITED PERSONS.**

(2) **REVIEW AND CLASSIFICATION OF DEVICES.**—Not later than 1 year after the date of the enactment of the Drug and Food Administration Modernization Act of 1997, the Secretary shall establish and publish in the Federal Register announcing such classification.

(2) **REQUIREMENTS REGARDING REVIEW.**

(A) **IN GENERAL.**—In making a recommendation to the Secretary under paragraph (1), an accredited person shall provide to the Secretary in writing the reasons for the recommendation.

(B) **TIME PERIOD FOR REVIEW.**—Not later than 30 days after the date on which the Secretary is notified under subparagraph (A) by an accredited person with respect to a recommendation of an initial classification of a device, the Secretary shall make a determination with respect to the initial classification of the device.

(C) **SPECIAL RULE.**—The Secretary may change the initial classification under section 513(f)(1) that is recommended under paragraph (1) by an accredited person in a case that provides to such person, and the person who submitted the report under section 510(k) for the device, a statement explaining in detail the reasons for the change.

(3) **CERTAIN DEVICES.**

(A) **IN GENERAL.**—An accredited person may not be used to perform a review of—

(i) a class III device;

(ii) a class II device which is intended to be permanently implantable or life sustaining or life supporting;

(iii) a class II device which requires clinical data in the report submitted under section 510(k) for the device, except that the number of such reports to which clauses (i) and (ii) apply, may not exceed 5 percent of the number that is equal to the total number of reports submitted to the Secretary under such section for such year less the number of such reports to which such clauses apply for such year.

(B) **ADJUSTMENT.**—For a year the ratio described in subparagraph (A)(iii), the Secretary shall not include in the numerator class III devices that the Secretary reclassified under reason (d) of section 510(e) and, the Secretary shall include in the denominator class II devices for which reports under section 510(k) were not required to be submitted by reason of the operation of section 510(m).

(1) **PROGRAMS.**—The Secretary shall provide for such accreditation through programs administered by the Food and Drug Administration, other government agencies, or by other qualified nongovernment organizations.

(2) **ACCREDITATION.**

(A) **IN GENERAL.**—Not later than 180 days after the date of the enactment of the Food and Drug Administration Modernization Act of 1997, the Secretary shall establish and publish in the Federal Register criteria to accrediting or deny accreditation to persons who request to perform the duties specified in subsection (a). The Secretary shall respond to a request for accreditation within 60 days of the receipt of the request. The accreditation of such person shall specify the particular activities under subsection (a) for which the person is accredited.

(B) **WITHDRAWAL OF ACCREDITATION.**—The Secretary may suspend or withdraw accreditation of any person accredited under this paragraph after providing such person with an opportunity for an informal hearing, when such person is substantially not in compliance with the
requirements of this section or poses a threat to public health or fails to act in a manner that is consistent with the purposes of this section.

(C) PERFORMANCE AUDITING.—To ensure that persons covered by this section will continue to meet the standards of accreditation, the Secretary shall—

(i) make onsite visits on a periodic basis to each accredited person to audit the performance of such person; and

(ii) take such additional measures as the Secretary deems to be necessary.

(D) ANNUAL REPORT.—The Secretary shall include in the annual report required under section 523(g) the names of all accredited persons and training activities under subsection (a) for which each such person is accredited and the name of each accredited person whose accreditation has been withdrawn during the year.

(E) QUALIFICATIONS.—An accredited person shall, at a minimum, meet the following requirements:

(A) Such person may not be an employee of the Federal Government.

(B) Such person shall be an independent organization which is not owned or controlled by a manufacturer, supplier, or vendor of devices and which has no organizational, material, or financial affiliation with such a manufacturer, supplier, or vendor.

(C) Such person shall be a legally constituted entity permitted to conduct the activities for which it seeks accreditation.

(D) It shall not engage in the design, manufacture, promotion, or sale of devices.

(E) The operations of such person shall be in accordance with generally accepted professional and ethical business practices and shall agree in writing that as a minimum it will—

(i) certify that reported information accurately reflects data reviewed;

(ii) limit work to that for which competence and capacity are available;

(iii) treat information received, records, reports, and recommendations as proprietary information;

(iv) promptly respond and attempt to resolve complaints regarding its activities for which it is accredited; and

(v) protect against the use, in carrying out subsection (a) with respect to a device, of any officer or employee of the person who has a financial interest in the activities described in section 523, and annually make available to the public disclosures of the extent to which the person, and the officers and employees of the person, have maintained compliance with requirements under this clause relating to financial conflicts of interest.

(F) SELECTION OF ACCREDITED PERSONS.—The Secretary shall, in each program or subprogram of accreditation, select one for a specific regulatory function.

(G) COMPENSATION OF ACCREDITED PERSONS.—Compensation for an accredited person shall constitute an agreement, between the accredited person and the person who engages the services of the accredited person, and shall be paid by the person who engages such services.

(H) DURATION.—The authority provided by this section terminates—

(1) 5 years after the date on which the Secretary notifies Congress that at least 2 persons accredited under subsection (b) are available to review at least 60 percent of the submissions under section 510(k);

(2) 4 years after the date on which the Secretary notifies Congress that the Secretary has made a determination described in paragraph (1)(B) of subsection (a) for at least 35 percent of the devices that are subject to review under paragraph (1) of such subsection, whichever occurs first.

(b) RECORD KEEPING.—Section 704 (21 U.S.C. 374) is amended by adding at the end the following:

"(f)(1) A person accredited under section 523 to review clinical data under section 510(k) and make recommendations of initial classifications of devices to the Secretary shall maintain records documenting the training qualifications and experience of the personnel of the person, the procedures used by the person for handling confidential information, the compensation arrangements made by the person, and the procedures the person to identify and avoid conflicts of interest. Upon the request of an officer or employee designated by the Secretary, the person shall permit the officer or employee, at all reasonable times, to have access to, to copy, and to verify, the records.

"(2) Within 15 days after the receipt of a written request from the Secretary to a person accredited under section 523 for copies of records described in paragraph (1), the person shall produce the copies of the records at the place designated by the Secretary."

"(g) CONFORMING AMENDMENT.—Section 301 (21 U.S.C. 331), as amended by section 204(b), is amended by adding at the end the following:

"(y) In the case of a drug, device, or food—

"(1) the support or recommendation by a person accredited under section 523 that is false or misleading in any material respect;

"(2) the disclosure by a person accredited under section 523 of confidential commercial information or any trade secret without the express written consent of the person who submitted such information or secret to such person; or

"(3) the receipt by a person accredited under section 523 of a bribe in any form or the doing of any corrupt act by such person associated with a responsibility delegated to such person under this Act."

(d) REPORTS ON PROGRAM OF ACCREDITATION.—

(1) C O M P T O R 3 E R 3 G E N E R A L.—

(A) IMPLEMENTATION OF PROGRAM.—Not later than 5 years after the date of the enactment of this Act, the Comptroller General of the United States shall submit to the Committee on Commerce of the House of Representatives and the Committee on Labor and Human Resources of the Senate a report describing the use of accredited persons under such section 523, and the extent to which the amendment made by subsection (a) has been implemented.

(B) E V A L U A T I O N O F PROGRAM.—Not later than 5 years after the date of the enactment of this Act, the Comptroller General shall submit to the Committee on Commerce of the House of Representatives and the Committee on Labor and Human Resources of the Senate a report describing the use of accredited persons under section 523, including an evaluation of the extent to which such use assisted the Secretary in carrying out the duties of the Secretary under such Act with respect to devices, and the extent to which such use promoted actions which are contrary to the purposes of such Act.

(2) I N C L U S I O N O F CERTAIN DEVICES WITHIN PROGRAM.—Not later than 3 years after the date of the enactment of this Act, the Secretary of Health and Human Services shall submit to the Committee on Commerce of the House of Representatives and the Committee on Labor and Human Resources of the Senate a report describing the extent to which the amendment made by subsection (a) has been implemented.

"(2) The Secretary shall by regulation require a manufacturer to conduct surveillance of a device within 6 months prior to the date on which, pursuant to the amendment made by subsection (a), the limitation established in clause (iii) of section 513(h) is amended; or

"(E) by striking paragraph (9); and

"(F) by inserting at the end the following:

"(10) In the case of a drug, device, or foodublished.
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the same extent and in the same manner as such paragraphs apply to manufacturers and importers;''

(2) by striking subsection (d); and

(3) inserting in its place the following:

``(f) by striking ''importer'', or distributor'' each place it appears and inserting ''or importer''.

(b) REGISTRATION.—Section 510(g) (21 U.S.C. 360(e)) is amended—

(1) by redesignating paragraph (4) as paragraph (5);

(2) by inserting after paragraph (3) the following:

``(4) any distributor who acts as a wholesale distributor of devices, and who does not manufacture, repack, process, or relabel a device; or''

(3) by adding at the end the following flush sentence:

``In this subsection, the term ''wholesale distributor'' means any person other than the manufacturer or the initial importer who distributes a device from the original place of manufacture to the person who makes the final delivery or sale of the device to the ultimate consumer or user.''.

(c) DE VICE USER FACILITIES.—

(1) in general.—Section 519(b) (21 U.S.C. 360(b)) is amended—

(A) in paragraph (1)(C)—

(i) in the first sentence, by striking ''a semi-

annual basis'' and inserting ''an annual basis'';

(ii) in the second sentence, by striking ''and July 1''; and

(iii) by striking the matter after and below clause (iv); and

(B) in paragraph (2)—

(i) in subparagraph (A), by inserting ''or'' after the comma at the end;

(ii) by striking clause (iv); and

(iii) by striking subparagraph (C).

(2) SENTINEL SYSTEM.—Section 519(b) (21 U.S.C. 360(b)) is amended—

(A) by redesigning paragraph (5) as paragraph (6); and

(B) by inserting after paragraph (4) the following paragraphs:

``(5) With respect to device user facilities:

``(A) The Secretary shall by regulation limit or interfere with the authority of a health care practitioner-patient relationship. This section shall not limit any existing authority of the Secretary to establish and enforce restrictions on the sale or dispensing, at the time of the labeling, of a device that are part of a determination of substantial equivalence, established as a condition of approval, or promulgated through regulations. Further, the Secretary shall not change any existing prohibition on the promotion of unapproved uses of legally marketed devices.''

SEC. 215. NONINVASIVE BLOOD GLUCOSE METER.

(a) IN GENERAL.—Section 515(j)(4)(C) (21 U.S.C. 360j(h)(4)) is amended to read as follows:

``(4) The Secretary, after notice and opportunity for public hearing, may by order establish, modify, or revoke standards of performance or labeling for medical devices which the Secretary determines are necessary to ensure that scientifically sound noninvasive blood glucose meter would likely improve control and management of diabetes, and existing blood testing devices require repeated piecing of the blood stream.

``(7) The pain associated with existing blood testing devices creates a disincentive for people with diabetes to test blood glucose levels,

particularly children;

``(8) A safe and effective noninvasive blood glucose meter would likely improve control and management of diabetes by increasing the number of tests conducted by people with diabetes, particularly children;

``(9) the Food and Drug Administration is responsible for regulating new medical devices in the United States.

(b) SENSE OF CONGRESS.—It is the sense of the Congress that the availability of a safe, effective, noninvasive blood glucose meter would greatly enhance the health and well-being of all people with diabetes across America and the world.

SEC. 216. USE OF DATA RELATING TO PREMARKET APPROVAL; PRODUCT DEVELOPMENT PROTOCOL.

(a) Use of Data Relating to Premarket Approval.—

``In order to ensure that the Secretary has the best available scientific information for approving a new medical device, the following shall be considered, in determining whether a medical device is safe and effective

``(i) approving another device;

``(ii) determining whether a product development protocol has been completed, under section 515 for another device;

``(iii) establishing a performance standard or special control under this Act; or

``(iv) classifying or reclassifying another device under section 513 and subsection (1)(2).

``(B) The Secretary may use data from clinical trials and other information from the clinical and preclinical tests or the application for premarket approval filed with the Secretary pursuant to section 515(c) (including information from clinical and preclinical tests or studies that demonstrate the safety and effectiveness of a device, but excluding the description of the methods of methods of manufacture and product composition and other trade secrets) shall be available,

6 years after the application has been approved by the Secretary, for use by the Secretary in—

``(i) approving another device;

``(ii) determining whether a product development protocol has been completed, under section 515 for another device;

``(iii) establishing a performance standard or special control under this Act; or

``(iv) classifying or reclassifying another device under section 513 and subsection (1)(2).

``(C) The Secretary shall provide the Committee on Commerce of the House of Representatives, and to the Committee on Labor and Human Resources of the Senate, a copy of the development plan developed by the Secretary under subparagraph (A) and the progress that has been made toward the implementation of the plan.''

SEC. 214. PRACTICE OF MEDICINE.

Chapter IX is amended by adding at the end the following:

``SEC. 906. PRACTICE OF MEDICINE.

Nothing in this Act shall be construed to limit the authority of a health care practitioner who prescribe or administer any legally marketed device to a patient for any condition or disease within a legitimate health care practitioner-patient relationship. This section shall not limit any existing authority of the Secretary to establish and enforce restrictions on the sale or dispensing, at the time of the labeling, of a device that are part of a determination of substantial equivalence, established as a condition of approval, or promulgated through regulations. Further, the Secretary shall not change any existing prohibition on the promotion of unapproved uses of legally marketed devices.''

(b) PRODUCT DEVELOPMENT PROTOCOL.—Sec-

tion 515(f)(2) (21 U.S.C. 360(e)(2)) is amended by striking ''he shall'' and all that follows and inserting the following: ``the Secretary shall provide the Committee on Commerce of the Senate, refer the proposed protocol to the appropriate panel under section 513 for its recommendation respecting approval of the protocol; or''

(3) by adding at the end thereof the following:

``(C) Notwithstanding the provisions of clauses (A)(i) and (B), a claim of the type described in subparagraph (A)(i) which is not authorized by the Secretary in a regulation promulgated in accordance with clause (B) shall be

SEC. 310. FLEXIBILITY FOR REGULATIONS REGARDING CLAIMS.

Section 403(r) (21 U.S.C. 343(r)) is amended by adding at the end thereof:

``(1) The Secretary shall use the approved regulations issued under this paragraph effective upon publication pending consideration of public comment and publication of a final regulation if the Secretary determines that such action is necessary—

``(A) to enable the Secretary to review and act promptly on petitions the Secretary determines provide for information necessary to improve health or maintain healthy dietary practices; or

``(B) to enable consumers to develop and maintain healthy dietary practices;''

SEC. 301. FLEXIBILITY FOR REGULATIONS REGARDING CLAIMS.

Section 403(r) (21 U.S.C. 343(r)) is amended—

(a) by adding after the first sentence the following:

``(2) The Secretary and the Committee on Commerce of the House of Representatives, and to the Committee on Labor and Human Resources of the Senate, a copy of the development plan developed by the Secretary under subparagraph (A) and the progress that has been made toward the implementation of the plan.''

(b) P R O D U C T DEVELOPMENT PROTOCOL.—Sec-

tion 515(f)(2) (21 U.S.C. 360(e)(2)) is amended by striking ''he shall'' and all that follows and inserting the following: "the Secretary shall provide the Committee on Commerce of the Senate, refer the proposed protocol to the appropriate panel under section 513 for its recommendation respecting approval of the protocol; or"
authorized and may be made with respect to a food if—

(ii) a scientific body of the United States Government with official responsibility for public health protection or research directly relating to human nutrition (such as the National Institutes of Health or the Centers for Disease Control and Prevention) or the National Academy of Sciences or any of its subdivisions has published an authoritative statement, which is currently in effect, about the relationship between a nutrient and a disease or health-related condition to which the claim refers; and

(iii) a person has submitted to the Secretary, at least 120 days (during which the Secretary has not submitted all the information required by such clause) before the first introduction into interstate commerce of the food with a label containing the claim, (I) a notice of the claim, which shall include the exact words used in the claim and shall include a concise description of the basis upon which such person relied for determining that the requirements of subclause (i) have been satisfied, (II) a copy of the statement referred to in subclause (i) upon which such person relied in making the claim, and (III) a balanced representation of the scientific literature relating to the nutrient level to which the claim refers; 

(iii) the claim and the food for which the claim is made are in compliance with clauses (A) and (B) and (C) and (D) and (E) and (F) and (G) and (H) and (I) and (J) and (K) and (L) and (M) and (N) and (O) and (P) and (Q) and (R) and (S) and (T) and (U) and (V) and (W) and (X) and (Y) and (Z); and

(6) that the requirements of subclause (C) have not been met, including finding that the regulation has become effective, or

(7) that the requirements of clause (G) have not been met, including finding that the petitioner had not submitted all the information required by such clause; or

(iv) a district court of the United States in an enforcement proceeding under chapter III has determined that the requirements of clause (G) have not been met.

SEC. 305. REFERRAL STATEMENTS.

Section 403(r)(2)(B) (21 U.S.C. 343(r)(2)(B)) is amended—

(1) in paragraph (1)—

(A) by striking the words "and (B)" and inserting "(B)"; and

(B) by striking the end of paragraph (2) and inserting "or";

(2) by inserting after paragraph (2) the following:

"(3) (as added by paragraph (3)) and inserting "subparagraph (5)";";

(3) by striking the matter following paragraph (5) and inserting the following flush sentence:

"While such a regulation relating to a food additive, or such a notification under subsection (h) relating to a food additive that is a food contact substance, is in effect, and has not been revoked pursuant to subsection (i), a food shall not, by reason of bearing or containing such food additive in accordance with the regulation or notification, be considered adulterated under section 402(a)(1)."

SEC. 306. DISCLOSURE OF IRRADIATION.

Chapter IV (21 U.S.C. 341 et seq.) is amended by inserting after section 403B the following: 

"DISCLOSURE

SEC. 403C. (a) In the case of section 402(n), 403(a), or 409 shall be construed to require on the label or labeling of a food a separate radiation disclosure statement that is more prominent than that containing the name of ingredients required by section 403D(2)."

(b) In this section, the term ‘radiation disclosure statement’ means a written statement that discloses that a food has been intentionally subject to radiation."

SEC. 307. IRRADIATION PETITION.

Not later than 60 days following the date of the enactment of this Act, the Secretary of Health and Human Services shall make a final determination on any petition pending with the Food and Drug Administration that would permit the irradiation of red meat under section 409(b)(1) of the Federal Food, Drug, and Cosmetic Act. If the Secretary does not make such determination, the Secretary shall, not later than 90 days following the enactment of this Act, provide the Committee on Commerce of the House of Representatives, the Senate an explanation of the process followed by the Food and Drug Administration in reviewing the petition referred to in paragraph (1) and the reasons action on the petition was delayed.

SEC. 308. GLASS AND CERAMIC WARE.

(a) In General.—The Secretary may not implement any regulation which would ban, as unsafe or adulterated, the use of lead and cadmium based enamel on glass and ceramic ware before the expiration of one year after the date such regulation is published.

(b) Lead and Cadmium Based Enamel.—Unless the Secretary determines, based on available data, that lead and cadmium based enamel on glass and ceramic ware—

(1) which has less than 60 micrograms of decorating area below the external rim, and

(2) which is not, by design, representation, or customary usage intended for use by children, is unsafe, the Secretary shall not take any action before January 1, 2003, to ban lead and cadmium based enamel on such glass and ceramic ware.

Any action taken after January 1, 2003, to ban such enamel on such glass and ceramic ware as an unapproved food additive shall be taken by regulation and such regulation shall provide that such products shall not be removed from the market before 1 year after publication of the final regulation.

SEC. 309. FOOD CONTACT SUBSTANCES.

FOOD CONTACT SUBSTANCES.—Section 409(a) (21 U.S.C. 348(a)) is amended—

(1) in paragraph (1)—

(A) by striking "subsection (i)" and inserting "subparagraph (5)"; and

(B) by striking the end of paragraph (2) and inserting "or";

(2) by inserting after paragraph (2) the following:

"(3) in the case of a food additive as defined in this Act that is a food contact substance, there is—

(A) in effect, and such substance and the use of such substance are in conformity with, a regulation promulgated under this section prescribing the conditions under which such additive may be safely used; or

(B) a notification submitted under subsection (h) that is effective; and

(4) by striking the matter following paragraph (3) (as added by paragraph (3)) and inserting the following flush sentence:

"While such a regulation relating to a food additive, or such a notification under subsection (h) relating to a food additive that is a food contact substance, is in effect, and has not been revoked pursuant to subsection (i), a food shall not, by reason of bearing or containing such food additive in accordance with the regulation or notification, be considered adulterated under section 402(a)(1)."

SEC. 402(a)(1).''.

SEC. 409(a) (21 U.S.C. 348(a)) is amended—

(1) in paragraph (1)—

(A) by striking "subsection (i)" and inserting "subparagraph (5)"; and

(B) by striking the end of paragraph (2) and inserting "or";

(2) by inserting after paragraph (2) the following:

"(3) in the case of a food additive as defined in this Act that is a food contact substance, there is—

(A) in effect, and such substance and the use of such substance are in conformity with, a regulation promulgated under this section prescribing the conditions under which such additive may be safely used; or

(B) a notification submitted under subsection (h) that is effective; and

(4) by striking the matter following paragraph (3) (as added by paragraph (3)) and inserting the following flush sentence:

"While such a regulation relating to a food additive, or such a notification under subsection (h) relating to a food additive that is a food contact substance, is in effect, and has not been revoked pursuant to subsection (i), a food shall not, by reason of bearing or containing such food additive in accordance with the regulation or notification, be considered adulterated under section 402(a)(1)."

SEC. 409(a) (21 U.S.C. 348(a)) is amended—

(b) LEAD AND CADMIUM BASED ENAMEL.—Unless the Secretary determines, based on available data, that lead and cadmium based enamel on glass and ceramic ware—

(1) which has less than 60 micrograms of decorating area below the external rim, and

(2) which is not, by design, representation, or customary usage intended for use by children, is unsafe, the Secretary shall not take any action before January 1, 2003, to ban lead and cadmium based enamel on such glass and ceramic ware.

Any action taken after January 1, 2003, to ban such enamel on such glass and ceramic ware as an unapproved food additive shall be taken by regulation and such regulation shall provide that such products shall not be removed from the market before 1 year after publication of the final regulation.
Secretary of the identity and intended use of the food contact substance, and of the determination of the manufacturer or supplier that the intended use of such food contact substance is safe under the conditions of use prescribed in subclause (c)(3)(A). The notification shall contain the information that forms the basis of the determination and all information required to be submitted by regulations promulgated by the Secretary.

(2)(A) A notification submitted under paragraph (1) shall become effective 120 days after the date on which the Secretary and the food contact substance may be introduced or delivered for introduction into interstate commerce, unless the Secretary makes a determination within that 120-day period that, based on the data and information before the Secretary, such use of the food contact substance has not been shown to be safe under the standard described in subsection (c)(3)(A), and informs the manufacturer or supplier of such determination.

(B) A decision by the Secretary to object to a notification shall constitute final agency action subject to judicial review.

(C) In this paragraph, the term ‘food contact substance’ means the substance that is the subject of a notification submitted under paragraph (1), and does not include a similar or identical substance manufactured or prepared by a person other than the manufacturer identified in the notification.

(3)(A) The process in this subsection shall be utilized for authorizing the marketing of a food contact substance except where the Secretary determines that notification and review of the substance under subsection (b) is necessary to provide adequate assurance of safety, or where the Secretary and any manufacturer or supplier agree that such a process is not warranted or beneficial, the manufacturer or supplier may submit a petition under subsection (b).

(B) The Secretary is authorized to promulgate regulations to identify the circumstances in which notification under subsection (b) is necessary to provide adequate assurance of safety, or where the Secretary and any manufacturer or supplier agree that such a process is not warranted or beneficial.

4. Dissemination of information

(a) General

(1) In general—The Secretary shall maintain an official labeling for the drug or device that is the subject of a notification under this subsection.

(i) The Secretary shall maintain the official labeling for the drug or device that is the subject of a notification under this subsection if the information in the notification is necessary to provide adequate assurance of safety, or where the Secretary and any manufacturer or supplier agree that such a process is not warranted or beneficial.

(ii) The Secretary shall provide the official labeling for the drug or device that is the subject of a notification under this subsection if the information in the notification is necessary to provide adequate assurance of safety, or where the Secretary and any manufacturer or supplier agree that such a process is not warranted or beneficial.

(C) In this paragraph, the term ‘food contact substance’ means the substance that is the subject of a notification submitted under paragraph (1), and does not include a similar or identical substance manufactured or prepared by a person other than the manufacturer identified in the notification.

(TITLE IV—GENERAL PROVISIONS

SEC. 403. DISSEMINATION OF INFORMATION ON NEW USES.

(a) In general—The Secretary determines, after providing notice of such determination and an opportunity for a meeting with respect to such determination, that the information submitted by a manufacturer under subsection (b)(3)(B), with respect to the use of a drug or device for which the manufacturer intends to disseminate information, fails to provide data, analyses, or other written matter that is objective and scientifically valid for the information dissemination. In that case, the Secretary may require the manufacturer to disseminate—

(i) additional objective and scientifically valid information that pertains to the safety or effectiveness of the use and is necessary to provide adequate assurance of safety, or where the Secretary and any manufacturer or supplier agree that such a process is not warranted or beneficial.

(ii) The Secretary determines, after providing notice of such determination and an opportunity for a meeting with respect to such determination, that the information submitted by a manufacturer under subsection (b)(3)(B), with respect to the use of a drug or device for which the manufacturer intends to disseminate information, fails to provide data, analyses, or other written matter that is objective and scientifically valid for the information dissemination. In that case, the Secretary may require the manufacturer to disseminate—

(i) additional objective and scientifically valid information that pertains to the safety or effectiveness of the use and is necessary to provide adequate assurance of safety, or where the Secretary and any manufacturer or supplier agree that such a process is not warranted or beneficial.

(ii) A copy of the information to be disseminated.

(C) ADDITIONAL INFORMATION.—If the Secretary determines, after providing notice of such determination and an opportunity for a meeting with respect to such determination, that the information submitted by a manufacturer under subsection (b)(3)(B), with respect to the use of a drug or device for which the manufacturer intends to disseminate information, fails to provide data, analyses, or other written matter that is objective and scientifically valid for the information dissemination, the Secretary shall submit a report to the Committee on Labor and Human Resources of the Senate and the Committee on Appropriations of the House of Representatives describing the circumstances in which a petition was filed under subsection (b).

(TITLE IV—GENERAL PROVISIONS

SEC. 551. REQUIREMENTS FOR DISSEMINATION OF TREATMENT INFORMATION ON DRUGS OR DEVICES.

(a) In general—Notwithstanding sections 301(d), 302(f), and 505, and section 351 of the Public Health Service Act (42 U.S.C. 262), a manufacturer may disseminate—

(1) a health care practitioner; or

(2) a pharmacy or dispensing pharmacist; or

(3) a health insurance issuer;

(4) a group health plan; or

(5) a Federal or State governmental agency;

written information concerning the safety, effectiveness, or benefit of a use not described in the approved labeling of the drug or device if the manufacturer meets the requirements of subsection (b).

(b) SPECIFIC REQUIREMENTS.—A manufacturer may disseminate information under subsection (a) on a new use only if—

(1) the information being disseminated is in effect for the drug an application filed under subsection (b) or (i) of section 505 or a biologics license issued under section 351 of the Public Health Service Act; and

(2) in the case of a device, the device is being commercially distributed in accordance with a regulation under subsection (d) or (e) of section 513, an order under subsection (f) of such section, or the approval of an application under section 515.

(1) the information being disseminated is not derived from clinical research conducted by another manufacturer if or if it was derived from research conducted by another manufacturer, the manufacturer disseminating the information has the permission of such other manufacturer to make the dissemination;

(2) the manufacturer has, 60 days before such dissemination, submitted to the Secretary—

(A) a copy of the information to be disseminated;

and

(B) any clinical trial information the manufacturer has relating to the safety or effectiveness of the new use, any reports of clinical experience pertinent to the safety of the new use, and a summary of such information;

(3) the manufacturer has complied with the requirements of section 554 (relating to a supplemental application for such use);

(4) the manufacturer includes along with the information to be disseminated under this subsection—

(A) a prominently displayed statement that discloses—

(i) that the information concerns a use of a drug or device that has been approved or cleared by the Food and Drug Administration; and

(ii) if applicable, that the information is being disseminated at the expense of the manufacturer.

(5) if applicable, the name of any authors of the information who are employees of, consultants to, or have received compensation from, the manufacturer, or who have a significant financial interest in the manufacturer.

(1) the official labeling for the drug or device and all updates with respect to the labeling;

(2) if applicable, a statement that there are products or treatments that have been approved or cleared for the use that is the subject of the information being disseminated pursuant to subsection (a)(1); and

(3) the information to be disseminated is not derived from clinical research conducted by another manufacturer if or if it was derived from research conducted by another manufacturer, the manufacturer disseminating the information has the permission of such other manufacturer to make the dissemination;

(4) the manufacturer includes along with the information to be disseminated under this subsection—

(A) a prominently displayed statement that discloses—

(i) that the information concerns a use of a drug or device that has been approved or cleared by the Food and Drug Administration; and

(ii) if applicable, that the information is being disseminated at the expense of the manufacturer.

(5) if applicable, the name of any authors of the information who are employees of, consultants to, or have received compensation from, the manufacturer, or who have a significant financial interest in the manufacturer.

(1) the official labeling for the drug or device and all updates with respect to the labeling;

(2) if applicable, a statement that there are products or treatments that have been approved or cleared for the use that is the subject of the information being disseminated pursuant to subsection (a)(1); and

(3) the information to be disseminated is not derived from clinical research conducted by another manufacturer if or if it was derived from research conducted by another manufacturer, the manufacturer disseminating the information has the permission of such other manufacturer to make the dissemination;
SEC. 552. INFORMATION AUTHORIZED TO BE DISSEMINATED.

(a) AUTHORIZED INFORMATION.—A manufacturer may disseminate information under section 551 on the information described in paragraph (1) if—

(1) in the form of an unabridged—

(A) reprint or copy of an article, peer-reviewed by scientific training or experience to evaluate the safety or effectiveness of the drug or device involved, which was published in a scientific or medical journal (as defined in section 556(7)), which is about a clinical investigation with respect to the drug or device, and which would be considered to be scientifically sound by such experts; or

(B) a publication, described in subsection (b), that includes information about a clinical investigation with respect to the drug or device that would be considered to be scientifically sound by experts qualified by scientific training or experience to evaluate the safety or effectiveness of the drug or device that is the subject of such a clinical investigation; and

(2) is not false or misleading and would not pose a significant risk to the public health.

(b) REFERENCE PUBLICATION.—A reference publication referred to in subsection (a)(1)(B) is a publication that—

(1) has not been written, edited, excerpted, or published specifically for, or at the request of, a manufacturer of a drug or device;

(2) is not solely distributed through such a manufacturer but is generally available in bookstores or on distribution channels where medical textbooks are sold;

(4) does not focus on any particular drug or device of a manufacturer that disseminates information under section 551, and does not have a primary focus on new uses of drugs or devices that are marketed or under investigation by a manufacturer supporting the dissemination of information; and

(5) presents materials that are not false or misleading.

SEC. 553. ESTABLISHMENT OF LIST OF ARTICLES AND PUBLICATIONS DISSEMINATED AND LIST OF PROVIDERS THAT RECEIVED ARTICLES AND REFERENCE PUBLICATIONS.

(a) IN GENERAL.—A manufacturer may disseminate information under section 551 on a new use only if the manufacturer prepares and submits to the Secretary a list containing the titles of the articles and reference publications relating to the new use of drugs or devices that were disseminated by the manufacturer under section 551(a) for the 6-month period preceding the date on which the manufacturer submits the list to the Secretary; and

(b) a list that identifies the categories of providers (as described in section 551(a)) that received the articles and reference publications for the 6-month period described in paragraph (1).

SEC. 554. REQUIREMENT REGARDING SUBMISSION OF SUPPLEMENTAL APPLICATION FOR NEW USE; EXEMPTION FROM REQUIREMENT.

(a) IN GENERAL.—A manufacturer may disseminate information under section 551 on a new use only if the information—

(A) the manufacturer has submitted to the Secretary a supplemental application for such use; or

(B) the manufacturer meets the condition described in subsection (b) or (c) (relating to a certification that the manufacturer will submit such an application); or

(2) there is in effect for the manufacturer an exemption under subsection (d) from the requirement of paragraph (1).

(b) CERTIFICATION ON SUPPLEMENTAL APPLICATION; CONDUCT OF CASED STUDIES.

For purposes of subsection (a)(1)(B), a manufacturer may disseminate information on a new use if the manufacturer has submitted to the Secretary an application containing a certification that—

(1) the studies needed for the submission of a supplemental application for the new use have been completed; and

(2) the supplemental application will be submitted to the Secretary not later than 6 months after the date of dissemination of information under section 551.

(c) CERTIFICATION ON SUPPLEMENTAL APPLICATION; CONDITION IN CASE OF PLANNED STUDIES.

(1) IN GENERAL.—For purposes of subsection (a)(1)(B), a manufacturer may disseminate information on a new use if—

(A) the manufacturer has submitted to the Secretary an application containing—

(i) a proposed protocol and schedule for conducting the studies needed for the submission of a supplemental application for the new use; and

(ii) a certification that the supplemental application will be submitted to the Secretary not later than 36 months after the date of initial submission under section 551 (or, as applicable, not later than such date as the Secretary may specify pursuant to an extension under paragraph (3)); and

(B) the Secretary has determined that the proposed protocol is adequate and that the schedule for completing such studies is reasonable.

(2) PROGRESS REPORTS ON STUDIES.—A manufacturer that submits to the Secretary an application under paragraph (1) shall submit to the Secretary periodic reports describing the status of the studies involved.

(3) EXTENSION OF TIME REGARDING PLANNED STUDIES.—The period of 36 months authorized in paragraph (1) for the completion of studies may be extended by the Secretary if—

(A) the Secretary determines that the studies needed to support such an application cannot be completed within 36 months; or

(B) the manufacturer involved submits to the Secretary a written request for the extension and the Secretary determines that the manufacturer involved has conducted the studies in a timely manner, except that an extension under this subparagraph may not be provided for more than 24 additional months.

(d) EXEMPTION FROM REQUIREMENT OF SUPPLEMENTAL APPLICATION.—

(1) IN GENERAL.—For purposes of subsection (a)(2), a manufacturer may disseminate information on a new use if—

(A) the manufacturer has submitted to the Secretary an application for an exemption from the requirement of subsection (a)(1); and

(B)(i) the Secretary has approved the application and under section 555(b)(3) order the manufacturer to cease disseminating the information pursuant to subsection (a)(1); or

(ii) the size of the population expected to receive the drug or device for the manufacturer to conduct the studies needed for the submission of such application is the standard of medical practice established by the Secretary.

(2) CONDITIONS FOR APPROVAL.—The Secretary may approve an application under paragraph (1) for an exemption if the Secretary makes a determination described in subparagraph (A) or (B) and—

(A) the Secretary makes a determination that, for reasons defined by the Secretary, it would be economically prohibitive with respect to the information the manufacturer is required to submit the cost of providing the required information to the Secretary; or

(B) the Secretary makes a determination that, for reasons defined by the Secretary, it would be unethical to conduct the studies necessary to support such a supplemental application for the new use involved to not be effective or may present a significant risk to public health, the Secretary shall, after consultation with the manufacturer, take such actions as the Secretary determines to be appropriate for the protection of the public health, which may include ordering that the manufacturer cease disseminating the information.

(3) RESPONSIBILITIES OF MANUFACTURERS TO SUBMIT DATA.—After a manufacturer disseminates information under section 551, the manufacturer shall submit to the Secretary a notification of any additional knowledge of the manufacturer on clinical research or other data that relate to the safety or effectiveness of the new use involved. If the manufacturer is in possession of the data, the notification shall include the data. The Secretary shall by regulation establish the scope of the responsibilities of manufacturers under this paragraph, including such limits on the responsibilities as the Secretary determines to be appropriate.

(4) FAILURE OF MANUFACTURER TO COMPLY WITH REQUIREMENTS.—The Secretary may order a manufacturer to cease the dissemination of information pursuant to section 551 if the Secretary determines that the information being disseminated does not comply with the requirements established in this subchapter. Such an order may be issued only if the Secretary has provided notice to the manufacturer of the intent of the Secretary to issue the order and (unless paragraph (2)(B) applies) has provided an opportunity for a meeting with respect to such intent. If the failure of the manufacturer constitutes a minor violation of this subchapter, the Secretary shall consider in (addition to any other considerations the Secretary finds appropriate)—

(i) the lack of the availability of law or an appropriate procedure during which the manufacturer would have exclusive marketing rights with respect to the new use involved; and

(ii) the size of the population expected to benefit from approval of the supplemental application.
Secretary shall delay issuing the order and provide to the manufacturer an opportunity to correct the violation.

(2) **SUPPLEMENTAL APPLICATIONS.**—The Secretary determines that the supplemental application to cease disseminating information pursuant to section 551—

(A) in the case of a manufacturer that has submitted an application for a new use pursuant to section 554(a)(1), the Secretary determines that the supplemental application does not contain adequate information for approval, or new use for which the application was submitted;

(B) in the case of a manufacturer that has submitted a certification under section 554(b), the manufacturer, within the 6-month period involved, submitted the supplemental application referred to in the certification; or

(C) in the case of a manufacturer that has submitted a certification under section 554(c) but has not yet submitted the supplemental application referred to in the certification, the Secretary, after an informal hearing, determines that the manufacturer is not acting with due diligence to complete the studies involved.

(3) **TERMINATION OF DEEMED APPROVAL OF EXEMPTION REGARDING SUPPLEMENTAL APPLICATIONS.**—In the case of a manufacturer that has submitted a deemed approval under section 554(d)(3) the Secretary terminates a deemed approval of an exemption, the Secretary may order the manufacturer involved to cease disseminating the information. A manufacturer shall comply with an order under the preceding sentence not later than 60 days after the receipt of the order.

(4) **CORRECTIVE ACTIONS BY MANUFACTURERS.**—

(A) **IN GENERAL.**—In any case in which under this section the Secretary orders a manufacturer to cease disseminating information, the Secretary shall, at the manufacturer's request and to take action to correct the information that has been disseminated, except as provided in paragraph (2).

(B) **TERMINATION OF DEEMED APPROVAL OF EXEMPTION REGARDING SUPPLEMENTAL APPLICATIONS.**—In the case of an order under subsection (b)(3) to cease disseminating information, the Secretary may not order the manufacturer involved to take action to correct the information that has been disseminated unless the Secretary determines that the new use described in the information would pose a significant risk to the public health.

**SEC. 556. DEFINITIONS.**—

"For purposes of this subchapter—

(1) a "health care practitioner" means a physician, or other individual who is a provider of health care, who is licensed under the law of a State to prescribe drugs or devices.

(2) the terms "health insurance issuer" and "group health plan" have the meaning given such terms under section 732 of the Public Health Service Act.

(3) the term "manufacturer" means a person who manufactures a drug or device, or who is licensed by such person to distribute or market the drug or device.

**SEC. 557. RULES OF CONSTRUCTION.**—

(a) **UNAUTHORIZED ACTIVITY.**—Nothing in section 551 shall authorize the Secretary to bar a person from engaging in an activity that is not an approved use of a drug or device, in accordance with section 551, 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 for the official labeling of the drug or device. Such dissemination shall not be considered by the Secretary as advertising, misbranding, or misbranding of the drug or device.

(b) **PATENT PROTECTION.**—Nothing in section 551 shall affect patent rights in any manner.

(c) **AUTHORIZATION FOR DISSEMINATION OF ARTICLES AND FEES FOR REPRINTS OF ARTICLES.**—Nothing in section 551 shall be construed as prohibiting an entity that publishes a scientific journal, as defined in section 556(d), from requiring authorization from the entity to disseminate an article published by such entity or charging fees for the purchase of reprints of published articles.

(d) **PROHIBITED ACT.**—Section 301 (21 U.S.C. 331), as amended by section 210, is amended by adding at the end the following:

(1) the dissemination of information in violation of section 551.

(e) **REGULATIONS.**—Not later than one year after the date of enactment of this Act, the Secretary shall, if necessary, promulgate regulations to implement the amendments made by this section.

(f) **EFFECTIVE DATE.**—The amendments made by this section shall take effect 6 months after the date of enactment of this Act, or upon the Secretary's issuance of final regulations pursuant to subsection (c), whichever is sooner.

(g) **REPORT.**—Not later than January 1, 2002, the Comptroller General of the United States shall conduct a study to determine the impact of subchapter D of chapter V of the Federal Food, Drug, and Cosmetic Act, as added by this section, on the resources of the Department of Health and Human Services.

(h) **STUDIES AND REPORTS.**—

(1) **GENERAL ACCOUNTING OFFICE.**—

(A) **IN GENERAL.**—The Comptroller General of the United States shall conduct a study to determine the impact of subchapter D of chapter V of the Federal Food, Drug, and Cosmetic Act, as added by this section, on the Department of Health and Human Services.

(B) **REPORT.**—Not later than January 1, 2002, the Comptroller General of the United States shall prepare and submit to the Committee on Labor and Human Resources of the Senate and the Committee on Commerce of the House of Representatives a report of the results of the study, which is later.

(i) **STUDIES AND REPORTS.**—

(1) **SUBCHAPTER E—GENERAL PROVISIONS RELATING TO DRUGS AND Devices.**—

(2) **SEC. 556. EXPANDED ACCESS TO UNAPPROVED THERAPIES AND DIAGNOSTICS.**—

(a) **EMERGENCY SITUATIONS.**—The Secretary may, under appropriate conditions determined by the Secretary, authorize the shipment of investigational drugs or investigational devices for the diagnosis, monitoring, or treatment of a serious disease or condition in emergency situations.

(b) **INDIVIDUAL PATIENT ACCESS TO INVESTIGATIONAL PRODUCTS INTENDED FOR SERIOUS DISEASES.**—Any person, acting through a physician licensed in accordance with State law, may request from a manufacturer or distributor, and any manufacturer or distributor may, after complying with the provisions of this subsection, provide to such physician an investigational drug or investigational device for the diagnosis, monitoring, or treatment of a serious disease or condition in emergency situations.

(c) **REPORT.**—Not later than January 1, 2002, the Secretary shall submit to the Committee on Commerce of the House of Representatives a report of the results of the study.
“(4) the sponsor, or clinical investigator, of the investigational drug or investigational device submits to the Secretary a clinical protocol consistent with the provisions of section 505(i) or 520(g), including any regulations promulgated under section 505(i) or 520(g), describing the use of the investigational drug or investigational device in a single patient or a small group of patients.

“(c) TREATMENT INVESTIGATIONAL NEW DRUG APPLICATIONS AND TREATMENT INVESTIGATIONAL DEVICE EXEMPTIONS.—On submission by a sponsor or principal investigator of a protocol that would permit widespread access to an investigational drug or investigational device for eligible patients (referred to in this subsection as an ‘expanded access protocol’), the Secretary shall—

“(1) under the treatment investigational new drug application or treatment investigational device exemption, the investigational drug or investigational device is intended for use in the diagnosis, monitoring, or treatment of a serious or immediately life-threatening disease or condition;

“(2) there is no comparable or satisfactory alternative therapy available to diagnose, monitor, or treat diseases in the condition in the population of patients to which the investigational drug or investigational device is intended to apply;

“(3)(A) the investigational drug or investigational device is under investigation in a controlled clinical trial for the use described in paragraph (1) with an expanded access protocol; or

“(B) working with sponsors to facilitate the development, issuance, and use of guidance documents and shall monitor the development and submission of data to support supplemental applications.

“(d) COLLABORATION.—The Secretary shall—

“(1) encourage the prompt review of supplemental applications for the approved articles described in subsection (a). The guidelines shall—

“(1) clarify circumstances in which published matter may be the basis for approval of a supplemental application;

“(2) specify data requirements that will avoid duplication of previously submitted data by recognizing the availability of data previously submitted in support of an original application; and

“(3) define supplemental applications that are eligible for priority review.

“(e) RESPONSIBILITIES OF CENTERS.—The Secretary shall—

“(1) by redesignating subsections (b) and (c) as subsections (d) and (e), respectively, and (2) specify data requirements that will avoid duplication of previously submitted data by recognizing the availability of data previously submitted in support of an original application; and

“(f) working with sponsors to facilitate the development, issuance, and use of guidance documents and shall monitor the development and submission of data to support supplemental applications.

“(g) DETERMINATION.—The Secretary may, at any time, with respect to a sponsor, physician, manufacturer, or investigator described in this section, terminate expanded access provided under this section for an investigational drug or investigational device if the requirements under this section are no longer met.

“(h) DEFINITIONS.—In this section, the terms ‘investigational drug’, ‘investigational device’, ‘treatment investigational new drug application’, and ‘treatment investigational device exemption’ shall have the meanings given the terms in regulations prescribed by the Secretary.”

“SEC. 403. APPROVAL OF SUPPLEMENTAL APPLICATIONS FOR APPROVED PRODUCTS.

“(a) STANDARDS.—Not later than 180 days after the date of enactment of this Act, the Secretary shall issue final guidelines to clarify the requirements for, and facilitate the submission of data to support, the approval of supplemental applications for the approved articles described in subsection (a). The guidelines shall—

“(1) define supplemental applications that are eligible for priority review.

“(2) specify data requirements that will avoid duplication of previously submitted data by recognizing the availability of data previously submitted in support of an original application; and

“(3) define supplemental applications that are eligible for priority review.

“(c) RESPONSIBILITIES OF CENTERS.—The Secretary shall—

“(1) by redesignating subsections (b) and (c) as subsections (d) and (e), respectively, and (2) specify data requirements that will avoid duplication of previously submitted data by recognizing the availability of data previously submitted in support of an original application; and

“(3) define supplemental applications that are eligible for priority review.

“(d) COLLABORATION.—The Secretary shall—

“(1) encourage the prompt review of supplemental applications for the approved articles described in subsection (a). The guidelines shall—

“(1) clarify circumstances in which published matter may be the basis for approval of a supplemental application;

“(2) specify data requirements that will avoid duplication of previously submitted data by recognizing the availability of data previously submitted in support of an original application; and

“(3) define supplemental applications that are eligible for priority review.

“(e) RESPONSIBILITIES OF CENTERS.—The Secretary shall—

“(1) by redesignating subsections (b) and (c) as subsections (d) and (e), respectively, and (2) specify data requirements that will avoid duplication of previously submitted data by recognizing the availability of data previously submitted in support of an original application; and

“(f) working with sponsors to facilitate the development, issuance, and use of guidance documents and shall monitor the development and submission of data to support supplemental applications.

“(g) DETERMINATION.—The Secretary may, at any time, with respect to a sponsor, physician, manufacturer, or investigator described in this section, terminate expanded access provided under this section for an investigational drug or investigational device if the requirements under this section are no longer met.

“(h) DEFINITIONS.—In this section, the terms ‘investigational drug’, ‘investigational device’, ‘treatment investigational new drug application’, and ‘treatment investigational device exemption’ shall have the meanings given the terms in regulations prescribed by the Secretary.”

“SEC. 404. DISPUTE RESOLUTION.

“Subsection (e) of chapter V, as added by section 402, is amended by adding at the end the following:

“SEC. 562. DISPUTE RESOLUTION.

“(f) regarding any concerns drugs or devices under this Act or section 351 of the Public Health Service Act, there is a scientific controversy between the Secretary and a person who is the sponsor, manufacturer, and no specific provision of the Act involved, including a regulation promulgated under such Act, provides a right of review of the matter in controversy through a hearing established by regulation, to establish a procedure under which such sponsor, applicant, or manufacturer may request a review of such controversy, including a review by an appropriate panel described in section 505(n) or an advisory committee described in section 515(g)(2)(B). Any such review shall take place in a timely manner. The Secretary shall promulgate such regulations within 1 year after the date of the enactment of the Food and Drug Administration Modernization Act of 1997.

“SEC. 405. INFORMAL AGENCY STATEMENTS.

“Section 701 (21 U.S.C. 371) is amended by adding at the end the following:

“(1)(A) The Secretary shall develop guidance documents with public participation and ensure that information identifying the existence of such documents and the documents themselves are made available to the public in written form and, as feasible, through electronic means. Such documents shall not create or confer any rights for or on any person, although they present the views of the Secretary on matters under the jurisdiction of the Food and Drug Administration.

“(B) Although guidance documents shall not be binding on the Secretary, the Secretary shall ensure that employees of the Food and Drug Administration do not deviate from such guidance without appropriate justification and shall provide training to employees in how to develop and use guidance documents and shall monitor the development and issuance of such documents.

“(C) For guidance documents that set forth initial interpretations of a statute or regulation, change in interpretation or policy that are of more than a minor nature, complex scientific issues, or highly controversial issues, the Secretary shall ensure public participation prior to implementation of guidance documents. Unless the Secretary determines that such prior public participation is not feasible or appropriate. In such cases, the Secretary shall provide for public comment upon implementation and take such comment into account.

“(D) For guidance documents that set forth existing practices or minor changes in policy, the Secretary shall provide for public comment upon implementation.

“(E) In developing guidance documents, the Secretary shall ensure uniform nomenclature for such documents and uniform application procedures for approval of such documents. The Secretary shall ensure that guidance documents and revisions of such documents are properly dated and indicate the nonbinding nature of the documents. The Secretary shall periodically review all guidance documents and, where appropriate, revise such documents.

“(F) The Secretary, acting through the Commissioner, shall maintain electronically and update and publish periodically in the Federal Register a list of guidance documents. All such documents shall be made available to the public.

“(G) The Secretary shall ensure that an effective appeals mechanism is in place to address complaints that the Food and Drug Administration is developing, promulgating, or implementing guidance documents in accordance with this subsection.

“(H) Not later than July 1, 2000, the Secretary shall promulgate the effective date of Good Guidance Practices document, published in the Federal Register at 62 Fed. Reg. 8961, shall promulgate a regulation consistent with this subsection specifying the policies and procedures of the Food and Drug Administration for the development, issuance, and use of guidance documents.

“SEC. 406. FOOD AND DRUG ADMINISTRATION MISSION AND ANNUAL REPORT.

“(a) MISSION.—Section 903 (21 U.S.C. 393) is amended—

“(1) by redesignating subsections (b) and (c) as subsections (d) and (e), respectively, and

“(2) by inserting after subsection (a) the following:

“(d) MISSION.—The Administration shall—

“(1) promote the public health by promptly and efficiently reviewing clinical research and taking appropriate action on the marketing of regulated products in a timely manner, and

“(2) with respect to such products, protect the public health by ensuring that—

“(A) human and veterinary drugs are safe, wholesome, sanitary, and properly labeled;

“(B) human and veterinary drugs are safe and effective;

“(C) the public can reasonably rely on the safety and effectiveness of devices intended for human use;
(D) cosmetics are safe and properly labeled; and
(E) public health and safety are protected from electronic product radiation;
(F) support health, in appropriate processes with representatives of other countries to reduce the burden of regulation, harmonize regulatory requirements, and achieve appropriate reciprocal requirements for the Food and Drug Administration, after consultation with appropriate scientific and academic experts, health care professionals, representatives of patient and consumer advocates, and governmental public health, and in cooperation with consumers, users, manufacturers, importers, packers, distributors, and retailers of regulated products.
(b) ANNUAL REPORT.—Section 903 (21 U.S.C. 393), as amended by subsection (a), is further amended by adding at the end the following: 'SEC. 742. EDUCATION.

(a) IN GENERAL.—The Secretary shall conduct training and education programs for the employees of the Food and Drug Administration related to the regulatory responsibilities and policies established by this Act, including programs for—
(1) scientific training;
(2) training to improve the skill of officers and employees authorized to conduct inspections under section 704;
(3) training to achieve product specialization in such inspections; and
(4) training in administrative process and procedure and integrity issues.
(b) INTRAMURAL AND OTHER TRAINING PROGRAMS.—The Secretary, acting through the Commissioner, may, through fellowships and other training programs, conduct and support intramural research training for predoctoral and postdoctoral scientists and physicians.'.
(c) CENTERS FOR DISEASE CONTROL AND PREVENTION.—

(1) IN GENERAL.—Part B of title III of the Public Health Service Act is amended by inserting after section 317F (42 U.S.C. 247b-7) the following:

"SEC. 317G. FELLOWSHIP AND TRAINING PROGRAMS.

The Secretary, acting through the Director of the Centers for Disease Control and Prevention, shall establish fellowship and training programs to be conducted by such Centers to train individuals to develop skills in epidemiology, surveillance, laboratory analysis, and other disease detection and prevention methods. Such programs shall be designed to enable health professionals and health personnel trained under such programs to work, after receiving such training, in local, State, national, and international efforts toward the prevention and control of diseases, injuries, and disabilities. Such fellowships and training may be administered through the use of either appointment or nonappointment procedures.'.
(2) EFFECTIVE DATE.—The amendment made by this subsection is deemed to have taken effect July 1, 1995.
SEC. 409. CENTERS FOR EDUCATION AND RESEARCH ON THERAPEUTICS.

Title IX of the Public Health Service Act (42 U.S.C. 299 et seq.) is amended by adding at the end of part A the following new section: 'SEC. 905. DEMONSTRATION PROGRAM REGARDING THE DEVELOPMENT, TESTING, AND RESEARCH ON THERAPEUTICS.

(a) IN GENERAL.—The Secretary, acting through the Commissioner of Food and Drugs, shall establish a demonstration program for the purpose of making one or more grants for the establishment and operation of one or more centers to carry out the activities specified in subsection (b).
(b) REQUIRED ACTIVITIES.—The activities referred to in subsection (a) are the following:
(1) The conduct of state-of-the-art clinical and laboratory research for the following purposes:
methods and approaches to harmonize regulatory requirements.

"(4) The Secretary shall, not later than 180 days after the date of enactment of the Food and Drug Administration Modernization Act of 1997, make public a plan that establishes a framework for achieving mutual recognition of good manufacturing practices inspections.

"(5) Paragraph (2) does not apply with respect to products defined in section 101(ff)."

SEC. 411. ENVIRONMENTAL IMPACT REVIEW

Chapter VII of title 21, section 371 et seq., as amended by section 401, is further amended by adding at the end the following:

"SUBCHAPTER E—ENVIRONMENTAL IMPACT REVIEW

"SEC. 766. ENVIRONMENTAL IMPACT.

"(a) 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 of Aug. 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. 4323(2)(C))."

SEC. 412. NATIONAL UNIFORMITY FOR NONPRESCRIPTION DRUGS AND COSMETICS.

(a) Nonprescription Drugs—Chapter VII (21 U.S.C. 371 et seq.), as amended by section 411, is further amended by adding at the end the following:

"SUBCHAPTER F—NATIONAL UNIFORMITY FOR NONPRESCRIPTION DRUGS AND PREEMPTION FOR LABELING OR PACKAGING OF COSMETICS

"SEC. 751. NATIONAL UNIFORMITY FOR NONPRESCRIPTION DRUGS.

"(a) In General.—Except as provided in subsection (b), (c), (d), or (e), no State or political subdivision thereof, the Secretary may by regulation or report relating to public information or any other form of public communication.

"(b) Exemption.—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—

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

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

"(iii) 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).

"(c) Scope.—

"(1) In General.—This section shall not apply to—

"(A) any State or political subdivision requirement that relates to the practice of pharmacy;

"(B) any State or political subdivision requirement that relates to the practice of a drug of domestic origin only upon the prescription of a practitioner licensed by law to administer such drug.

"(2) Safety or Effectiveness.—For purposes of subsection (a), a requirement that relates to the regulation of a drug shall be deemed to include any requirement relating to public information or any other form of public communication relating to a warning of any kind for a drug.

"(3) Exceptions.—

"(1) In General.—In the case of a drug described in subsection (a)(1) that is not the subject of an application approved under section 505 or section 507 (as in effect on the day before the date of enactment of the Food and Drug Administration Modernization Act of 1997) or a final regulation promulgated by the Secretary establishing conditions under which the drug is generally acknowledged to be safe and effective and not misbranded, subsection (a) shall apply only with respect to a requirement of a State or political subdivision of a State that relates to the same subject as is described in addition to, or that is otherwise not identical with—

"(A) a regulation in effect with respect to the drug pursuant to a statute described in sub-

"(2) any other requirement in effect with respect to the drug pursuant to an amendment of such a statute made on or after the date of enactment of the Food and Drug Administration Modernization Act of 1997.

"(2) State Initiatives.—This section shall not apply to a State requirement adopted by a State public initiative or referendum enacted prior to September 1, 1997.

"(b) Exemption.—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 for labeling or packaging that—

"(1) protects an important public interest that would otherwise be unprotected;

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

"(3) would not unduly burden interstate commerce.

"(c) Scope.—For purposes of subsection (a), a reference to a State requirement that relates to the packaging or labeling of a cosmetic means any specific requirement relating to the same aspect of such cosmetic as a requirement specifically applicable to that particular cosmetic or class of cosmetics under this Act, the Poison Prevention Packaging Act of 1970 (15 U.S.C. 1471 et seq.), or the Fair Packag-

"(d) COSMETICS.—Subchapter F of chapter VII, as amended by subsection (a), is further amended by adding at the end the following:

"SEC. 413. FOOD AND DRUG ADMINISTRATION STUDY OF MERCURY COMPOUNDS IN DRUGS AND FOOD.

(a) List and Analysis.—The Secretary of Health and Human Services, acting through the Food and Drug Administration—

"(1) compile a list of drugs and foods that contain intentionally introduced mercury compounds.

"(2) provide a quantitative and qualitative analysis of the mercury compounds in the list under paragraph (1).

The Secretary shall compile the list required by paragraph (1) within 2 years after the date of enactment of the Food and Drug Administration Modernization Act of 1997 and shall provide the analysis required by paragraph (2) within 2 years after such date.
Drug Administration, shall conduct a study of the effect on humans of the use of mercury compounds in nasal sprays. Such study shall include data from other studies that have been made.

(c) **STUDY OF MERCURY SALES.**—

(1) **STUDY.**—The Secretary of Health and Human Services, acting through the Food and Drug Administration, shall conduct, or subject to paragraph (2), shall contract with the Institute of Medicine of the National Academy of Sciences to conduct, a study of the effect on human health of the use of elemental, organic, or inorganic mercury when offered for sale as a drug or dietary supplement. Such study shall, among other things, evaluate—

(A) the adverse effects of mercury use as a drug or dietary supplement; and

(B) the adverse effects on health of children and other sensitive populations resulting from exposure to, or ingestion or inhalation of, mercury when so used.

In conducting such study, the Secretary shall consult with the Administrator of the Environmental Protection Agency, the Chair of the Consumer Product Safety Commission, and the Administrator of the Agency for Toxic Substances and Disease Registry, and, to the extent necessary or appropriate, with any other Federal or private entity.

(2) **REGULATIONS.**—If, in the opinion of the Secretary, the use of elemental, organic, or inorganic mercury when offered for sale as a drug or dietary supplement poses a threat to human health, the Secretary shall promulgate regulations restricting the sale of mercury intended for such use. At a minimum, such regulations shall be designed to protect the health of children and other sensitive populations from adverse effects resulting from, or exposure to, or ingestion or inhalation of, mercury. Such regulations, to the extent feasible, should not unnecessarily interfere with the availability of mercury for use in religious ceremonies.

**SEC. 434. INTERAGENCY COLLABORATION.**

Section 903 (21 U.S.C. 393), as amended by section 406, is further amended by inserting after subsection (b) the following:

"(c) **INTERAGENCY COLLABORATION.**—The Secretary shall implement programs and policies that will foster collaboration between the Administration, the National Institutes of Health, and other Federal agencies. The Secretary shall have the scientific and technical expertise available to the Secretary in the conduct of the duties of the Secretary with respect to the development, evaluation, and postmarket monitoring of emerging medical therapies, including complementary therapies, and advancing their evaluation and use ("complementary therapy ") ."

**SEC. 437. CONTRACTS FOR EXPERT REVIEW.**

Chapter IX (21 U.S.C. 391 et seq.), as amended by section 214, is further amended by adding at the end the following:

"(a) **REQUEST.**—A person who submits an application or submission described in paragraph (1), unless using such authority would reduce the quality, or unduly increase the cost, of such review. The Secretary may use such authority whenever the Secretary determines that use of such authority would result in a more efficient or effective review of the application or submission. Each use of such authority shall be included in the definition of "timeliness of the review of an application or submission described in paragraph (1)."

(b) **CONFIDENTIALITY.**—Unless otherwise required by law, the Secretary shall provide for the confidentiality of information.

**SEC. 418. CLARIFICATION OF SECRECY AUTHORITY.**

Section 304(d)(1) (21 U.S.C. 334(d)(1)) is amended—

(1) in the fifth sentence, by striking "paragraphs (1) and (2) of section 801(e)" and inserting "subparagraphs (A) and (B) of section 801(e)", and

(2) by inserting after the fifth sentence the following:

"Any person seeking to export an imported article pursuant to any of the provisions of this subsection shall establish that the article was intended for export at the time the article entered commerce ."

**SEC. 419. INTERSTATE COMMERCE.**

Section 709 (21 U.S.C. 379j et seq.), as amended by section 412, is further amended by adding at the end the following:

""SUBCHAPTER G—SAFETY REPORT "SEC. 756. 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 that is a food, drug, device, dietary supplement, or cosmetic) under this Act and any release by the Secretary of the report or information, no information shall not be construed to reflect necessarily a conclusion by the Secretary that the report or information constitutes an admission that the product is involved in a malfunction, caused or contributed to an adverse experience, or otherwise caused or contributed to a death, serious injury, or serious illness. 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 in a malfunction, caused or contributed to an adverse experience, or otherwise caused or contributed to a death, serious injury, or serious illness.

**SEC. 420. LABELING AND ADVERTISING REGARDING COMPLIANCE WITH STATUTORY REQUIREMENTS.**

Section 301 (21 U.S.C. 331) is amended by striking paragraph (i).

**SEC. 422. RULE OF CONSTRUCTION.**

Nothing in this Act or the amendments made by this Act shall be construed to affect the question of whether the Secretary of Health and Human Services has any authority to regulate any tobacco product, tobacco ingredient, or tobacco additive. Such authority, if any, shall be exercised under the Federal Food, Drug, and Cosmetic Act as in effect on the date of enactment of this Act.

**TITLE V—EFFECTIVE DATE**

**SEC. 501. EFFECTIVE DATE.**

Except as otherwise provided in this Act, this Act and the amendments made by this Act, other than the provisions of this Act amendments made by sections 111, 121, 125, and 307, shall take effect 90 days after the date of enactment of this Act.

And the House agree to the same.

That the House recede from its amendment to the title of the bill.

JOE BARTON,

TOM BLILEY,

MICHAEL BILIRAKIS,

JOE BARTON,

November 9, 1997

H10474
November 9, 1997


JIM EFFORDS, Dan Coats, Judd Gregg, Bill Frist, Mike DeWine, Edward M. Kennedy, Christopher Dodd, Tom Harkin, Barbara A. Mikulski, Managers of the Part of the Senate.

JOINT EXPLANATORY STATEMENT OF THE COMMITTEE OF CONFERENCE

The managers on the part of the House and the Senate at the conference on the disagreeing votes of the two Houses on the amendments of the House 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, submit the following joint statement to the House and the Senate in explanation of the effect of the agreement reached by the managers and recommended in the accompanying conference report:

The House amendment to the bill struck all of the Senate bill after the enacting clause and inserted a substitute text.

The Senate recedes from its disagreement to the amendment of the House with an amendment substituted for the Senate bill and the House amendment. The differences between the Senate bill, the House amendment, and the substitute agreed to in conference, except for clerical corrections, conforming changes made necessary by agreements reached by the conferees, and minor drafting and clerical changes.

The conference agreement on S. 830, the Food and Drug Administration Modernization Act of 1997, provides for (1) the reauthorization of the Prescription Drug User Fee Act of 1992; (2) the improvement of regulation of drugs through such reforms as those pertaining to pediatric studies and drugs that fail to meet the requirements for drugs and biological products; (3) the improvement of regulation of medical devices through such reforms as those pertaining to device standards and data requirements, procedures relating to humanitarian and breakthrough devices, tracking and postmarket surveillance, and accredited party review; (4) the improvement of oversight of food through such reforms as those pertaining to the timetable and regulatory authority of the Secretary in processing health and nutrient content claims, postmarket substance notifications, and information relating to irradiation treatment; and (5) general provisions pertaining to the dissemination of information on investigational therapies, and consumer access to information about clinical trials of investigational therapies.

Certain matters agreed to in conference are noted below:

TITLe I—PROmotion OF regulaTion OF drugS

The conferees believe it is important to place the PDUFAs reauthorization provisions of the conference report into the context of the legislative agreements which have been put into place by the 1997 Balanced Budget Agree-

ments (BBA). This Act preserves the original PDUFAM adjustment factor and therefore the basic understanding behind the 1992 enactment of this provision: that is, the industry will have a mechanism for enhanced performance in the drug approval process. Nonetheless, the conferees acknowledge that the 1997 BBA places tight constraints on the appropriations process, particularly in the out years. The conferees expect the appropriators will make every effort to meet the trigger so that FDA is allowed to collect and expend user fees. However, it must be acknowledged that particularly in the fifth year of BBA, budgetary pressures on all discretionary spending will be high.

Breakdowns of the actual spending levels at FDA have not traditionally been provided to the appropriators, making it difficult to conduct oversight. In Fiscal Year 1998, appropriators will require FDA to submit a directed operating budget as part of the annual budget request. This will serve as a functional breakdown of how appropriated dollars are spent, similar to the report FDA submits annually to show how the agency spent collected PDUFAs user fees.

The conferees expect the President’s budgetary request for FDA for salaries and expenses to meet the PDUFA levels specified for each year that is based on any assumption of the enactment of new substantiative user fees on other FDA regulated industries.

Pediatric studies of drugs (Sec. 111)

The conference agreement provides that if the Secretary determines that information about a drug may produce health benefits in a pediatric population and makes a written request for pediatric studies (including a time frame for completing the studies), and the studies are completed and are accepted by the Secretary, then the sponsor or manufacturer will qualify for 6 months of extra market exclusivity. The agreement authorizes the Secretary to determine the time frame for completing the studies, but the conferees emphasize that such studies should be sought, conducted, and completed at the earliest possible opportunity. The conferees do not intend that such studies be artificially timed for market advantage.

The agreement provides that no new market exclusivity may be applied to any new drug products promulgated prior to the enactment of this agreement. The agreement provides that, until the Secretary establishes procedures under subsection (c)(1) described below, neither a New Drug Application (NDA) nor an Abbreviated New Drug Application (ANDA) is required to contain a pediatric request for FDA for salaries and expenses to meet the PDUFA levels specified for each year that is based on any assumption of the enactment of new substantiative user fees on other FDA regulated industries.

The agreement provides for retroactive payment for FDA approval or request to review any drugs approved or listed after January 1, 2002. These drugs will be eligible for a period of exclusivity remaining available if the Secretary determines that information required for pediatric studies (including a time frame for completing the studies) is premature or would not be useful.

Positron emission tomography (Sec. 121)

The conference agreement provides for regulation of positron emission tomography (PET) drugs and replaces earlier industry guidance and regulatory standards for PET products. The agreement provides that, until the Secretary establishes procedures under subsection (c)(1) described below, neither a New Drug Application (NDA) nor an Abbreviated New Drug Application (ANDA) is required to contain a pediatric request for FDA for salaries and expenses to meet the PDUFA levels specified for each year that is based on any assumption of the enactment of new substantiative user fees on other FDA regulated industries.

The agreement requires the Secretary, in two years to establish procedures for approving PET products, including compounded PET products, and good manufacturing practices for such products, taking account of relevant differences between commercial manufacturers and non-profit organizations.

The agreement also requires the Secretary to review existing guidance and develop additional guidance, as appropriate, on the inclusion of women and minorities in clinical trials, to require participation of women and minorities in any particular trial. Furthermore, FDA is required to consult with the National Institutes of Health, which has developed inclusion guidelines for subjects in federally funded clinical research, and with representatives of the drug manufacturing industry, to ensure that ethical, scientific, and legal issues specific to privately funded clinical research are considered. The conferees expect the President’s budgetary request for FDA for salaries and expenses to meet the PDUFA levels specified for each year that is based on any assumption of the enactment of new substantiative user fees on other FDA regulated industries.

Clinical investigations (Sec. 115)

The conferees note that the requirement for the Secretary to review existing guidance and develop additional guidance, as appropriate, on the inclusion of women and minorities in clinical trials is premature or would not be useful.

Consumer protection (Sec. 202)

The conferees expect the President’s budgetary request for FDA for salaries and expenses to meet the PDUFA levels specified for each year that is based on any assumption of the enactment of new substantiative user fees on other FDA regulated industries.

The conferees expect the President’s budgetary request for FDA for salaries and expenses to meet the PDUFA levels specified for each year that is based on any assumption of the enactment of new substantiative user fees on other FDA regulated industries.

The conferees expect the President’s budgetary request for FDA for salaries and expenses to meet the PDUFA levels specified for each year that is based on any assumption of the enactment of new substantiative user fees on other FDA regulated industries.
Application of Federal law to practice of pharmacy compounding (Sec. 127)

The conference report includes provisions on pharmacy compounding that reflect the conferences' extensive work with the Food and Drug Administration and other interested parties to reach consensus. It is the intent of the conferences to ensure continued availability of compounded drug products as a component of patient chemotherapy, while limiting the scope of compounding so as to prevent manufacturing under the guise of compounding. Section 503A establishes parameters for compounding and is intended to change or otherwise affect the Act with respect to reconstitution or other similar processes that would affect a manufacturer's approved labeling, and other directions from such manufacturer that are consistent with that labeling. In general, such practices, as determined by the practitioner for an identified individual patient, are appropriately regulated by state boards of pharmacy. The conferences intend that facilities registered to work with the FDA, including those which are engaged in non-patient specific compounding and reconstitution activities, are appropriately regulated by the Federal Food, Drug and Cosmetic Act.

Finally, with regard to the effective date described in paragraph (b), the conferences expect the FDA to work diligently to consult with necessary parties to promulgate the required regulations and lists. Nothing in paragraph (b) is intended to abrogate the Secretary's responsibility to promulgate such regulations through the notice and comment rulemaking process.

Reauthorization of the Clinical Pharmacology Program (Sec. 129)

The conference agreement extends through fiscal year 2002 the authorization of appropriations for the Clinical Pharmacology Training Program, a program originally authorized under P.L. 100-574, P.L. 101-222. Nothing in this section of the agreement prohibits the Secretary from continuing the awarding of grants to the original and current grantees. The conferees strongly recommend that the Secretary continue the development of the clinical pharmacology programs at the colleges and universities originally selected for the purpose of conducting clinical pharmacology research. Regulations for sunscreen products (Sec. 129)

The conference agreement includes a provision requiring the FDA to continue diligently with its work to complete its rulemaking process on sunscreen products and to issue regulations within 18 months. The conferences recognize that various technical and scientific issues may take longer to resolve than other aspects of the rulemaking. The conferences intend that the regulation in this area be complete or comprehensive by a specified date.

Title II—Improving Regulation of Devices

Scope of review (Sec. 205)

The conference agreement addresses the issue of regulation by ensuring that the impact of the Secretary's necessary review, approval, and oversight functions is not inappropriate. This assurance is achieved by requiring the Secretary to consider, in consultation with an applicant for device approval, the method for evaluating the device's effectiveness and whether it would appropriately lead to reasonably likely to result in the device's approval. The conferences believe that this language is necessary to and consistent with improving communications between the FDA and regulated persons, increasing regulatory efficiency, and decreasing the length of product review and approval.

Premature notification (Sec. 206)

The conference agreement exempts class I devices from premarket notification under section 510(k), except those types that present a potential unreasonable risk of illness or injury, or that present substantial importance in preventing impairment of human health. The agreement also requires the Secretary to publish a notice listing the types of class I devices that are exempt from premarket notification. The Secretary must publish this initial list within 60 days.

Thereafter, class II devices may be exempted by the Secretary on the Secretary's own initiative or through a petition process. The agreement provides that the Secretary must respond to any such petition within 90 days or the petition will be deemed granted.

The conferences do not intend by this provision that the Secretary classify low-risk class I device in order to avoid exempting them. The conferences believe the appropriate exemption of class I and certain class II devices will allow the Secretary to expend limited premarket review resources on potentially risky and technologically advanced devices. Focusing resources in this manner will ensure devices to be adequately protected and will still benefit from the earlier availability of new products.

Accredited party review (Sec. 210)

The conference agreement makes no modifications to the provisions requiring the Secretary to establish the process by which the Secretary will accredit person to review and initially classify 510(k) devices. The agreement does not include requirements for the duration of the pilot program specify that an accreddited person may review a class III device, a class II device that is permanently implantable or life-supporting, or a class II device for which clinical data are required. The latter category is limited in size to not more than six such 510(k) submissions, the agreement provides for the termination of the pilot program after the Secretary has met specified targets for inclusion of eligible devices.

Reports (Sec. 213)

The conference agreement amends Section 529 of the Federal Food, Drug and Cosmetic Act to reduce the reporting requirements for distributors, importers, and manufacturers. Because distributors will no longer be submitting reports to the Secretary, copies of reports will be submitted to the manufacturers. This is not intended to provide the FDA with any new statutory authority to require distributors to keep records and make them available to the Secretary on request. Because distributors will no longer be submitting reports to the Secretary, copies of reports will be submitted to the manufacturers.
that the reports under this section are not required from any manufacturer, importer, or distributor who also is regulated and required to make such reports under the Radiation and Public Health and Safety Act of 1968 (21 U.S.C. 3011).

Practice of medicine (Sec. 214)

The conference agreement includes a provision intended by the conferences to emphasize that the FDA should not interfere with the practice of medicine. Specifically, the conferences note that the off-label use of a medical device by a physician using his or her best medical judgment is not the province of the American Medical Association and that when to use the medical product for the care of a particular patient is not the province of the FDA. It is the intent of the conferences that this provision be construed to affect medical professional liability.

TITLE III—IMPROVING REGULATION OF FOOD

Flexibility for regulations regarding claims (Sec. 301)

The conference agreement clarifies the parameters within which the Secretary may use the flexibility for regulations regarding claims. The conferences recognized that the Secretary must act to expedite the process by which such claims are removed from the approved labeling of the product. The agreements made minor modifications to the House provision that would enable the Secretary to conduct a review of the data submitted by the sponsors. The conferences intend that the Secretary use the authority to expedite review of the data submitted by the sponsors.

Food contact substances (Sec. 309)

The conference agreement establishes a notification process for the regulation of food contact substances, which are substances that are intentionally added to foods. The conference agreement permits the Secretary to issue regulations to ensure that food contact substances are safe and that the labeling of foods treated with such substances is accurate.

Health and nutrient content claims (Secs. 303, 304)

The conference agreement makes streamlined procedures available for the Secretary to expedite the review of petitions for health and nutrient content claims. The conferences recognize the importance of the Secretary's role in the notification process and the ability of the Secretary to provide adequate determination of safety. The conferences intend that the Secretary use the authority to expedite the process by which such claims are removed from the approved labeling of the product.
The conferees believe that FDA's new provisions intended to void State regulations dealing with cosmetics. The conferees want to make clear that "Little FTC" laws, as they have been historically interpreted and applied, are not preempted. The scope of national uniformity is modified to only apply to state requirements that relate to labeling and packaging, or, if they go beyond labeling and packaging, to requirements relating to warnings. Thus, advertising issues relating to claims substantiation, fair balance, and misleading or deceptive claims are outside the scope of preemption.

Effect of national uniformity on state food labeling laws

This provision is not intended to pre-empt or prohibit States from prohibiting the labeling of food which derives from animals treated with non-prescription drugs. Nor are these provisions intended to void State regulations on the use of these drugs.

Product classification (Sec. 416)

Subsections (b) and (c) have been amended to make clear that FDA may only modify product classifications for public health reasons based on scientific information.

LEAVE OF ABSENCE

By unanimous consent, leave of absence was granted to:

Mr. UNDERWOOD (at the request of Mr. GEPHARDT) for today and the balance of the week, on account of official business.

Mr. YATES (at the request of Mr. GEPHARDT) for November 8 after 12 noon and November 9, on account of personal reasons.

SENATE BILLS AND CONCURRENT RESOLUTION REFERRED

Bills and a concurrent resolution of the Senate were taken from the Speaker's table and, by unanimous consent, leave of absence was granted to:

Mai Hoo ("Jasmin") Salehi; to the Committee on the Judiciary.